Protocol

PAROXETINE 29060/329

September 25 1996

Title: A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Item attached for approval: Protocol Amendment #2

Agreed By:

Coordinating Author: _____(signed)_____

_____ [redacted] Date

Biostatistician _____(signed)_____

_____ [redacted] Date

Clinical Project Director: _____(signed)_____

_____ [redacted] Date

Approved By:

[redacted] _____

_____ [redacted]

Date

Comments and questions can be directed to [redacted]

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STUDY DRUG : BRL 29060/PAROXETINE (PAXIL)

A MULTI-CENTER, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

PROTOCOL NUMBER 29060/329

PROTOCOL	August 20, 1993	Date of approval:	August 26, 1993
Amendment #1:	March 24, 1994	Date Amendment Approved:	April 17, 1994
Amendment #2:	October 2, 1996	Date Amendment Approved:	October 29, 1996

CONFIDENTIAL

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PROTOCOL NUMBER 29060/329

Principal Investigators:

_____

Name

_____

Study Site Address

SB Responsible Physician: [redacted]

I, the undersigned, have reviewed the protocol, including Appendices and Amendment #1 and I will conduct the clinical study as described and will adhere to the Ethical and Regulatory Considerations stated.

_____ _____

Investigator's Signature Date Month Year

STUDY DRUG BRL 29060/*PAROXETINE* (PAXIL)

PROTOCOL NUMBER 29060/329
Approved: 26 August 1993

A MULTICENTER DOUBLE BLIND PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

Amendment #1 Approved: April 17, 1994

Section 5.2.1 Screening Phase

Revised: 1) Diagnostic assessments will be done using the K-SADS-L in place of the K-SADS-P.
2) In subjects for whom a diagnosis of major depression may be equivocal, the case will be discussed with a principal investigator at a separate site (see Appendix H) who will have access to the interview tapes. If the external reviewer and investigator disagree on inclusion, the external reviewer's opinion shall take precedence.

Rationale: The K-SADS-L is an enhancement of the K-SADS-P in that it includes disorders omitted from the K-SADS-L (e.g. ADHD, antisocial personality disorder, social phobia). Additionally, the K-SADS-L provides for lifetime inquiry. The external review was added to assure uniformity of diagnosis.

Section 5.2.3 Treatment Phase Assessments

Added: In addition to the 12 lead EKG performed at weeks 4 and 8, a rhythm strip EKG will be carried out at all other visits.

Revised: The criterion for heart rate level requiring a dose adjustment has been changed. Patients whose heart rate exceeds 110 bpm on two consecutive visits or 130 bpm at any time will have their dosage decreased by one level if they are at dose level 5 or 6; if the patient is currently treated at dose level 4 or below, the patient will be removed from the study.

Added: Blood levels of imipramine and desipramine will be analyzed in real time following the week 4 and 8 visits. Patients whose combined serum levels of imipramine and desipramine exceed 500 mcg/ml will be withdrawn from the trial.

Rationale: The rhythm strips and the serum analysis have been added to provide additional safety monitoring for patients receiving tricyclic anti-depressants. The revised heart rate criterion agrees with FDA guidelines for studies in adolescents.

Section 7.5.2 Reporting Serious Adverse Events

Revised: The SB medical monitor has been changed from [redacted]

STUDY DRUG ; BRL 29060/*PAROXETINE* (PAXIL)

PROTOCOL NUMBER 29060/329
Approved: 26 August 1993
Amendment #1 Approved 17 April 1994

A MULTICENTER DOUBLE BLIND PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

Amendment #2 Approved: October 28, 1996

Study Medication: Study medication supplies are limited necessitating change in target enrollment in both the acute and continuation phase.

Acute Phase: For the acute phase, the target enrollment will be reduced from 300 patients to approximately 275 patients. It is anticipated that this reduction in sample size will have no adverse effect on the estimated 80% power of this study to detect a four point difference between placebo and active groups. The initial sample size of 300 patients was based on an effect size of 0.4 in the HAMD. However, the actual variability in the HAMD measured for the initial 100 patients enrolled (standard deviation of 8) is smaller than estimated in the protocol at study start (standard deviation of 10). Thus, if the lower variability is maintained, 275 patients would provide greater than 80% power to detect the estimated difference of 4 points on the HAMD.

Continuation Phase The limited supply of blinded continuation medication may preclude up to 10 qualified patients from entering the extension phase. This amendment provides two options for responding patients who qualify for further treatment, but for whom blinded medication is unavailable.

Option #1) Provide same medication as used in acute phase of the trial. In this case, the patient will be withdrawn from the trial and continued treatment will be provided by a third party not associated with the trial. The third party will be provided the identity of the study medication.

Option #2) Initiate open label paroxetine. In this case, the patient is withdrawn from the trial but can elect to remain under

the care of the present study physician. If this option is deemed appropriate, the patient will be down titrated and after a one week wash out period, may begin open label paroxetine for up to six months.

There was no formal hypothesis established for the continuation phase. The primary objective is to provide long term safety data. Thus the small reduction in the number of patients entering this phase should not significantly impact the objective.

Regardless of which option is selected, the study medication identity will not be revealed to any personnel associated with the trial, unless required to treat an adverse event.

Information collected after the acute phase of the trial from patients selecting either of the two options will not be included in the formal study analysis. However, in so far as data are available, these will be summarized separately using descriptive statistics.

Section 7.5.2 : The address and phone number of the SB Medical Monitors has been changed to reflect new location.

SYNOPSIS

TITLE	A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression
DRUG UNDER STUDY	Imipramine (up to 300 mg) Paroxetine (up to 40 mg) Placebo
INTENDED INDICATION	Treatment of adolescents with unipolar major depression
OBJECTIVES OF STUDY	1. To compare the safety and efficacy of imipramine and Paroxetine to placebo in the treatment of adolescents with unipolar major depression. 2. To assess the rate of relapse among imipramine, Paroxetine and placebo responders who are maintained on treatment).
INVESTIGATORS	Multicenter, USA
STUDY DESIGN	Multicenter, double blind, placebo controlled, parallel group study
DURATION OF TREATMENT	8 Week acute phase with a 6 month extension.
NUMBER OF PATIENTS	300 patients with 100 randomized to each treatment group.

PRINCIPAL END POINTS

- Primary Efficacy Variables
  - Change in total HAMD score from beginning of treatment phase to the endpoint of the acute phase.
  - The proportion of responders at the end of the eight week acute treatment phase. Responders are defined as 50% or greater reduction in the HAM-D or a HAM-D score equal to or less than 8.
- Secondary Efficacy Variables
  - Change from baseline to endpoint (acute phase) in the depression items of the K-SADS-L, global impressions, autonomic function checklist, self perception profile and sickness impact scale.
  - The number of patients who relapse during the maintenance phase.
- Safety Variables
  - Safety evaluation will be based on adverse experience monitoring, laboratory evaluation, cardiovascular parameters, vital signs and physical examinations.

DURATION OF STUDY

- It is anticipated the study will start in November '93. Recruitment will be for three years, the 8-month study should complete 2Q97.

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1.0 INTRODUCTION

Similarities between adolescent and adult depression in symptomotology, family history, and prospective course provide compelling rationale for investigating the efficacy of antidepressant drug therapy in young patients with depression. But unlike adults, the evidence from trials in adolescents does not support drug efficacy, although the existing studies have collectively evaluated fewer than 200 patients, a number hardly adequate for reliable clinical or statistical inferences.

This apparent difference in response between adults and younger patients has been the subject of much debate, and recent reviews (Conners, 1992; Strober, 1992; Jenson et al., 1992) have focused on three major areas of concern. These include: (1) deficiencies in study design, methodology and conduct; (2) the adequacy of diagnostic criteria and various nosological problems; and (3) developmental issues in that children and adolescents who suffer from adult-like depression may respond in a pharmacologically different manner due to quantitative and/or qualitative developmental differences in neurotransmitter/receptor systems.

The study outlined in this protocol proposes to re-examine antidepressant therapies in adolescents with unipolar major depression using a study plan designed to avoid the perceived flaws of previous studies. This will be a multi-center placebo controlled trial with a target enrollment that will provide sufficient power to detect clinical differences among treatment groups, if these differences exist. The study has rigorous inclusionary and exclusionary criteria so that the study population is more homogenous than reported in previous trials. Diagnostic interviews will be reviewed among the various sites to confirm criteria symptoms of depression and to promote uniformity in diagnosis. Responders will be prospectively defined.

One of the treatment arms will be paroxetine (Paxil), an orally administered antidepressant with a chemical structure unrelated to other selective serotonin reuptake inhibitors (SSRI), or heterocyclic or other antidepressant medications. It has recently been approved by the Food and Drug Administration for the treatment of depression based, in part, on clinical trial data in over 3000 adult patients with major depressive illness. Paroxetine has not been systematically studied in adolescent depression.

A second arm will be imipramine. This tricyclic has been the subject of two small open labeled clinical trials in adolescents, one of which has demonstrated a modest therapeutic response in patients with nondelusional depression.

Please refer to the Paxil (paroxetine) and Tofranil (imipramine) prescribing information for detailed information.

Adolescents from ages 12 years 0 months through 18 years 11 months inclusive who are currently in an episode of major depressive disorder (DSM-III-R) with a minimum duration of eight weeks and have a Hamilton severity score of 12 or greater will be included in this 8 week double-blind placebo controlled study. At the completion of the 8 week acute study, clinical responders will be blindly continued on the same medication in a 6 month extension study. Non-responders at the end of the 8 week acute period will be withdrawn and treated openly.

2.0 OBJECTIVES

2.1 Primary

- To compare the efficacy and safety of imipramine and paroxetine to placebo in the treatment of adolescents with unipolar major depression .

2.2 Secondary

- To identify predictors of treatment outcomes across clinical subtypes. The following indicators of differential response will be examined, but no directional hypotheses are formulated: endogenous subtype, age at onset, number of prior episodes, duration and severity of current episode, comorbidity with separation anxiety disorder, attention deficit disorder, and conduct disorder.

- To provide information on the safety profile of paroxetine and imipramine when these agents are given for an extended period of time.

- To estimate the rate of relapse among imipramine, paroxetine and placebo responders who are maintained on treatment.

3.0 STUDY PLAN

3.1 Study Design

This will be a multicenter double-blind placebo controlled trial. Adolescents from ages 12 years 0 months through 18 years 11 months inclusive who are currently in an episode of major depressive disorder (DSM-III-R) with a minimum duration of eight weeks and have a Hamilton severity score of 12 or greater will be included in this 8 week double-blind placebo controlled three cell study of the efficacy of paroxetine and the efficacy of imipramine versus placebo.

The treatment period will be of 8 weeks duration. During this time, patients will make weekly visits to the clinic and the effects of treatment on depression will be evaluated using standardized instruments and as well as global assessments. In addition, various safety assessments will be carried out at each visit. Section 5 below describes the study procedures in detail and Appendix D presents the study flow in schematic fashion.

At the completion of the 8 week acute study, clinical responders will be blindly continued on the same medication in a 6 month extension study. Non-responders at the end of the 8 week acute period will be withdrawn and treated openly. Throughout the study, at each site the number of subjects assigned will be approximately equal and each cell will be approximately group balanced for several potentially important covariates.

4.0 STUDY POPULATION

4.1 Number of patients

Three hundred patients will be entered in up to 6 centers and randomized to receive either imipramine (100 patients) paroxetine (100 patients) or placebo (100 patients). Each center will recruit approximately 12 -15 patients per year.

4.2 Inclusion criteria

1. Adolescents between the ages of 12 years 0 month and 18 years 11 months inclusive.

2. Currently in an episode of major depression (DSM-III-R) for at least 8 weeks. A diagnosis of major depression will be made on summary data aggregating parent and child report. In addition, both adolescent and parent(s) must agree that the adolescent has a disorder meriting treatment.

3. A severity score less than 60 on the Child Global Assessment Scale (C-GAS).

4. A score of 12 or greater on the 17-item Hamilton Depression Scale (HAM-D).

5. Medically healthy as determined by physical examination, medical history and laboratory screening.

6. IQ □ 80 by Peabody Picture Vocabulary Test.

4.3 Exclusion Criteria

1. Patients with current or lifetime DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia nervosa, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder.

2. Patients with a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R).

3. Patients who have had an adequate trial of anti-depressants within 6-months prior to beginning this study. An adequate trial is defined as a treatment of at least four weeks or more with imipramine, desipramine, or amitriptyline at a dosage of 150 mg per day or greater, with nortriptyline at a dosage of 50 mg per day or greater, or with fluoxetine at a dosage of 20 mg per day or greater.

4. Patients who have suicidal ideation with a definite plan, or who have made a suicide attempt within the current episode, or who have ever made a suicide attempt by medication overdose.

5. Patients with medical illness which contraindicate the use of heterocyclic antidepressants (e.g. cardiovascular disease).

6. Patients using (1) psychotropic medications including anticonvulsants, anxiolytics, neuroleptics, lithium carbonate, or (2) illicit drugs as documented by a drug screen within two weeks of starting the study.

7. Patients with organic brain disease, epilepsy or mental retardation.

8. Patients who are pregnant or lactating.

9. Sexually active girls who are not using a reliable methods of contraception (oral contraception, surgical sterilization. I.U.D., diaphragm in conjunction with spermicidal foam and condom on partners).

10. Use of an investigational drug within 30 days of entry into the study or within five half lives of the investigation drug (the longer period will apply).

5.0 CONDUCT OF STUDY

The study will be conducted according to Good Clinical Practice, the Declaration of Helsinki (Appendix A) and US 21 CRF Part Protection of Human Subjects, and Part 56 - Institutional Review Board.

5.1 Ethical Considerations

5.1.1 Ethics Review Committee (ERC)/Institutional Review Board (IRB)

This protocol will be submitted to an appropriate Committee or Board and their written unconditional approval obtained and submitted to the sponsor before commencement of the study.

SB will supply relevant data for the investigator to submit to the hospital/university/independent ERC/IRB for the protocol's review and approval. Verification of the ERC/IRB's unconditional approval of the protocol and either the written informed consent statement or sample oral witnessed consent form with written information to be given to the subjects will be transmitted to the SB Study Monitor prior to shipment of drug supplies and CRFs to the site. This approval must refer to the study by exact protocol title and number, identify the documents reviewed and state the date of review.

The ERC/IRB must be informed by the investigator of all subsequent protocol amendments and of serious or unexpected adverse experiences occurring during the study which are likely to affect the safety of the subjects or the conduct of the study. Approval for such changes must be transmitted in writing to the SB Study Monitor via the investigator.

5.1.2 Informed Consent

The principals of informed consent in the current edition of the Declaration of Helsinki (Appendix A) should be implemented in each clinical study before protocol-specified procedures are carried out.

Informed consent will be obtained in accordance with 21 CFR 50.25.

Information should be given in both oral and written form whenever possible and deemed appropriate by the ERC/IRB. Subjects, their relatives, guardians or, if necessary, legal representatives must be given ample opportunity to inquire about details of the study.

The consent form generated by the investigator with the assistance of SB, must be approved (along with the protocol) by the ERC/IRB and be acceptable to SB. Consent forms must be in a language fully comprehensible to the prospective subject or the subject's legally authorized representative.

The written consent document will embody the elements of informed consent as described in the Declaration of Helsinki and will also comply with local regulations. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

Consent must be documented either by the subject's dated signature or by the signature of an independent witness who records the subject's assent. In either event the signature confirms the consent is based on information that has been understood. Each subject's signed informed consent form must be kept on file by the investigator for possible inspection by Regulatory Authorities and/or SB professional and Regulatory Compliance persons.

5.2 Study Method

A patient log will be kept of all patients considered for the study including those not entering the trial. The reasons for excluding patients from the study will be recorded.

The study will consist of three phases: 1) a screening phase of 7-10 days to assess the suitability of a patient for inclusion into the trial; 2) an acute treatment phase of 8 weeks duration in which eligible patients will be randomly assigned to receive either imipramine, paroxetine or placebo, and 3) an extension phase of 6 months duration during which clinical responders will be blindly continued

on their randomized medication. Non responders at the end of the 8-week acute period will be withdrawn and treated openly.

Appendix D provides a summary in tabular form of the study procedures and timings.

5.2.1 Screening Phase

Subjects will initially be screened by telephone. All sites will use the Screening for Youth Depression. This screen will review depressive syndrome criteria and major inclusion and exclusion criteria. Subjects who appear likely to meet the study criteria will be evaluated promptly thereafter.

Revised

24 March 1994

Diagnostic assessment will be done using the K-SADS-L with both the adolescent and parent(s). The K-SADS-L semi-structured clinical interview (revised to include present and past psychiatric disorders) will be administered in the fashion described in the instructions for that instrument and will be used to assess the presence or absence of each of the criteria symptoms for depression including a scale for atypical depression. The parent(s) and the adolescent are separately interviewed to assess each symptom. The clinician forms a summary rating based on best overall information combining all sources. For those symptoms where there is significant discrepancy between information provided by the adolescent and information provided by the parent(s), the clinician, adolescent and parent(s) all sit together and discuss the information provided by each source and reach a best conclusion.

Overall global functioning will be assessed at the initial interview using the Child Global Assessment Scale (C-GAS).

All K-SADS interview data will be directly confirmed by a senior clinician (psychiatrist or psychologist) who will interview both the adolescent and parent(s) and will confirm each of the positive criteria for depression by direct interview. The psychiatrist or psychologist will also review each of the items for the Hamilton Depression Rating Scale.

Diagnostic interviews will be audiotaped. If a prospective subject refuses to be audiotaped, this will not be a reason to deny entry. Cases will be reviewed by the Principal

investigator or Co-Principal Investigator at the local site who will confirm each patient meets the study entrance criteria.

Added
24 March 1994

If a subject meets 6 or fewer DSM III-R criteria for major depression disorder or the investigator reviewing the diagnosis is uncertain, the investigator must contact one of the principal investigator at a separate site (see Appendix H) to discuss the case. The external reviewer must review the audiotape and return a decision within 2 days. If investigator and external reviewer disagree on inclusion, the external reviewer's opinion shall take precedence.

Following the initial assessment of an adolescent who meets the inclusion criteria and signs the informed consent, the subsequent seven to ten days will be used to obtain medical or psychiatric records of prior treatment where indicated, and to document that the depressive symptomotology is stable after the initial psychiatric contact.

During this time a physical examination will also be conducted to assure the patient is in good medical health. The exam will include clinical laboratory studies (Appendix E) and a cardiovascular evaluation to include 12 lead EKG, heart rate and blood pressure measurements.

At the end of this interval, the adolescent will return to the clinic and will be re-evaluated. Only subjects continuing to meet inclusion criteria (DSM-III-R major depression and the Hamilton Rating Scale total score of 12 or greater) will be included.

Additional instruments to be administered at the end of the assessment period include the Autonomous Functioning Checklist, the Self Perception Profile for Adolescents and the Sickness Impact Scale.

During the assessment interval, a family history will be obtained on all first degree family members using the mother as informant (or other parent or parent surrogate if required). The mother will be interviewed about her lifetime history using the SADS-L and family history of all other first degree relatives using the Family History-Research Diagnostic Criteria (FH-RDC).

A brief description of the various scales and instruments is provided in Appendix F.

5.2.2 Randomization

Randomized Assignment of Subjects to Treatment

A computer generated randomization list will be used in which treatments are balanced within blocks of 6 consecutive patients. Patients will be allocated from 001 to 360. The master randomization list will be held by SmithKline Beecham. The treatment codes may be broken during the study for an individual patient in case of emergency. However, every effort should be made to contact SmithKline Beecham Medical Monitor prior to breaking the treatment code.

5.2.3 Treatment Phase

Assessments during study visits

During the eight week acute phase of the study, each patient will make weekly visits to the clinic. At each visit the following assessments will be carried out:

- HAM-D
- Depression section from the K-SADS-L (every other week)
- Clinical Global Improvement Scale
- Adverse Events
- Cardiovascular Functioning
- Clinical Laboratory Studies (Week 8)

Cardiovascular functioning will be assessed at baseline by obtaining a 12 lead EKG, heart rate, and blood pressure measurements. At each clinic visit, each subject will have a repeat blood pressure sitting and standing and heart rate assessment.

Revised

A 12 Lead EKG will be performed at visits 4 and 8. Rythym strip
24 March 1994 EKG will be carried out at all other visits. Cardiovascular limits to titration (i.e. acceptable limits requiring no change in study medication) will be as follows, using criteria developed by [redacted] and [redacted]

resting heart rate < 130*.
resting systolic BP < 140; resting diastolic BP < 85
PR interval < 0.21
QRS interval < 0.12 and less than 150% of baseline
QTC < 0.48

* If the resting heart rate exceeds 110 bpm on two consecutive visits, a dose adjustment is required.

Cardiovascular parameters outside those described above will result in decreasing medication dosage by one tablet level. If a patient is at level 4 or below (see Section 6.0 - Study Drug Administration), he or she will be removed from the study.

Serum Levels

Revised

24 March 1994

Blood samples for analysis of paroxetine as well as imipramine and desipramine will be obtained on all subjects no matter to which treatment they are assigned. Blood will be collected at baseline and after 4 and 8 weeks of treatment and the samples shipped to the Clinical Trials Center of SmithKline Clinical Laboratories (SBCL) in VanNuys California. Written instructions for the collection, preparation and shipping of the samples will be provided to each investigator.

The paroxetine samples will be stored by SBCL until the completion of the study when the plasma will be analyzed for paroxetine concentration. The imipramine/desipramine sample will be analyzed when received by the SBCL. The concentration of imipramine and desipramine data will be retained by SBCL until the completion of the trial. However, if in a given patient, the combined levels of imipramine and desipramine exceed 500 mcg/ml of serum, the investigator will be immediately notified and that patient will be withdrawn from the study. Any further treatment will be as deemed appropriate.

Medical Management -- Psychotherapy

Experience in protocols in depressed adolescents suggest that patients and families expect psychotherapy and are reluctant to consider a course of medication treatment alone, especially

where the medication may be solely placebo. On the other hand, a provision of treatment with a psychotherapy which, in retrospect, turned out to be extraordinarily efficacious might well preclude the demonstration of a real, significant, and clinically meaningful medication effect. There are currently several research groups beginning the process of examining different specific psychotherapies (e.g. cognitive behavioral and interpersonal) for adolescent depression. As of yet, however, there are no completed controlled studies which would suggest a "reference" psychotherapy treatment. The present study will include supportive psychotherapy, similar to the management as described by Fawcett in Appendix G.

Modified

24 March 1994

Please note, however, that the procedures in this appendix are meant to serve as a guideline. Where differences exists between the appendix and the protocol (e.g. dosing criteria), the protocol takes precedence.

Weekly visits will consist of a 45 minute visit with the therapist. In unusual circumstances, emergency contact of greater duration is permitted. Duration of all contact including phone calls will be systematically documented.

Definition of "responders" and "non-responders" at the end of eight-week acute treatment

To be classified as a "responder" and continue to the continuation phase, a subject must have a HAM-D score ≤ 8 or a decrease in baseline HAM-D total score □ 50%:

Termination at end of acute study for non-responders

At the end of the acute phase subjects who are "non-responders", as defined above, will be terminated from the study. Medication/placebo will be tapered off over a 7-17 day period at which time their care will be transferred to clinical personnel who are not part of this study. The patient and family, all clinical personnel, and all research personnel will remain blind to medication assignment of all subjects even after termination of the acute phase.

In some subjects, for safety reasons, it may be necessary for the clinical personnel to be informed which medication the subject was on. The decision to unblind the clinical personnel will be made jointly with clinical personnel at the site and clinical personnel at SmithKline Beecham.

5.2.4 Extension study

Subjects who are "responders" at the end of the double-blind acute study will be blindly continued on the current (final) dose of imipramine/paroxetine/placebo for an additional six months. For the purposes of this study, it is estimated that 65% of subjects in both active treatment will be "responders" and 40% of subjects on placebo will be a "responder".

The aims of the continuation phase are: 1) to provide an estimate of the benefits of extended treatment with anti-depressant medications and 2) to provide a safety profile of antidepressants given for an extended period of time.

Procedures for 6-month follow-up:

1. Maintain last medication/placebo dose blindly.

Revised
24 March 1994

2. Monthly psychiatric and safety assessments:

   a) Affective section of K-SADS-L interview
   b) Hamilton depression rating scale
   c) Adverse Events
   d) Clinical Global Assessment Scales
   e) EKG rhythm strip, blood pressure, and heart rate assessment
   f) Clinical Laboratory Studies (Week 20)
   g) Serum Drug Levels (Week 20)

3. Assessment at termination of the 6-month extension:

   a) Full K-SADS-L
   b) Hamilton Depression rating scale
   c) Adverse Events
   d) Clinical Global Assessment Scales
   e) 12 lead EKG strip, blood pressure, and heart rate assessment
   f) Clinical Laboratory Studies
   g) Serum Drug Levels

6.0 DRUG SUPPLIES AND PACKAGING

6.1 Formulations

Medication will be administered in the form of green capsules. Paroxetine will be provided as 10 mg over encapsulated tablets, imipramine will be 50 mg over encapsulated tablets while placebo will be provided in a tablet dosage form identical in appearance to paroxetine, over encapsulated.

6.2 Study Drug Administration

Dose of study medication

There will be six dosing levels. All patients will be titrated to level 4 regardless of response. Levels 5 and 6 are optional for those who do not respond after reaching level 4. The timings and dosage at each level are as follows:

	DAY	IMIPRAMINE	PAROXETINE
Level 1	1 - 7	50 mg	20 mg
Level 2	8 - 14	100 mg	20 mg
Level 3	15 - 21	150 mg	20 mg
Level 4	22 - 28	200 mg	20 mg
Level 5	*	250 mg	30 mg
Level 6	*	300 mg	40 mg

6.3 Blinding

The study will use 10 and 20 mg paroxetine tablets and the corresponding placebos. Also to be used will be the 50 mg imipramine tablets and corresponding placebo tablets. The "paroxetine placebos" will be identical in size, color and shape to the 10 and 20 mg paroxetine un-monogrammed tablets. Likewise, the imipramine placebo tablet will be the same size, shape and color as the active imipramine.

6.4 Concomitant Medication

All concomitant medication taken during the study must be recorded in the case report form with indication, daily dose, and dates of administration.

Subjects will not be allowed to take other psychotropic medications. Subjects will be permitted to take medications without CNS effects for medical illnesses or conditions as necessary. Medications which are not psychotropic, but which may have CNS effects (e.g. prednisone, antihistamines) should be avoided or used for the minimum length of time consistent with good medical care.

6.5 Packaging

The capsules will be packaged using blister cards. One card will hold sufficient supplies for a one week treatment period (10 days). Patients will be instructed to take medication twice daily, one dose in the morning and one at night. The number of capsules for each dose will depend on the dosing level achieved; the minimum number of capsules to be taken daily is two, the maximum is six.

6.6 Labeling and Preparation

For all phases, the tear off portion of the label must be affixed to the CRF when medication is dispensed to the patient. All unused cards must be returned to the sponsor at the end of the study.

6.7 Storage

Study medications must be kept in a locked area and dispensed according to the protocol. Records of dispensed supplies must be kept current on forms which the sponsor will also supply. All unused supplies must be returned to the sponsor at the end of the study.

6.8 Drug Accountability

The investigator will sign that he or she has received the clinical supplies for this study and that the study supplies will be handled and stored safety and properly.

6.9 Assessment of Compliance

A record of the amount of drug dispensed, taken, and returned will be recorded in the CRF for each patient, to assess compliance. The patient will be instructed to return the previous intervals drug container, including any unused medication at each visit.

If a patient takes less than 80% or more than 120% of study drug at each of two consecutive visits, the patient will be considered non-compliant and withdrawn from the study. A patient who misses two consecutive visits will also be withdrawn from the study.

6.10 Overdosage

The following information on overdosage is provided in the prescribing information for Paxil and Tofranil.

For paroxetine, treatment should be consistent with those general measures employed in the management of overdosage with any antidepressant. There are no specific antidotes for paroxetine. Establish and maintain an airway, ensure adequate oxygenation and ventilation. Gastric evacuation either by the induction of emesis or lavage or both should be performed. In most cases, following evacuation, 20 to 30 grams of activated charcoal may be administered every 4-6 hours during the first 24-36 hours after ingestion. An ECG should be taken and monitoring of cardiac function instituted if there is any evidence of abnormality. Supportive care with frequent monitoring of vital signs and careful observation is indicated. Due to the large volume of distribution of paroxetine, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit.

A specific caution involves patients taking paroxetine or recently having taken paroxetine who might ingest by accident or intent excessive quantities of a tricyclic antidepressant or a MAO inhibitor. In such a case, accumulation of the parent tricyclic and its active metabolite may increase the possibility of clinically significant sequalae and extend the time needed for close observation.

In managing overdosage, consider the possibility of multiple drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of overdosage.

For imipramine:

Children have been reported to be more sensitive than adults to an acute overdosage of imipramine hydrochloride. An acute overdose of any amount in infants or young children, especially, must be considered serious and potentially fatal.

Signs and Symptoms:

These may vary in severity depending upon factors such as the amount of drug absorbed, the age of the patient, and the interval between drug ingestion and the start of treatment. Blood and urine levels of imipramine may not reflect the severity of poisoning; they have chiefly a qualitative rather than quantitative value, and are unreliable indicators in the clinical management of the patient. CNS abnormalities may include drowsiness, stupor, coma, ataxia, restlessness, agitation, hyperactive reflexes, muscle rigidity, athetoid and choreiform movements, and convulsions.

Cardiac abnormalities may include arrhythmia, tachycardia, ECG evidence of impaired condition, and signs of congestive failure.

Respiratory depression, cyanosis, and diaphoresis may also be present.

Treatment:

The recommended treatment for overdosage with tricyclic antidepressants may change periodically. Therefore, it is recommended that the physician contact a poison control center for current information on treatment. Because CNS involvement, respiratory depression and cardiac arrhythmia can occur suddenly, hospitalization and close observation may be necessary, even when the amount ingested is thought to be small or the initial degree of intoxication appears slight or moderate. All patients with ECG abnormalities should have continuous cardiac monitoring and be closely observed until well after cardiac status has returned to normal; relapses may occur after apparent recovery.

In the alert patient, empty the stomach promptly by lavage. In the obtunded patient, secure the airway with a cuffed endotracheal tube before beginning lavage (do not induce emesis). Instillation of activated charcoal slurry may help reduce absorption of imipramine.

Minimize external stimulation to reduce the tendency to convulsions. If anticonvulsants are necessary, diazepam, and phenytoin may be useful.

Maintain adequate respiratory exchange. Do not use respiratory stimulants.

Shock should be treated with supportive measures, such as appropriate position, intravenous fluids, and if necessary, a vasopressor agent. The use of corticosteroids in shock is controversial and may be contraindicated in cases of overdosage with tricyclic antidepressants. Digitalis may increase conduction abnormalities and further irritate an already sensitized myocardium. If congestive heart failure necessitates rapid digitalization, particular care must be exercised.

Hyperpyrexia should be controlled by whatever external means are available, including ice packs and cooling sponge baths, if necessary.

Hemodialysis, peritoneal dialysis, exchange transfusions and forced diuresis have been generally reported as ineffective because of the rapid fixation of imipramine in tissues. Blood and urine levels of imipramine may not correlate with the degree of intoxication, and are unreliable indicators in the clinical management of the patient.

The slow intravenous administration of physostigmine salicylate has been used as a last resort to reverse CNS anticholinergic manifestations of overdosage with tricyclic antidepressants; however, it should not be used routinely, since it may induce seizures and cholinergic crises.

7.0 ADVERSE EXPERIENCES

The recording of adverse experiences is an important aspect of study documentation. Detailed guidelines are set out below.

7.1 Eliciting and Documenting Adverse Experiences

It is the responsibility of the investigator to document all adverse experiences which occur during the investigation. An adverse experience includes any noxious, pathologic or unintended change in anatomical, physiologic or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of the clinical trial whether associated with drug or placebo and whether or not considered drug related.

This includes an exacerbation of pre-existing conditions or events, intercurrent illnesses, drug interaction or the significant worsening of the disease under investigation that is not recorded elsewhere in the case report form under specific efficacy assessments. Anticipated day-to-day fluctuations of the disease under study that do not represent a clinically significant exacerbation or worsening need not be considered an adverse event.

All adverse experiences occurring after the start of the study must be reported. Subject entry into the study is defined as the time at which informed consent is obtained. (This must be before any protocol-specific diagnostic procedures or interventions.) All subsequent adverse experiences, whether no drug (ie. during reference 'run-in' or 'wash-out' period) or when active drug or placebo is being administered, must be reported REGARDLESS OF WHETHER OR NOT THEY ARE CONSIDERED DRUG RELATED.

At each visit/assessment, adverse experiences will be evaluated by the investigator. Adverse experiences not previously documented in the study will be recorded in the adverse experience section of the subject's case record form. The nature of each experience, data and time (where appropriate) of onset, duration, severity and relationship to treatment should be established. Details of changes to the dosage schedule or any corrective treatment should be recorded on the appropriate pages of the case record form.

Adverse experiences already documented in the CRF ie. at a previous assessment and designated as 'continuing' should be

reviewed. If these have resolved, the documentation in the CRF should be completed. NB. If an adverse experience changes in frequency or severity during a study period, a new record of the experience will be started.

Ask the subject a non-leading question such as: "Do you feel different in any way since starting the new treatment/the last assessment."

7.2 Assessment of Severity

Maximum intensity should be assigned to one of the following categories:

Mild: For example, an adverse experience which is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities.

Moderate: For example, an adverse experience which is sufficiently discomforting to interfere with normal everyday activities.

Severe: For example, an adverse experience which is incapacitating and prevents normal everyday activities.

7.3 Assessment of Causality

Every effort should be made by the investigator to explain each adverse experience and assess its relationship, if any, to study drug treatment. Causality should be assessed using the following categories: unrelated, probably unrelated, possibly related, related.

The degree of certainty with which an adverse experience is attributed to drug treatment (or alternative causes, e.g. natural history of the underlying diseases, concomitant therapy, etc.) will be determined by how well the experience can be understood in terms of the following:

- Known pharmacology of the drug
- Reaction of similar nature being previously observed with this drug or class of drug
- The experience having often been reported in literature for similar drugs as drugs related, e.g. skin rashes, blood dyscrasia

- The experience being related by time to drug ingestion terminating with drug withdrawal (dechallenge) or reproduced on rechallenge.

7.4 Following-up of Adverse Experiences

Investigators should follow-up subjects with adverse experiences until the event has subsided (disappeared) or until the condition has stabilized. Reports relative to the subject's subsequent course must be submitted to the clinical study monitor.

7.5 Serious Adverse Experiences

7.5.1 Definition of Serious Adverse Experiences:

A serious adverse experience is any event which is fatal, life threatening, disabling or incapacitating or results in hospitalization, prolongs a hospital stay or is associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event.

Life threatening - definition:

An adverse experience is life threatening if the subject was at immediate risk of death from the event as it occurred; i.e. it does not include a reaction that if it had occurred in a more serious form might have caused death. For example, drug induced hepatitis that resolved without evidence of hepatic failure would not be considered life threatening even though drug induced hepatitis can be fatal.

Disability/incapacitating definition:

An adverse experience is incapacitating or disabling if the experience results in a substantial and/or permanent disruption of the subject's ability to carry out normal life functions.

7.5.2 Reporting Serious Adverse Experiences

Any serious adverse experiences which occur during the clinical study or within 30 days (or five half lives whichever is the longer) of receiving the last dose of study medication, whether or not related to the study drug, must be reported by the investigator to the study monitor (by telephone within 24 hours).

All serious adverse experiences must be reported by telephone within 24 hours to the study monitor:

Revised
24 March 1994

The Medical Monitor for this protocol is:

[redacted]

The Back-up Monitor for this protocol is:

[redacted]

The telephone report should be followed by a full written summary detailing relevant aspects of the adverse experiences in question. Where applicable, information from relevant hospital case records and autopsy reports should be obtained.

Instances of death, cancer or congenital abnormality if brought to the attention of the investigator AT ANY TIME after cessation of study medication and linked by the investigator to a previous clinical trial, should be reported to the study monitor.

7.6 Overdosage

Any instance of overdosage (suspected or confirmed) must be communicated to SmithKline Beecham within 24 hours and be fully documented as a serious adverse experience. Details of any signs or symptoms and their management should be recorded including details of any antidote(s) administered.

7.7 Pregnancy

Subjects who become pregnant during the study should discontinue the study immediately, unless the protocol states otherwise.

Patients should be instructed to notify the investigator if it is determined after completion of the study that they become pregnant either during the treatment phase of the study or within 30 days or five half-lives after the treatment period, whichever is longer.

Whenever possible a pregnancy should be followed to term, any premature termination reported, and the status of the mother and child should be reported to SmithKline Beecham after delivery.

7.8 Breaking the Study Blind

Only in the event of a serious adverse experience which the investigator feels cannot be adequately treated without knowing the identity of the study medication, may the medication code be broken for a particular subject. Every effort must be made to contact an SB Medical Monitor prior to breaking the code. If this is not possible and the situation is an emergency the investigator may break the code and contact the Medical Monitor as soon as possible thereafter.

8.0 SUBJECT COMPLETION AND WITHDRAWAL

8.1 Definitions

For the purpose of this protocol, a patient will be considered to be a "completed subject if they complete the 8 week acute phase". A withdrawal will be any subject who enters the study i.e. gives informed consent, and does not complete the 8 week study period (whether or not subject received study medication).

Because the extension phase is addressing maintenance therapy, it is anticipated that some patients will relapse. Accordingly, the definition of a "completed subject will be modified to be any patient who completes the full six months of therapy or any patient who withdrawals from therapy because of a relapse".

8.2 Procedures for Handling Withdrawals

It is anticipated that in a few subjects the study will be terminated early because of medication side effects. potential reasons for early termination include cardiovascular side effects beyond those permitted (see above), allergic reaction to medications, etc. Decisions for early study termination for medical or other reasons should be the responsibility of the principal investigator at each site. In all cases, subjects terminated early for any reason including medical reasons will be included in data analysis. Decision to terminate or not will be made blind to actual medication/placebo status--the blind will be broken only after termination is decided.

Should a patient decide to terminate the study early, a discontinuation taper is strongly recommended. If this accepted by the family, the medication will be tapered off in a linear fashion over a 7 to 17 day period.

8.3 Reason for withdrawal

A patient may withdraw from the study prior to completion for one of six possible reasons:

1. Adverse experiences including intercurrent illness
2. Insufficient therapeutic effect
3. Deviation from protocol including non-compliance

4. Lost to follow-up
5. Termination by SB
6. Other (specify).

The investigator should determine the primary reason for withdrawal and cite the one reason.

9.0 DATA EVALUATION

9.1 Criteria for Efficacy

9.1.1 Primary efficacy variables

a) The change in total HAMD score from beginning of the treatment phase to the endpoint of the acute phase.

b) The proportion of responders at the end of the eight week acute treatment phase.

9.1.2 Secondary efficacy variables

a) Changes from baseline to endpoint in the following parameters:

- Depression items in K-SAD-L
- Global Impressions
- Autonomic Function Checklist
- Self Perception Profile
- Sickness Impact Scale.

b) Predictors of response (endogenous subtypes, age, prior episodes, duration and severity of present episode, comorbidity with separate anxiety, attention deficit, and conduct disorder).

c) The number of patients who relapse during the maintenance phase.

9.2 Statistical Methods

9.2.1 Comparisons of interest

The comparison of primary interest is active treatment versus placebo. Hypotheses concerning these comparison will be tested at the alpha level of 0.05

9.2.2 Sample size determination

This study is designed to have adequate power to detect a clinically meaningful difference in both active-placebo comparisons at a two tailed alpha level of 0.05 and power 0.80. The sample size estimates are further based on an effect size of 0.40. The rationale for this effect size is as follows:

- A difference of 4 in the HAMD Total change from baseline scores at endpoint. This is a smaller difference than that seen in previous studies with antidepressants in adults, yet it is large enough to be clinically meaningful, and

- A standard deviation of 10. This is 20% larger than observed in studies with anti-depressants in adults and should reflect the greater variability in response expected in adolescent depression.

These parameter estimates result in 100 patients per treatment group.

9.3 Efficacy Analysis

9.3.1 Intent to Treat Analysis

All patients who receive double-blind medication will be considered as part of the ITT population. This patient population will be considered the primary population.

9.3.2 Patients Valid For The Efficacy Analysis

All patients randomized to study treatment and for whom at least one valid post-treatment efficacy evaluation is available will be valid for inclusion in an 'intent-to-treat' analysis. Patients who meet the following criteria will be eligible for the efficacy analysis:

a) No major protocol violation exists with regard to inclusion or exclusion criteria.

b) No other major protocol violation during the first 8 weeks of active treatment has occurred.

Only primary efficacy variables will be analyzed using this population. Patients to be excluded from the efficacy analysis will be identified before the randomization code is broken.

9.3.3 Statistical Methodology

Psychometric scales using at least an ordinal measurement scale will be analyzed using parametric analysis of variance, effects in the model will include treatment, investigator and treatment by investigator interaction. If the treatment by investigator interaction is not significant ($p > 0.1$) the interaction term will be dropped from the model. This analysis will be performed using the General Linear Models procedure of the SAS system. The ordinal scales which have very few levels (such as the CGI Severity of Illness) will also be analyzed using nonparametric methodology to ensure that the results are consistent across modes of analysis.

Dichotomous variables such as response (based on HAMD criteria) will be analyzed using Logistic Regression methodology. Effects in the model will include treatment, investigator, and treatment by investigator interaction; if the interaction is not significant then it will be dropped from the model. These analyses will be performed using the LOGISTIC procedure of the SAS system.

Summary statistics will be presented for demography, disease history, and baseline measures of efficacy.

An analysis of covariance will be performed to evaluate the effect of possibly important prognostic variables on the HAMD total score at endpoint. These include endogenous subtype, age at onset, gender, number of prior episodes, duration and severity of current episode, comorbidity with separate anxiety disorder, attention deficit disorder and conduct disorder.

9.3.4 Test of Significance

Tests of hypothesis regarding model assumptions such as the significance of treatment by investigator interactions will be made at the 10% level.

All other statistical tests will be two-tailed and performed at the 5% significance level.

9.3.5 Patient Characteristics At Baseline

Demographic and diagnostic variables at baseline will be checked for homogeneity between the treatment groups. If major differences exist for variables predictive of treatment response, their impact on the trial results will be investigated.

9.4 Safety Analysis

9.4.1 Patients Valid for Clinical Safety & Tolerability

All patients who receive coded medication will be assessed for clinical safety and tolerability.

9.4.2 Adverse Experiences

Adverse experiences will be coded for each subject with reference to body system and preferred terms. The treatment groups will be compared regarding the incidence of the reported adverse experiences with reference to both preferred term and body system. The comparison between treatments with regard to incidence of adverse experiences will be performed primarily by using descriptive statistics.

9.4.3 Other Clinical Safety Variables

Information regarding demographic data, vital signs, physical examination, adverse experiences and abnormal laboratory values will be presented as listings and tables. All deviations from the study protocol and study withdrawals will be documented.

10.0 ADMINISTRATIVE MATTERS

To comply with Good Clinical Practice, important administrative obligations relating to investigator responsibilities, monitoring, archiving data, confidentiality and publications must be fulfilled as given in Appendix B.

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Appendices

APPENDIX A

DECLARATION OF HELSINKI

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Recommendations guiding physicians in
biomedical research involving human subjects

Adopted by the 18th World Medical Assembly,
Helsinki, Finland, June 1964,
Amended by the 29th World Medical Assembly,
Tokyo, Japan, October 1975,
35th World Medical Assembly,
Venice, Italy, October 1983
and the
41st World Medical Assembly
Hong Kong, September 1989

INTRODUCTION

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration", and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely

scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings for further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded with careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the

interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE
(Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS
(Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers -- either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

APPENDIX B

ADMINISTRATIVE MATTERS

I. RESPONSIBILITIES OF THE INVESTIGATOR

- To ensure that he/she has sufficient time to conduct and complete the study and has adequate staff and appropriate facilities which are available for the duration of the study and to ensure that other studies do not divert essential subjects or facilities away from the study at hand.

- To submit an up-to-date curriculum vitae and other credentials (e.g. medical license number in the United States) to the sponsor and - where required - to relevant authorities.

- To acquire the normal ranges for laboratory tests performed locally and, if required by local regulations, obtain the Laboratory License or Certification.

- To prepare and maintain adequate case histories designed to record observations and other data pertinent to the study.

II. PROTOCOL AMENDMENTS

No changes to the study protocol will be allowed unless discussed in detail with the SmithKline Beecham (SB) Medical Monitor and filed as an amendment/modification to this protocol.

Any amendment/modification to the protocol will be adhered to by the participating centre (or all participating centres) and will apply to tall subjects following approval as appropriate by the Ethical Review Committee or Institutional Review Board.

III. SPONSOR'S TERMINATION OF STUDY

SB reserves the right to discontinue the clinical study at any time for medical or administrative reasons. When feasible, a 30-day written notification will be tendered.

IV. CASE REPORT FORM INSTRUCTIONS

Prior to screening the first potential participant, the investigator will provide a list showing the signature and handwritten initials of all individuals authorized to make or change entries and case report forms (CRFs). If the authorized individuals should change during the study, the investigator is to inform SB.

CRFs (and subject diary cards, if applicable), will be supplied by SB for recording all data. It is the responsibility of the investigator or co-investigator to ensure that CRFs (and subject diary cards) are legible and completely filled in with a black ink ballpoint pen. Include the subject's identification (2-3 alphabetic letters representing initials or first letter of subject's name) on the front page of the CRF, the allocation number (if not pre-printed) and the visit date.

Errors must be corrected by drawing a single line through the incorrect entry and writing in the new value/data positioned as close to the original as possible. The correction must then be initialed, dated and justified by the authorized individual making the change. Do not obliterate, write over, or erase the original entry when making a correction.

When a subject completes a visit, it is anticipated that relevant sections of the CRF will be completed by the investigator (or designated staff) within 24 hours of the last data becoming available, but in no case later than 5 days. Similarly, when a subject completes a study, it is anticipated that all relevant CRF pages will be completed with in 24 hours of the last data becoming available, but in no case later than 5 days. This also applies to forms for potential study participants who were not randomized to a treatment group.

As soon as the subject has completed/withdrawn from the study and the CRF is completed the principal investigator or designated physician(s) under his/her supervision will sign the adverse experience page(s) as well as study conclusion page of t he CRF to confirm that they have reviewed the data and that the data are completed and accurate. If sections of a CRF are to be brought into SB prior to study conclusion, a section conclusion signature is required.

An original (top copy) CRF must be submitted for all subjects who have undergone protocol specific procedures, whether or not the subject completed the study.

While completed CRFs will be reviewed by an SB professional monitor at the study side, error detected by subsequent in-house CRF review may necessitate

clarification or correction of errors and documentation and approval by the investigator.

Any questions or comments related to the CRF should be directed to the assigned study monitor.

V. MONITORING BY SMITHKLINE BEECHAM (i.e. the Sponsor)

Monitoring visits by a professional representative of the sponsor will be scheduled to take place before entry of the first subject, during the study at appropriate intervals and after the last subject is completed.

These visits are for the purpose of verifying adherence to the protocol and the completeness and exactness of data entered on the CRF and Drug Inventory Forms. The monitor will verify CRF entries by comparing them with the hospital/clinic/office records which will be made available for this purpose. The monitor will retrieve completed CRF sections at each visit. Adequate time and space for these visits should be made available by the investigator.

Investigator must ensure provision of reasonable space and adequate qualified personnel for monitoring visits.

VI. ARCHIVING OF DATA

The investigator must retain subject records and CRFs as well as drug disposition records in an easily retrievable form until disposal has been agreed in writing with SB. The investigator must have a 'key' linking the subject's study identification number (i.e., treatment number) to the subject's clinical file. If the investigator moves or retires, he/she should nominate someone in writing to be responsible for record keeping. Archived data may be held on microfiche or electronic record, provided that a back-up exists and a hard copy can be obtained from it if required.

SB agrees to retain a copy of the protocol, documentation, approvals and all other documents related to the study, including certificates that satisfactory audit and inspection procedures have been carried out.

VII. AUDITS

For the purpose of compliance with Good Clinical Practice and Regulatory Agency Guidelines it may be necessary for SB or a Drug Regulatory Agency to conduct a site audit. This may occur at any time from start to after conclusion of the study.

When an investigator signs the protocol, he agrees to allow Drug Regulatory Agency and SB auditors to inspect his/her study records. Furthermore, if an investigator refuses an inspection, his/her data will not be accepted in support of a New Drug Registration and/or Application.

SB has a substantial investment in clinical studies. Having the highest quality data and studies are essential aspects of drug development. SB has a Regulatory Compliance staff who audit investigational sites. Regulatory Compliance assesses the quality of data with regard to accuracy, adequacy and consistency. In addition, Regulatory Compliance assures that SB sponsored studies are in accordance with the relevant Good Clinical Practices regulation/guidelines are being followed.

To accomplish these functions, Regulatory Compliance selects investigational sites to audit. These audits usually take 1 to 2 days. The SB audits entail review of source documents supporting the adequacy and accuracy of CRFs, review of documentation required to be maintained, and checks on drug accountability. The SB audit therefore helps prepare an investigator for a possible regulatory agency inspection as well as assuring SB of the validity of the database across investigational sites.

The Inspector will be especially interested in the following items:

- Log of visits from the sponsor's representatives
- ERC/IRB approval
- Test article accountability
- Approved study protocol and amendments
- Informed consent of the subjects (written or witnessed oral consent)
- Medical records supportive of CRF data
- Reports to the ERC/IRB and the sponsor
- Record retention.

SB will gladly help investigators prepare for an inspection

VIII. CONFIDENTIALITY AND PUBLICATION

You agree that all information communicated to you by SB is the exclusive property of SB and you will ensure that the same shall be kept strictly confidential by you or any other person connected with the work and shall not be disclosed by you or such person to any third party.

We agree that you shall have the right to publish or permit the publication of any information or material relating to or arising out of the work after prior submission to us provided that if we shall so request you will delay publication for a maximum of six months to enable us to protect our rights

in such information or material. Any proposed publication or presentation (e.g. manuscript, abstract or poster) for submission to a journal or scientific meeting, should be sent to the study monitor prior to submission. SB will undertake to comment on such documents within four weeks.

All rights and interest worldwide in any inventions, know-how or other intellectual or industrial property rights which arise during the course of and/or as a result of the clinical study which is the subject of this protocol or which otherwise arise from the information or materials supplied under this Agreement, shall be assigned to, vest in and remain the property of SmithKline Beecham plc.

In drafting this section, additional stipulations can be included in accordance with local custom and practice but the above aspects.

APPENDIX C

SAMPLE INFORMED CONSENT

Study Title: A Multicenter, Double-blind Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression.

Protocol Number: 29060/329

1. Nature and Purpose of the Project

I authorize Dr. _____ to include me in the research study "Multicenter, Double-blind Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression." I have been asked to participate in a research project which is designed to learn if paroxetine and/or imipramine has any benefit in the long-term treatment of unipolar depression in adolescents. It has been explained to me that I have been asked to participate in this research study because I have a diagnosis of unipolar depression. Both paroxetine and imipramine have been shown to be effective in treating unipolar depression in adults; however, it is not known if either paroxetine or imipramine has similar effects in adolescents with this illness. I understand that the study proposes to examine the clinical benefits of both paroxetine and imipramine in this disorder.

Procedures

I understand that if I participate in this research study, I will be interviewed by the research team to determine my history of emotional or psychiatric disturbance, and I will be asked questions about the psychiatric status of other members of my family. I also understand that I may be asked permission for research staff to contact these members of my family for further history of their emotional disturbance, and that I may deny this request.

I will also undergo various standard medical tests, including a complete physical exam, blood and urine tests, and a test of heart function to make sure that I am free of any physical or medical problems that would advise against use of the medications to be used in this study. I understand that at intake my urine will be screened for any drugs in my system.

It has been explained to me that I will be eligible to enter the study after the research staff has determined that I meet the criteria for depression and am in generally good medical health. At this point, I will be assigned randomly to receive paroxetine, imipramine, or a placebo sugar substitute. I will not find out what kind of mediation I am taking until completion of the study, which could run for as long as five years. In order to learn the benefits of anti-depressant medication, it is essential that neither I nor my doctors know to which treatment I have been assigned.

During the study, I will be interviewed by members of the research team every week for eight consecutive weeks. If my condition improves I may elect to continue treatment for additional 6 months. During this time I will be interviewed by the research team on a monthly basis. At the interviews, I will be asked questions about my behavior and mood and whether I have been taking the prescribed number of pills on a regular basis. I understand that no costs will be incurred for my participating in this phase of the research. Payment for lengthy sessions (two or more hours) with the adolescent and family for initial evaluation will be $ per subject. Participants will be reimbursed for the weekly and subsequently monthly evaluation sessions including blood drawing at $ per visit. No visit in connection with my participation in this phase of the study will be billed to me or my insurance carrier.

2. Discomforts and Risks

It is possible that paroxetine or imipramine will relieve depression in some adolescents as in adults. If so, assignment to placebo treatment might result in a lesser degree of treatment.

I understand that I may experience some discomfort as a result of the medication I receive. Treatment with paroxetine could produce side effects, the most common side effects are:

> General fatigue and muscular pain, sweating, nausea, itching, rashes, decreased appetite, sleepiness, dizziness, insomnia, nervousness, coughs, running nose, muscular tremors, changes in weight, and changes in heart rate.

Treatment with imipramine could produce side effects. The most common are:

> Dry mouth, blurred vision, rashes, nausea, and stomach upset, changes in heart rate, fainting, restlessness and agitation.

I understand that I am not more likely to experience side effects as a result of my participation in this study than if I were being treated with paroxetine or

imipramine in the usual manner. If I experience side effects, the doctors will attempt to adjust the dose.

If I cannot continue to take the medication because of side effects, I will not continue in the study and will receive the best alternative treatment. I understand that if I am a female I will be counseled by the research staff as to the risks involved in becoming pregnant while participating in the study. I am also aware that I may experience discomfort when having blood drawn; this may be a source of mild pain, and some mild swelling may occur at the site of the blood draw. Although it is uncommon, this may also cause me to feel faint, to bleed slightly, or to develop an infection at the site of the blood draw.

The interviews that I will receive during the course of the study involve no specific risks or discomforts beyond those of a standard clinical interview situation such as feeling upset at a review of my psychiatric status, boredom, or fatigue.

3. Benefits

I understand that the possible benefits to society include furthering our knowledge of the treatment of depression in teenagers. I also understand that of the treatment, medication, and testing will be free of charge.

4. Appropriate Alternative Procedures Beneficial to the Subject

The findings of this study will contribute to the understanding of a possible role for antidepressant medication in adolescent patients with depression. The researchers also expect to learn more about the longer term effects of both paroxetine and imipramine in the teenage population. I understand that I may choose not to participate in this study. If I do not participate, I will receive the best available treatment as prescribed by my doctor.

5. Confidentiality

All records relating to this project will be handled and safeguarded according to standard University policy for medical records. Any information obtained in connection with this study that can be identified with the subject will remain confidential, and will be disclosed only with my permission. Information of a sensitive personal nature will not be part of the medical record, but will be stored in the investigators' research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location. If the data are used for publication in the medical literature or for teaching purposes, no names will be used, and other identifiers, such as audiotapes, will be used only with special written permission. I understand that I may hear the audiotape before

giving this permission. Should the research staff discover use of other drugs by me such information will be kept confidential to the extent allowed by law. No information about me will be released without my consent except as required by law.

6. Risk of Injury

The investigators do not expect any (further) unusual risks as a direct result of participation in this project. However, should any unforeseen physical injury occur, appropriate medical care will be provided, but no financial compensation will be given.

7. Contact

I understand that if I have any questions, comments, or concerns about this study or the informed consent process I may call Dr. _____ at _____, or write to him at _____. If I have any questions about my rights as a subject, I may call _____.

If I become ill or injured as a result of participation in this clinical study, medical treatment will be provided, and the reasonable cost of such treatment will be paid by SmithKline Beecham. If I have any questions concerning the availability of compensation/medial care or if I thing I have experienced a drug-related illness or injury I will contact _____ at _____.

I will be given a copy of this form to keep.

8. Refusal/Withdrawal

I understand that participation in this study is voluntary and that refusal to participate at any time will involve no penalty of loss of benefits to which I am otherwise entitled. I know that I can refuse to answer any question that I may not wish to answer and that I may refuse to participate or withdraw from the study at any time without negative consequences or effect on medical care being provided. Since abrupt discontinuation of medication can result in unwanted side-effects, if I wish to withdraw, I agree to permit the slow tapering of my medication over two week period.

*****

I ACKNOWLEDGE THAT I HAVE READ AND FULLY UNDERSTAND THE ABOVE EXPLANATION OF THE PROJECT, THAT ALL MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED. I AGREE TO PARTICIPATE IN THIS RESEARCH PROJECT.

_____ _____

Signature of Participant Date

*****

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE PATIENT THE NATURE AND PURPOSE, PROCEDURES, POSSIBLE RISKS AND POTENTIAL BENEFITS OF THIS RESEARCH PROJECT.

_____ _____

Signature of Investigator Date

APPENDIX D

SUMMARY OF STUDY PROCEDURES

Assessment Continuation Phase	Baseline		Acute Phase								Continuation Phase					
Time (Weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	X															
Medical History and Physical Exam	X															
Clinical Laboratory Studies	X									X			X			X
Serum Pregnancy	X						X*							X*		
ECG-12 Lead	X					X				X			X			X
ECG Rhythm Strip			X	X	X		X	X	X		X	X		X	X	
Hamilton Depression Scale	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Full K-SADS-L	X															X
Affect Section of K-SADS-L		X		X		X		X		X	X	X	X	X	X	X
C-GAS		X														
CGI		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SADS-L		X														
FH-RDC		X														
Autonomous Functioning Checklist	X									X						
Self Perception Profile	X									X						
Sickness Impact Scale	X									X						
Randomization		X														
Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Supportive Psychotherapy		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Plasma Sampling for Drug Analysis		X				X				X			X			X
Study Medication Record			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant Medication	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

* On suspicion of pregnancy

APPENDIX E

CLINICAL LABORATORY PARAMETERS

- Blood

Hematology:	RBC WBC (total and differential) Platelets
Biochemistry:	Liver function: Bilirubin, alkaline phosphatase SGOT, SGPT Renal function: Urea, creatinine, uric acid Other biochemistry Glucose, serum proteins

- Urine

  Blood, protein, glucose. If blood or protein noted in urine, microscopy will be performed. In addition a drug abuse screen will be performed at baseline.

- Prenancy Test - at baseline and on suspicion

- Plasma and Serum Drug Concentrtion

APPENDIX F

INSTRUMENTS

Family History Screen (FHE), Subject Version: The Family History Screen is a brief computer-scorable instrument which collects a pedigree and screens for DSM-III-R diagnoses in family members. The instrument has been shown to have good levels of sensitivity and specificity for adults reporting on themselves. (Lish et at)

Self Perception Profile for Adolescents: This scale (Harter, 1987) is an upward extension of the Self Perception Profile for Children which in turn is based on the Perceived Competence Scale (Harter, 1985). It is a measure of "self" as a dimension of competence in the proposed research. it consists of 45 item self report questionnaire, assessing perceived competence in 9 domains: Scholastic, social, athletic, physical appearance, job, romantic, conduct/morality, close friendship, and global self-worth. Psychometric information regarding this scale is available for a parochial school population. Subscale reliability is generally very high. Validity of the perceive competence scale has been supported by a number of recent studies (Cauce 1987; Nottelman 1987). Scores do not correlate with age.

Autonomous Functioning Checklist: The AFC is a parent-completed checklist designed to measure behavioral autonomous functioning in adolescents between the ages of twelve and eighteen. It contains seventy-eight items and is subdivided into four conceptually distinct subscales: Self-and Family Care, Management, Recreational Activity, and Social and Vocational Activity. Each item in the first three subscales is a short description of a behavior. The parent rates the adolescent in relation to each item on a five-point scale ranging from 0 (does not do) to 4 (does every time three is an opportunity). The items on the fourth subscale, Social and Vocational Activity, are rated by the parent on a dichotomous, yes/no scale. For each scale, high scores indicate that the adolescent routinely performs many of the activities listed.

Revised 24 March 1994

The K-SADS-L was initially developed by [redacted] M.D. and [redacted] M.D. The authors took as point of departure the audit SADS (developed by [redacted] M.D. and [redacted] Ph.D. with the assistance of other participants in the NIMH clinical Research Branch Collaborative Project on the Psychobiology of Depression), from which many items and scales remain. Guidelines for the unstructured interview were modified from [redacted] and [redacted] Interview with the child (Isle of Wight Study). A fourth version was written by [redacted] M.D. and [redacted] M.D. and present and past

members of the Child and Adolescent Depression Program contributed their experience and expertise and commented on prior versions of this draft. [redacted] Ph.D. in 1993 for lifetime inquiry (thus the designation K-SADS-L) and to provide diagnoses of ADHD, oppositional disorder, antisocial personality disorder, social phobia, tic disorders, and to expand the anxiety disorders.

These sections have made use of items from other interview schedules, especially the CHAMPS by [redacted] Ph.D. and [redacted], Ph.D. Investigators wishing to use this instrument should contact Dr. [redacted] Western Psychiatric Institute and Clinic, University of Pittsburgh School of Medicine, 3811 O'Hara Street, Pittsburgh, PA 15213.

The Sickness Impact Profile (SIP) is a behaviorally based measure of health-related dysfunction that was developed to provide a measure of health status useful in the assessment of individuals or populations with both chronic and acute illnesses. It may be either interviewer or self administered and is scored as a total SIP score or as two dimensions, physical and psychological. It has undergone extensive field testing and has demonstrated good reliability (internal consistency, Cronbach's alpha, ranges from 0.94 to 0.97; overall reproducibility score ranges from 0.88 to 0.92) and validity (SIP to self assessment of sickness ranges from 0.54 to 0.69 and dysfunction ranges from 0.52 to 0.69; SIP to NHIS ranges from 0.55 to 0.61). It is easily understood by patients and the version used in this study has been modified for an adolescent population and has been piloted in an adolescent outpatient affective disorders clinic where it has demonstrated good utility. (Bergner et al., 1976; ibid. 1985).

APPENDIX G

CLINICAL MANAGEMENT FOR ADOLESCENT DEPRESSION

Adolescent Depression Collaborative Research Group

A Modification of [redacted] Clinical Management - Imipramine/Placebo Administration Manual. Psychopharmacology Bulletin 23:309-324, 1987.

INTRODUCTION

The intent of The Clinical Management for Adolescent Depression (CMAD) Manual is to define a psychosocial interaction between clinicians and adolescent patients which will maximize the chance of observing a pharmacotherapeutic effect in a study of antidepressant medication, assure the careful and safe monitoring of patients, and maintain consistency of approach among clinicians. It attempts to encompass elements of care used by clinicians who have experience with psychiatrically-ill adolescents, and it intentionally includes the "nonspecific" effects associated with other psychosocial therapies, such as warmth, empathy, genuine interest in the patient's welfare, and optimism about the outcome of treatment. These aims are shared by the approach defined in the Clinical Management - Imipramine/- Placebo Condition (CMIPC), developed for the NIMH Treatment of Depression Collaborative Research Program (Fawcett, et. al., 1987), of which CMAD is a modification. We are indebted to Drs. [redacted], who developed the CMIPC and consented to this modification of their manual.

The CMIPC had a secondary aim of minimizing overlap with two psychotherapy conditions which were being compared in that study, Interpersonal Psychotherapy and Cognitive Therapy. This study does not contrast psychosocial therapies, so this is not a principal aim. Consistency across pharmacotherapeutic conditions is the first priority in this study. Nevertheless, the current study intends that observed clinical change will reflect effects of the medication under study rather than of active psychotherapies. Thus, while there is slightly greater overlap with interpersonal and cognitive therapies than with CMIPC, this clinical management condition intentionally maintains clear distinctions from those therapies. An additional rationale for maintaining these distinctions is the possibility of using this clinical management manual in future studies of active psychotherapies with adolescents.

A further intent of this approach is to maximize compliance with the treatment under study. Attrition from treatment trials and clinical studies can be high with adolescents.

The investigators share the impression that maintaining rapport with the adolescent patients and their families requires the addition, to the CMIPC, of defined contract with parents, a more specific educational component about the illness and its treatment, and a modest increase in the time spent in contract with the patients. For these reasons, the length of sessions was increased and four psychoeducational conjoint sessions, with the adolescent and at least one parent, were added. Additional adjustments to treatment with adolescents include an emphasis on flexibility and active concern about the adolescent's social, school and family life.

Because of the central importance of maintaining consistent adherence of therapists to the psychosocial approach - particularly in a multicenter study - a means of rating tapes of therapy sessions is needed. Considerable work went into the development of the Collaborative Study Psychotherapy Rating Scale (CSPRS-6) and an accompanying Raters Manual. Review of these instruments indicates that they can be used without modification to rate tapes of sessions with adolescents.

Modifications of the CMIPC manual are intentionally minimal. They consist essentially of setting aside discussions of the adult psychotherapy study, rephrasing references to medications to fit the current study medications and their administration, lengthening of sessions, and modifying references to family contact.

Adaptation of the clinical management approach to the context of adolescence is provided by added descriptions of the initial session, a subsequent session, and illustrations of approaches to three potential problem situations - a depressed adolescent's refusal to attend school because of conflicts with peers, a dispute between an adolescent and parents, and an increase in an adolescent patient's suicidal ideation.

I. Purpose of Study

The major aim of the study for which this manual has been generated is to evaluate the effectiveness of two antidepressant medications, paroxetine and imipramine, for treating nonbipolar nonpsychotic outpatient depressive illness in adolescents. The medications will be compared to treatment with a placebo, and all three conditions will be accompanied by a program of education and support, defined in this manual. The clinical management approach (CMAD) which this program follows and augments has been observed to be effective with many depressed adults (Elkin, et. al., 1989). Thus, it is intentionally not therapeutically neutral but rather a presumably effective supportive therapy which will be constant across the three treatment groups.

II. Aims of the CMAD

A. General Aims

In order to provide valid data with which to compare the effectiveness of the treatment and with which to address other major questions posed by this study, each of the study treatment conditions must be provided in an optimal fashion allowing for maximal therapeutic effectiveness. The purpose of this manual is to describe the Clinical Management Condition and to outline the procedures involved in the optimal delivery of this condition. The CMAD has been designed to resemble as closely as possible the manner in which medications would be most effectively adolescent administered in the clinical management of depressed adolescent outpatients.

B. Specific Aims

One of the main goals of the CMAD is to foster and maintain the kind of therapeutic relationship between patient and pharmacotherapist that will promote compliance with the treatment regimen in general and, in particular, compliance with medication. A second major goal of the CMAD is to promote the patient's continuation in the study throughout the entire 8-week study period. This will be most difficult to achieve both early and late in treatment: early if the patient is not receiving obvious benefit; later if the patient has a partial or complete therapeutic response and does not appreciate the need to continue therapy. Maintaining a very low attrition rate is crucial in producing reliable data.

III. Protocol for the CMAD

A. General Organization and Focus of the Psychopharmacotherapy Sessions

The pharmacotherapist must be responsive to the adolescent's complaints and needs while also maintaining control in the interview. This can best be accomplished through a rational and organized structuring of sessions. The pharmacotherapist's ability to focus and appropriately sequence the inquiry and discussion is of great importance for an effective psychopharmacotherapy session. In considering the issue of initial focusing, it is important to remember that the patient is finally entering a treatment situation after several weeks of preliminary screening and data gathering. The patient's clinical needs and treatment expectations are of the highest priority and deserve the utmost respect and attention as the pharmacotherapist proceeds with organizing the interview. The initial sessions should ideally be developed as therapist-patient collaborative efforts to characterize general and specific features of the depressive episode. A therapeutic agenda can thus be established on which to base treatment expectations consistent with the psychopharmacotherapy approach.

The appropriate organization and structuring of the CMAD sessions together with the inclusion of the appropriate content should sufficiently distinguish the sessions from psychotherapy and help prevent the pharmacotherapist from straying into "psychotherapeutic territory." We do not wish to encourage an interview structure or process so rigidly structured as to preclude opportunities from empathy, support, and those naturally spontaneous and more casual exchanges that permit treatment to be carried out in a warm and truly human way. However, open-ended inquiry into or discussion of interpersonal relationships is to be especially avoided.

The appropriate sequencing of clinical inquiry and therapeutic discussion is also an important factor influencing the effectiveness of the session. Generally, sessions should begin with a general review of the previous week's events and activities, with therapist eliciting information about domains not specifically covered, including school, home, friends, family, and specific inquiry about previously-identified important situations, activities, or relationships. Specific target symptoms should be asked about if not brought up spontaneously. Potential or past side effects should then be reviewed. Among the more frequent examples of inappropriate sequencing are the discussion of medication effects prior to the elicitation of target symptoms and the premature discussion of side effects prior to a thorough discussion of therapeutic benefits of the medication.

B. Initial Session

The initial patient visit will consist of a 1-hour session, divided approximately into 30 minutes with the adolescent and parent(s) and 30 minutes with the patient alone. During this session the pharmacotherapist will attempt to establish a positive relationship with the adolescent and parents in the content of a thorough discussion of the course of the present as well as previous episodes of depressive illness. The elucidation of the past history, family history, and relevant medical history will focus on elaborating information about clinical symptoms of major depression.

Considerable attention will be devoted to the establishment of the target symptoms* as a basis for ongoing clinical assessment and management within CMAD. The content of subsequent sessions will depend on the accurate and comprehensive establishment of target symptoms in the initial sessions. In addition to providing material for future sessions, discussion of target symptoms will help structure sessions so that active psychotherapeutic interventions can be avoided, thus keeping the pharmacotherapy sessions as free from "psychotherapeutic contamination" as possible. The initial comprehensive determination of target and accessory symptoms will also be necessary for later detection of study medication side effects. **The Symptom, Sign, Side-Effect Checklist will provide a basic inventory and format for obtaining the baseline and subsequent medication side-effect assessments. Also, in the process of assessing the patient's symptoms and experience of depressive illness, the pharmacotherapist should routinely and completely assess suicidal ideation and impulses. This will be particularly crucial in patients with a previous history of depressive illness involving suicidal ideation or behavior.

* Target the symptoms include sleep disturbance, appetite disturbance, diurnal mood variations, anhedonia, feelings of hopelessness, suicidal ideation, etc. Symptoms such as anxiety, irritability, and hypochondriacal preoccupation's should also be explored.

** The Term "study medication" will be used throughout the CMAD as a generic term for the active drugs or placebo.

A basic and easily understandable explanatory model of how and why antidepressant medication is effective should be provided. Theoretical and practical aspects of the treatment rationale should be presented in the patient's own language, and discussion of the patient's concerns and questions should be actively facilitated.

The rationale for the use of medication in the treatment of depression should be explained and any resistance to the idea of medication therapy should be addressed. The patient should be allowed and even encouraged to express his or her concerns, fears, and attitudes regarding medication in general and psychotropic drugs in particular. Common concerns of adolescents and parents should be addressed, such as the risk of becoming dependent on the medication, how long one needs to take medication, and potential side effects. The interpersonal ambience should provide the patient an opportunity to air prejudices, distortions, and fantasies regarding either the positive or negative effects of the medication. These distortions should be corrected by responding to the patient's questions with further clarification and support.

It is critically important to obtain a comprehensive history of previous experiences with and responses to pharmacotherapy (including specific medication dosages and the duration of treatment) prior to explanation and discussion of the current treatment. Educating the patient about the individual variability of responses often encountered with different antidepressants, coupled with assurances that medication response will be closely monitored, will help the patient and parents overcome possible negative attitudes based on previous experiences and/or ignorance or misinformation about antidepressant pharmacotherapy.

The adolescent and the parents should be instructed about the importance of taking the prescribed dosage of study medication and apprised of the fact that adjustment of the dosage may be necessary to achieve the desired effect. The patient should also be instructed that it may be 2 to 6 weeks before a therapeutic response is achieved and should be informed about which symptoms (e.g., sleep disturbance, appetite disturbance) are likely to respond to treatment initially. The concept of gradual response or progressive improvement should be discussed so that patients do not unrealistically expect an early "all or none" response.

The possibility of the occurrence of side effects during treatment should be discussed. Pharmacotherapists should mention the side effects which most frequently occurred during treatment (dry mouth, dizziness or lightheadedness, especially on changing positions, blurred vision, nonspecific sedative effects, and delayed micturition). The patient should be instructed that these side effects are not dangerous if reported to the pharmacotherapist and managed correctly. If mild side effects do occur, the patient will be instructed to continue the medication at the prescribed dose, if possible, until the physician can be reached. If more severe side effects occur and the patient is not able to reach the

pharmacotherapist immediately, the medication should be temporarily discontinued until the therapist is contacted.

The patient should be instructed that future visits will be 20 to 45 minutes in length, generally with patient alone. Up to 15 minutes of a session may be spent with the adolescent and parents(s) if the clinician, patient, or parents feel this is necessary. The session will be devoted to reviewing the patient's general progress, the current status of depressive signs and symptoms, and possible side effects, as well as to discussing his or her questions and concerns. It should be made clear that this time limit is relatively inflexible and will not be modified unless there is some pressing need. The patient should be instructed that these sessions will be conducted on a weekly basis but that in case of severe side effects or worsening symptoms of the illness, it will be possible to reach the pharmacotherapist or an associate by telephone.

Especially during the initial session, the pharmacotherapist should attempt to develop an accepting, understanding, and supportive relationship with the patient and to convey hope and optimism regarding the outcome of treatment. The pharmacotherapist should also clearly communicate any expectation that the patient will improve and should explicitly link this expectation of improvement or mitigation of target symptoms with the idea of positive therapeutic outcome as a result of antidepressant pharmacotherapy. By assisting the patient in developing a positive set of hopeful expectations linking the relief of core symptoms with medication effects, the pharmacotherapist creates opportunities for ongoing therapeutic discussions focused on those aspects of the medical treatment of depressive illness that are personally important to the patient.

Here we would like to present a brief sketch of an ideal first session. In such an idealized version of the initial psychopharmacotherapy session, we see the pharmacotherapist warmly greeting and welcoming the adolescent and his/her parent(s), and providing an explicit introduction that unambiguously establishes his/her role as the doctor who will be in charge of the patient's clinical care for the duration of the study. This introduction should distinguish the pharmacotherapist's role as primary managing clinician from the research roles of various study personnel the patient has previously seen. It is during the initial exchange that the pharmacotherapist clearly establishes the overall importance of the patient's clinical care and well-being in the study context. The psychiatrist should also demonstrate knowledge about the study in general.

After acknowledging review of the patient's diagnostic summary, the psychiatrist should begin an independent evaluation with the primary objective of establishing a set of core or target symptoms, manifestations of the underlying disease process which will serve as indicators of potential response to the treatment that will be prescribed. The therapist should inquire about all domains of the adolescent's life, e.g., school, home, friends, family, favorite activities, and how the symptoms have affected these. Accessory signs and symptoms can be simultaneously elicited. Screening for the presence of possible medication side effects at baseline can also be done as an associate component of this phase of the session; however, the use of the Symptom, Sign, Side-Effect Checklist as a primary device or method to maintain structure is definitely not recommended. At appropriate junctures, clinical attention and questions should be directed towards life problems with the objective of information gathering, learning about the patient as a person, and conveying empathic concern. The pharmacotherapist should not, however, engage in psychodynamic incursions and digressions.

We recommend that time be allowed for the psychiatrist to establish and convey a sense of warmth, concern, and authoritative responsibility and knowledgeability about the pharmacotherapy, to appropriately educate the patient about how and why the medication can help, and to allow for questions from the patient and further discussion.

C. Second and Subsequent Sessions

At the second and subsequent sessions, the pharmacotherapist will meet with the patient for approximately 20 to 30 minutes, extending to 45 minutes if necessary because of clinical concerns. Parents may be included for up to 15 minutes of this time, as described above. A systematic inquiry into the presence, intensity, and features of the already established target symptoms that characterize the patient's depression should provide the basis for the assessment of response to treatment, following the general sequence described in A. This systematic inquiry should also provide a framework for ongoing assessment during subsequent sessions. Similarly, a systematic evaluation for side effects will be made during the second and all subsequent sessions.

The Symptoms, Sign, Side-Effect Checklist will serve as a standard format for evaluating the above. Regarding technique when administering the Symptom, Sign, Side-Effect Checklist, we suggest that the pharmacotherapist inquire about the presence of items by presenting them in groups of related items, e.g., "Have you ever had weakness, faintness, dizziness, lightheadedness, headaches, visual disturbances?" This allows the screening for symptoms and signs to be done efficiently, leaving more time for other therapeutic tasks. Sitting and standing blood pressures should be routinely taken during the first, second, fourth and sixth sessions to assess for postural hypertension. If at any other time the patient presents with signs or symptoms suggestive of postural hypotension (i.e.,

dizziness or lightheadedness upon arising from a sitting or recumbent position), then the sitting and standing blood pressure should be taken, recorded, and appropriate clinical management initiated.

During the second session the patient will be asked about reactions to the medication, possible side effects, and possible early therapeutic effects. Patients who are unusually sensitive to the medication or who have idiosyncratic reactions (palpitations, etc.) will be identified at this time.

Since it is highly possible that no therapeutic response will have occurred by the second session, special effort will usually be necessary to reinforce the patient's continued hope and optimism regarding improvement. The patient should be encourage to continue the medication and should also be instructed that higher doses usually produce symptomatic improvement. Although it is unlikely that the patient will have any appreciable side effects to the medication at this point, there may be minor side effects, especially in patients who are apprehensive about taking medication. Further education efforts regarding the "hows" and "whys" of antidepressant medication may be helpful and perhaps necessary to avoid dropouts and/or noncompliance during the early stages of the pharmacotherapeutic treatment.

Here, we would like to emphasize the importance of flexibility in determining the duration of pharmacotherapy sessions. Time should be allowed to indicate general interest in the adolescent's life and to maintain a positive relationship. For some patients whose clinical course has demonstrated significant improvement, a 20-minute visit may be quite adequate and appropriate. On the other hand, we do not recommend visits under 15 minutes or over 45 minutes, except in extraordinary circumstances when the clinical management definitely requires an extended period of time.

D. Prescription of Study Medication

Study medication will be prescribed each week and will consist of identical containers of identical capsules for all three conditions. A sufficient number of capsules should be provided to cover the possibility of a missed appointment by the patient or pharmacotherapist, i.e., an additional 2 to 3 days of study medication may be prescribed. However, medication may only be prescribed for a maximum period of 10 days. If there is risk of an overdose, the pharmacotherapist may choose to have the patient return for an additional appointment that week in order to limit the total amount of medication the patient has in his/her possession at any one time. Patients are instructed to return all unused medication to the therapist at each session. The physician must maintain an accurate record of all unused study medication. The number of capsules prescribed and the number of unused capsules should be recorded at each session.

The CMAD dosage schedule is designed to optimize the possibility of a full response to the study medication by approximating usual clinical practice. To accomplish this, an attempt should be made to systematically expose each patient to a full dose of medication by the third week of the study a
nd to maintain this dosage of study medication for a period of at least 4 weeks. If, at any dosage, the patient manifests severe side effects which appear to be dose related (e.g., anticholinergic effects, drowsiness), this may signify that a lower dose is the maximum tolerated dose at that time. If the patient dose not appear to be responding optimally to the study medication at a given dosage level, the dosage may be increased up to the ceiling dose. This potential range of dosage combined with flexibility in the dosage schedule should assure an adequate trial of medication for each patient (see Appendix).

The very first dosages taken by the patient should constitute a test for hypersensitivity. If overwhelmingly severe side effects (e.g., extreme dysphoria or anxiety, massive sedation, headache) emerge in response to the initial dosage of the medication, the dose may be dropped. However, if the patient is not able to achieve a dosage of (x) without significant or severe side effects, he/she should then be considered hypersensitive to the medication and withdrawn according to the study guidelines.

If moderately severe side effects emerge as the dose is being increased, the patient should attempt to contact the pharmacotherapist. Several alternatives are then available. For example, the dosage may be redistributed over the course of the day in an attempt to increase patient tolerance, or the dosage may be temporarily reduced in order to allow the patient to accommodate. If dosage has been decreased because of side effects, the pharmacotherapist should later attempt to increase the dosage more gradually until a therapeutic level has been achieved unless there is a resurgence of severe side effects, the appearance of new and serious side effects, or clinical deterioration. Over the ensuing weeks, the pharmacotherapist may increase the medication up to the maximum dosage based on the patient's response to treatment.

Not all patients may be able to tolerate maximal levels of study medication. If only lower doses are tolerated, therapist should note the reason for this and use direct patient quotations when possible. Under no circumstances should patients be prescribed less than (x) per day of study medication. In the rare case where a patient cannot tolerate at least (x) of study medication, the patient should be withdrawn from the study and an appropriate referral should be made. If a patient misses a dose of medication, it should be recorded and the patient advised not to make up the missed dose, but to continue with the prescribed dosage schedule.

We would like to emphasize the importance of dosage flexibility. The schedule guidelines recommended here are not meant to be absolute, although there is, indeed, an upper limit of (x) of study medication which is not to be exceeded.

Some patients, because of unusual sensitivity to the medication, may need to be advanced more slowly than suggested. In these cases, the pharmacotherapist may adopt a scheduling strategy of alternating doses every other day to achieve a more gradual dosage increase.

Dosage changes and titration's are also recommended to manage side effects, although the therapist should, if possible, attempt to deliver the maximal therapeutic dose. In addition, dosage flexibility is also recommended during the latter weeks of treatment as patients may experience relapse when a decrease in dosage occurs. In such circumstances we recommend that the patient continue on sufficient medication to maintain the therapeutic response.

E. Pharmacotherapy Management Issues

Drug interaction with other medication. Patients should be instructed to avoid all other medications, including over-the-counter compounds, if possible, during the study treatment. The use of proprietary (nonprescription) medication that the patient may take under ordinary circumstance such as aspirin or acetaminophen for headache or laxatives for constipation is acceptable, but the use of prescription medication is not allowed. If the patient is using other medication (e.g., laxatives), he/she should be advised to allow at least a 2-hour interval between the time of ingesting study medication and the time of ingesting the laxative to avoid possible interference with absorption of the study medication. If the ingestion of a prescription medication is unavoidable (e.g., antibiotic for an acute febrile bacterial illness), the medication, dose, and reason for prescribing should be recorded. Patients should also be told that if they require dental work while on study medication, their dentist should be advised that they might be on a tricyclic medication that could interact adversely with the epinephrine-like medication often used in local anesthetic preparations.

Adolescents should be advised to refrain from the use of alcohol, marijuana, or other drugs. Substance use should be discussed frankly as something which may prolong their depression and make treatment ineffective. One should not, however, attempt to deter substance used by exaggerating the risks of concomitant use with study medication. Adolescents have often been given inaccurate information about effects of substance abuse and this approach is likely to impair the credibility of the therapist.

Laboratory work. At any time during the course of treatment, the CMAD psychiatrist may request laboratory tests (e.g., liver function tests) or an evaluation of the patient by a pediatrician.

Side-effects management. The thorough discussion and successful management of disconcerting or troublesome side effects early on in the course of treatment is often of critical significance with regard to pharmacotherapy compliance in

general. Detecting anxiety associated with an increase in dosage or disturbing side effects resulting from such an increase is necessary for the successful management of further dosage adjustments. Mild side effects may often be adequately managed by explaining to patients that the severity of side effects usually decreases over time. This is most effectively accomplished through discussion carried out in the context of a concerned, reassuring, and supportive attitude on the part of the pharmacotherapist. Moderately severe side effects are usually best managed by a temporary lowering of the dose. Advice may be given regarding physiological management of side effects (e.g., laxative diet for the mitigation of constipation). Managing more severe side effects may require a permanent lowering of the dosage. Other than the ordinary use of proprietary medication, adjunctive medication for the management of side effects (e.g., urecholine for the management of urinary retention) is not permitted.

F. General Management Issues

Avoiding dropouts. The avoidance of dropouts from the clinical management condition will depend to a great extent on the nature of the relationship established between the pharmacotherapist, the adolescent patient, and the parents. In order to avoid dropouts, it is important that the pharmacotherapist not only be supportive and encouraging, but remind the patient of the delayed effect of the medication and reiterate the possibility that the dosage may need to be increased. Without such attention and reassurance there is a danger that the patient who experiences an absence of therapeutic benefit particularly in the presence of side effects may discontinue treatment within the first 2 to 4 weeks.

Phone calls. Especially during the early weeks of treatment, the physician must be available to the patient and the parents for telephone calls between appointments for questions about side effects which may occur as medication dosage is increased. Phone calls allow the pharmacotherapist to receive clinical information from the patient about symptoms or medication side effects, make a determination about their significance, and provide an opportunity for immediate management of problems. In addition, they provide the patient with the reassuring knowledge that a concerned and available physician is managing the psychopharmacotherapy. The reassurance provided by such brief calls in everyday clinical practice often makes the difference between a successful outcome and early treatment dropout of a patient who might have responded to the medication. These phone calls can often provide the support necessary to assist the patient in continuing medication despite depressive feelings of hopelessness and discouragement or fears and anxieties stimulated by the occurrence of side effects. It is often reassuring to a patient to know that the physician will be available at a particular time of day to respond to phone calls if necessary. The patient should also be instructed that in the event the pharmacotherapist is not immediately available, there is an emergency number at which to contact a psychiatrist 24 hours a day. In addition, at the outset of the

study, each patient is provided with emergency numbers for contacting the Principal Investigator and Project Coordinator at that site. Phone calls are not to constitute supplementary or adjunctive therapy. The CMAD physician should keep an accurate record of every phone call received from the patient and his/her family. This information should be noted and should include date, time, length of call, content of call, specific and general concerns, and the therapist's response (e.g., advice, instructions, education, and medication adjustments).

Family accessory visits. The clinician will clearly indicate that sessions are primarily for the adolescent, but that input from parents is valued and that parents' concerns will be addressed. Parents will be included in up to 15 minutes of a session at least monthly, up to weekly in the case of urgent concerns on the part of the parent. Parents should be helped to share their observations or concerns in the presence of the adolescent, rather than meeting with the clinician alone, in order to minimize distrust by the adolescent.

These contacts should emphasize open airing of concerns, provide information about affective disorder and pharmacotherapy, and reassure parents that the safety of their son or daughter is being protected. Such intervention may result in increased family support, but active family therapy intervention is not to be conducted during the eight week study.

The parents will also be involved in the four psychoeducational sessions described below.

Clinical deterioration. A clinical management issue of major significance is the referral of unimproved or deteriorating patients for a clinical evaluation. If the patient has shown no improvement or begins to show clinical deterioration after a reasonable therapeutic trial of study medication and further continuation under such circumstance would be detrimental to the patient, a referral should be made for a clinical evaluation to determine whether the patient should be withdrawn from the study. Such clinical evaluations can be done by the PI or a psychiatrist designated by the PI. If the patient is withdrawn from the study, appropriate referral arrangements will be made by research staff. The pharmacotherapist has full responsibility and authority to refer the patient for clinical evaluation at any time regarding the patient's suitability for remaining in the study.

Crisis Management. Treatment of adolescents often requires the therapist to respond to crises which may involve risk of self-destructive or assaultive behavior, intensification of conflict in the family, or disruption of the relationship with the therapist. These possibilities should be anticipated in the initial session and in the four Psychoeducational sessions. Certain general principles should guide the management of such crises. The first priority must be to assess the degree of potential harm to the patient or others and to assure safety. The therapist should take an actively empathic, supportive role rather than being

neutral or distant. One may offer assistance with problem-solving, such as by asking the patient to talk about alternative options and their probable consequences. Simple advice or suggestions may be given. Sustained focus on interpersonal difficulties, e.g. role transitions or disputes other than the crisis itself, on cognitive distortions, or psychodydnamic interpretations are not part of CMAD. A general hierarchy of response, then, beginning with the most universal elements, is:

1. Evaluate risk of harm to self or others. Assure safety.
2. Empathic listening.
3. Assistance with problem-solving.
4. Advice or suggestions.

Options for response to crisis include extra sessions, more involvement of parents in sessions, consultation to school, and full or partial hospitalization. None of these interventions requires withdrawal of the subject from the study, as long as the medication protocol can be continued. Such additional interventions should be kept as brief as possible, with the patient returning to the study treatment schedule as soon as possible.

G. Termination

Even though active psychotherapy as such is not provided in the CMAD, a significant doctor-patient relationship will likely develop during the 8 weeks of the study. In light of this, discussion of termination should occur and will likely be an important issue in the last few sessions. A sensitively directed inquiry and guided discussion that permits the patient to express inquiry and guided discussion that permits the patient to express feelings and ideas about having participated in the study, attitude towards the therapist, fears about discontinuing medication, future plans, and possible future therapy needs is essential. Deficiencies in dealing with termination issues can led to instances of "acting out" (e.g., patients abruptly and unilaterally stopping their medications or not returning for tapering sessions). If previously unrecognized or currently unresolved termination issues still remain, an additional session during the tapering phase may be necessary to discuss such issues. However, this is not encouraged as termination issues should be adequately addressed during the final session.

If, at any time during the course of treatment, the patient inquires about continuing treatment beyond the 8-week study period, he/she should be reassured that the appropriate referral will be made if it appears that the patient needs further treatment at the conclusion of the study period.

IV. Maintenance and Continuation Phases

A. Medication and Evaluation Schedule

In most cases, patients who demonstrate a "medication response" will do so between the second and eighth week of treatment. The period after the demonstrated therapeutic response should be considered the maintenance phase.

It is crucial that the patient who is showing a medication response as evidenced by clinical improvement be educated regarding the need to continue medication throughout the entire study period. This should be emphasized especially at the point when the patient begins to show improvement as patients are at high risk for discontinuing treatment shortly after an initial improvement.

In the event that a patient shows a dramatic improvement and develops a state of euphoria or hypomania, it may be necessary to lower the dosage. If this occurs, the therapist should attempt to maintain at least the minimum medication dosage of "x" mg. If the episode progresses to definite mania, it may be necessary to discontinue medication and to withdraw this patient from the study.

The schedule and nature of evaluations in the Continuation Phase should be reviewed prior to the end of the acute treatment study.

B. Evaluation of Response to Treatment

The Symptom, Sign, Side-Effect Checklist will serve as a standard format for assessing symptoms as well as evaluating side effects, and will be completed after every session. Change in the number and intensity of target symptoms of depression and the presence and severity of side effects should be the primary referents for making decisions concerning changes in medication dosage. It is important that increases in the medication dosage be continued as long as any target symptoms of depression remain, since patients who achieve only partial improvement frequently relapse on medication several weeks later.

In the case of patients who fail to improve, the pharmacotherapist and/or the patient may assume that the patient has been receiving a placebo. However, it is important not to make this assumption as some patients may respond slowly, not showing a clinical response until exposed to an adequate blood level for several weeks (blood levels will be determined throughout the study, but will not be available to the clinicians for dosage adjustment). For this reason, it is essential to continue to increase the medication dosage if possible even though improvement has not been achieved. Since and adequate dose may make the difference in

response, it is entirely reasonable and honest to encourage a patient to continue treatment with the expectation of a possible future therapeutic response. In summary, pharmacotherapists should manage medication "as if" every patient were receiving active medication.

V. The Interpersonal Context

A. Therapist Factors

It is essential that pharmacotherapists have sufficient experience with the use of antidepressants to have an appreciation for the importance of adequate dosage as a condition for maximal therapeutic response. The should also be aware of the concept of delayed therapeutic response and its relationship to adequate dosage. Pharmacotherapists should also be familiar with the relative medical importance of side effects and methods for their management. A background of knowledge about, and clinical experience in, the use of antidepressants coupled with confidence in their therapeutic value will help foster a therapeutic relationship that can facilitate patient compliance, prevent premature discontinuation of medication, and contribute to a beneficial outcome.

The importance of this knowledge is highlighted by studies of the treatment-resistant depressions. In examining the reasons for patients' failure to respond to pharmacotherapy combined with supportive psychotherapy, researchers found that at least 50 percent of the patients did not receive an adequate trial of any antidepressant medication because the physician did not prescribe adequate doses of the medication or stopped the medication prematurely due to patient noncompliance or the emergence of side effects of little medical consequences. Furthermore, noncompliance was often a result of lack of an adequate relationship with the physician. For some patients, failure to comply with the treatment regimen was attributed to insufficient information about side effects or about the course of therapeutic effect.

B. Role of Therapist

Of critical importance is the pharmacotherapist's role as physician with primary clinical responsibility for the patient. The pharmacotherapist should function as the patient's physician just as physician would in a nonresearch clinical setting. Pharmacotherapists should not permit the study design, research procedures, or their role as members of a research team to interfere with their role of primary responsibility for the care of the patient. Pharmacotherapists should actively assure the patient and parents of their primary and unwavering commitment to the patient's care. The supportive ad therapeutic engagement of the patient is an integral component of the CMAD. In order to engage the patient rapidly in a positive relationship and inspire confidence in the treatment condition, pharmacotherapists should create an ambiance of warmth and trust and convey a positive and optimistic attitude about the patient's clinical treatment. Ideally pharmacotherapists should be able to communicate relevant clinical information

to the patient in understandable terms, if possible in the patient's own words, and convey their knowledge and experience in the pharmacotherapy of depressive disorders.

Any tendency to administer the pharmacotherapy condition mechanically, to maintain inappropriate distance, or to relate in a perfunctory way is antitherapeutic and must be avoided. The rationalization of antitherapeutic behavior such as distancing by conceptualizing it as consistent with the role of "research therapist" should be considered a breach of doctor-patient responsibility. Neither remoteness nor aloofness in the name of therapeutic neutrality has a place in the CMAD. It is hoped that the pharmacotherapy condition in this study will approximate the best and most effective treatment that could be provided by an eclectic psychiatrist, given the study constraints on active psychotherapeutic intervention.

C. Interpersonal Processes

Although pharmacotherapists should concentrate on target symptoms and side effects, certain interpersonal processes are both permitted and suggested in the CMAD conditions. Clinical management requires the basic keen observational skills, interpersonal sensitivities, and technical interventions that are ideally characteristic of any competent psychiatrist. As described above, flexibility, empathy with both the adolescent and the parents, and active interest are encouraged.

The pharmacotherapist should engage in the types of interpersonal interventions which foster a good doctor-patient relationship, while at the same time avoiding specific interpersonal interactions that would be characterized as formal psychotherapeutic interventions. For example, inquiry into the cognitive, affective, and behavioral-interpersonal realm for the purpose of clarifying the patient's current state or situation is permitted and can be successfully accomplished without utilizing a dynamic, cognitive, behavioral, or other specific organized, systematized psychotherapeutic approach. The separation of these two levels of inquiry and intervention is somewhat arbitrary and may be experienced by the pharmacotherapist as a constraint.

However, it is important that the prohibition on active psychotherapeutic intervention not result in the patient's receiving limited emotional support. The general injunction against "active psychotherapy" should not lead to self-consciousness or rigidity that diminishes the therapist's responsiveness to the patient's immediate need for supportive interaction. In summary, clinically indicated and appropriate supportive psychotherapeutic measures and interventions are sanctioned, whereas interventions related to specific organized systems of psychotherapy are not permitted. See the sample clinical vignettes.

The following sections define several areas of interpersonal process and types of intervention that are permitted within the context of the Clinical Management Condition and several that are not.

1. Interpersonal context factors. Depression is an illness in which the patient is frequently anxious and may have negative expectations regarding the treatment intervention and outcome. Because of this, it is critically important to elicit the patient's confidence in the treatment. This can be accomplished through attention to the interpersonal context of the treatment. Research has shown that the medication is more efficacious when it is administered within a supportive interpersonal context. Frequently, the patient will need reassurance to continue to take medication in spite of mild and medically insignificant but anxiety-provoking side effects such as dry mouth and blurred vision. The patient may also need support in the face of criticism by family, friends, or peers who communicate negative attitudes about the medication. The patient's positive and meaningful relationship with the physician is crucial in sustaining medication compliance under adverse or unsupportive psychosocial circumstances. If the patient has trust in the physician, believes in his/her knowledge and competence, and maintains a conviction that the medication will be helpful, the patient will persist in the course of therapy even in the absence of initial improvement.

2. Psychological support. Psychological support should be provided by the pharmacotherapist throughout the course of treatment. Conveying a sense of hope and optimism is especially necessary in the earlier phase of treatment when the patient is likely to develop doubts that the treatment will help in the face of an initial lack of improvement. Reassurance may be particularly important if the patient is having medication side effects or physical symptoms of depressive illness. Furthermore, the patient may need special reassurance in the face of criticism of medication use by relatives or friends.

3. Instruction, education, and information giving. It is particularly important that, in the first session, the patient be instructed about the characteristics of the medication and the reason that it is given for depression. In addition, there should be some discussion of the notion that depression may be related to a change in brain biochemistry which the medication may help correct. This explanation must be general enough to allow for the possibility that psychotherapeutic treatment can also be effective and the possibility that the type of medication used in the study may not be effective for each individual patient. Physical symptoms of depression and the side effects of the medication should also be discussed.

4. Advice. Frequently, patients will ask what they can do to help themselves out of their depression. The pharmacotherapist might give simple suggestions to the patient such as advising increased physical activity (e.g.,

age-appropriate exercise). Patients may also request advice concerning whether to make decisions or to attempt to engage in certain activities during a depressive episode. Simple advice is permitted within the context of the CMAD. For instance, a patient under certain circumstances might be advised to avoid a particular stressful situation or advised to socialize more, depending on the situation. Pharmacotherapists should keep notes on any such direct advise that is given.

5. Ventilation and abreaction. Patients will usually need to describe their depressive feelings at length and share their fears and doubts. Within the limited time frame of the CMAD sessions, patients should be permitted to do this to the extent that it is thought to be of help in sustaining a positive therapeutic relationship.

The following list defines several areas of interpersonal processes and types of intervention which are not permitted within the context of the CMAD:

1. Focusing on specific psychological themes, especially interpersonal relationships and cognitive distortions.

2. The interpretation of interpersonal events, styles of interpersonal relating, suppressed feelings, or distorted cognition's.

3. Interpretations relating to recent losses, secondary gain, and other psychological mechanisms.

4. Clarification of the patient's feelings toward others and toward the therapist.

5. Specific behavioral instructions or routines other than simple advice about activity such as instructions that the patient should be going out more as he/she shows improvement.

6. Explanations of the psychodynamics of depressive conditions (e.g., suppressed anger, shame, and helplessness).

7. Any involved interpersonal interactions.

DO'S and DON'T of CMAD

DO'S:

1. Speak about current experiences.
2. Inquire about feelings.
3. Acknowledge understanding of feelings.
4. Inquire about events not spontaneously reported.
5. Inquire about the patient's thoughts about solving problems
6. Express sympathy if misfortunes occur.
7. Communicate shared pleasure at positive events.
8. Congratulate patient for success.
9. Give the patient hope of the likelihood of his/her getting better.

DON'Ts:

1. Relate current conflict or attitudes to earlier experiences.
2. Draw analogies between behavior toward some people and other, such toward parent and toward friends, siblings, teachers, etc.
3. Challenge patient's view of self or others.
4. Give specific suggestions for resolving conflict.
5. Bring up childhood experiences.
6. Bring to the patient's attention that his/her behavior appears to represent specific difficulties, such as fear of failure, fear of rejection, etc.
7. Bring to the patient's attention that his/her behavior has intents that he/she is not acknowledging (i.e., punishing parents, getting revenge on friends, trying to prove is generous, etc.).

VI. Psychoeducational Program

All patients and at least one parent - both if possible - will participate in a psychoeducational program consisting of an initial two-session course on Weeks 1 and 2 and review session in Weeks 4 and 6. These will be up to 50 minutes in length.

The program will use the manual Living with Depression: A Survival Manual for Families, developed by Kim Poling, M.S.W., Western Psychiatric Institute and Clinic (1989). The eight sections will be covered in order in the two initial sessions, with the clinician presenting material variably, in the terms understandable to the patient and family, and responding to questions. The manual will be given to the family to read but it is expected that comprehension of the written material will vary. The clinician may answer questions about how the information fits a particular family, but the emphasis will be on sharing information rather than exploring family interactions. Consistent with the CMAD, simple advice can be given (see V. The Interpersonal Context, C.4).

In each of the two review sessions, the clinician will briefly review the outline of the manual and review areas of particular interest and respond to questions. The family and patient are likely to focus on the last three sections: The Family and Depression, Helping The Depressed Person, and Coping with Depression. When family conflicts are presented, the clinician's responses should communicate empathy for the stress of living with a depressed or irritable adolescent, and identification of problematic behaviors or interactions which may be the results of the depression. The family should be helped to be supportive and to avoid critical or pejorative comments, or punitive behavior which results from their frustration.

VII. Pharmacotherapist Training and Adherence Monitoring

Pharmacotherapists will be psychiatrists who have experience with adolescents and with the pharmacotherapy of affective disorders. All will review three videotaped sessions of CMAD and then conduct at least six session, with three different patient, using the model. Audiotapes of three tapes - one per patient - will be rated using the Collaborative Study Psychotherapy Rating Scale (CSPRS-6), an instrument developed by the NIMH Treatment of Depression Collaborative Research Program to assess adherence to the models used in that study, i.e. Cognitive Therapy, Interpersonal Psychotherapy, and Clinical Management.

After agreement by a committee of investigators ( ), a pharmacotherapist will be accepted for the study.

Continuing adherence will be assessed by reviewing 3 audiotapes from each pharmacotherapist every 6 months, using the CSPRS-6.

The CSPRS-6 is a 96 item instrument developed for rating audiotapes of therapy sessions with depressed adult outpatients. A review of the instrument indicates that it can be used without modification to rate sessions with adolescents. The instrument has scaled to assess Cognitive, Interpersonal and Clinical Management models, Facilitative Conditions (e.g. supportiveness, warmth), Explicit Directiveness, "Tangential" Cognitive and Interpersonal Therapy, and nonspecific strategies (e.g.), the entire instrument will be used to allow a full characterization of the Clinical Management sessions, including the degree of overlap with other models and the extent of the use of nonspecific therapeutic characteristics.

The use of the CSPRS-6 is described in the Raters Manual for the 96-item CSPRS-6. Performance of the instrument and its scale V are reviewed and selection and training of raters for the CSPRS-6 in the Final Report: System for Rating Psychotherapy Audiotapes.

APPENDIX H

EXTERNAL REVIEWERS

[redacted]

Blank Case Report Form (CRF)

Tracking Number

Project	Protocol	Center	Patient Number
29060	329	0	

SmithKline Beecham
Pharmaceuticals

CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

SCREENING/ELIGIBILITY - BINDER 1

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials ____ Country _____

SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

Assessments	Baseline		Acute Phase								Continuation Phase					
Time (weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	●															
Medical History and Physical Exam	●															
Clinical Laboratory Studies	● [1]									●			●			●
Serum Pregnancy	●		● [2]													
ECG	●			●		●		●		●			●			●
Vital Signs	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hamilton Depression Scale	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Full K-SADS-L	●															●
Affect Section of K-SADS-L		●		●		●		●		●	●	●	●	●	●	
C-GAS	●															
CGI		●	●	●	●	●	●	●	●	●	●	●	●		●	●
SADS-L	●															
FH-FHE	●															
Autonomous Functioning Checklist	●									●						●
Self Perception Profile	●									●						●
Sickness Impact Scale	●									●						●
Randomization		●														
Adverse Experiences		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Supportive Psychotherapy		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Plasma Sampling for Drug Analysis	●					●				●				●		●
Study Medication Record			●	●	●	●	●	●	●	●	●	●	●	●	●	●
Concomitant Medication	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

[1] - Clinical laboratory studies should include a Urine Drug Screen
[2] - On suspicion of pregnancy

GENERAL INSTRUCTIONS

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

Important: Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

DATE

Use the following three-letter abbreviations for month:

January	:=	JAN
February	:=	FEB
March	:=	MAR
April	:=	APR
May	:=	MAY
June	:=	JUN
July	:=	JUL
August	:=	AUG
September	:=	SEP
October	:=	OCT
November	:=	NOV
December	:=	DEC

Example: | 0 1 | J A N | 9 4 | = 1st January 1994
day month year

TIME

Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example: | 1 5 | 3 0 | = 3:30 p.m.
24 hr. clock

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MODULE PARAMETERS - SCREENING/ELIGIBILITY

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Tracking Number	
	Module Pages	*V0117*

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DEMOGRAPHY

Date of Birth ____ day month year

Sex ☐ Male ☐ Female

Race
☐ White
☐ Black
☐ Oriental
☐ Other - specify: _____

VITAL SIGNS

Weight	Height	Sitting		Standing	
☐ lbs ☐ kg	☐ in ☐ cm	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.		/		/	

ELECTROCARDIOGRAM

Were there any clinically significant abnormalities?

☐ Yes ☐ No

Record in the Significant Medical/Surgical History and Physical Examination section, page 3.

Date Performed (day month year)

Patient Initials ____ Country _____

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PERSONAL HISTORY

Record the highest level of education for mother and father.

Father	Mother	
☐	☐	Graduated JHS
☐	☐	Graduated HS (do not count G.E.D.)
☐	☐	Graduated Junior College (A.A.)
☐	☐	Graduated Senior College (B.A., B.S., B.F.A., etc)
☐	☐	Completed Masters Degree (M.A., M.S., M.S.W., etc.)
☐	☐	Completed Doctoral, Medical, Law or Comparable Degree
☐	☐	Dropped out of JHS
☐	☐	Dropped out of HS
☐	☐	Dropped out of College
☐	☐	Received G.E.D.

Record the occupation for mother and father. If retired or deceased, record prior to retirement or death.

Father	Mother	
☐	☐	Higher executive, proprietors of large concerns, major professionals
☐	☐	Business managers in large concerns, proprietors of medium-sized businesses, minor professionals
☐	☐	Administrative personnel, owners of small independent businesses, minor professionals
☐	☐	Clerical and sales workers, technicians, owners of little businesses
☐	☐	Skilled manual employees
☐	☐	Machine operators, semi-skilled employees
☐	☐	Unskilled employees
☐	☐	Not relevant (e.g., was never employed)

Family Composition

☐ 2 parents home
☐ Single parent alone
☐ Parent + 1 step-parent
☐ 1 parent + 1 common-law parent
☐ Other relative(s) is (are) caretaker
☐ Parent + other relative(s) are caretaker

Number of People in Household ☐☐

Adopted/Natural Offspring

☐ Adopted ☐ Natural

School Placement

☐ Regular Ed
☐ Special ED - specify: _____

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SIGNIFICANT MEDICAL/SURGICAL HISTORY AND PHYSICAL EXAMINATION

Is the patient presently suffering from or has he/she ever suffered from any SIGNIFICANT medical or surgical condition?

☐ No

☐ Yes ⟶ Provide diagnosis below, listing no more than one diagnosis per line

Diagnosis	Year of First Diagnosis	Past	Current/ Active
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐
For SB		☐	☐

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PRIOR MEDICATION

Has the patient taken any medication in the past month?

☐ No
☐ Yes ⟶ Record details below

➧ Where appropriate, medical conditions recorded here must correlate with conditions listed in the Significant Medical History section, utilizing the same terminology.

Drug Name (Trade Name Preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date * day month year	End Date * day month year	★
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						

* State dates as precisely as possible
★ If medication continues, mark box.

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LABORATORY TESTS

For SB | Lab Number Code

Sample Date ___ day ___ month ___ year

- Attach SBCL laboratory report behind this page.

- Was a urine sample taken and sent to SBCL for drug abuse analysis?
  - ☐ No
  - ☐ Yes

- Are there CLINICALLY SIGNIFICANT ABNORMAL laboratory values?
  - ☐ No
  - ☐ Yes → Record the findings and/or diagnosis in the Significant Medical/Surgical History and Physical Examination section, page 3.

PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

- ☐ No
- ☐ Yes

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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AUTONOMOUS FUNCTIONING CHECKLIST

Grade in School ____

Informant _____
(mother, father, guardian, other)

Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you ***believe*** or ***think*** he or she ***could*** do or ***could not*** do.

Second, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4
Does Not Do	**Does Only Rarely**	**Does About Half the Time There is an Opportunity**	**Does Most of the Time There is an Opportunity**	**Does Every Time There is an Opportunity**

Sample Item. Pick up trash in the yard. 0 1 2 3 4

0 - Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)

1 - Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.

2 - Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.

3 - Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.

4 - Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has ***never had the chance*** to do.

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AUTONOMOUS FUNCTIONING CHECKLIST

Some questions describe things that your teenager may do with help from others. Answer these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

My teenager:

1. Keeps own personal items and belongings in order (for example makes bed, puts away own clothing and belongings).	0	1	2	3	4
2. Prepares food that does not require cooking for himself/herself (for example, cereal, sandwich).	0	1	2	3	4
3. Care for his/her own clothing (for example, laundry, simple repair, shoe cleaning)	0	1	2	3	4
4. Travels to and from daily activities (for example, rides bike or walks, takes bus, arranges for transportation, drives car).	0	1	2	3	4
5. Prepares food that requires cooking for himself/herself (for example, hamburger, soup).	0	1	2	3	4
6. Performs simple first aid or medical care for himself/herself (for example, bandages, takes own temperature).	0	1	2	3	4
7. Purchases his/her own clothing and personal items that are used on a daily basis (for example, underwear, toiletries).	0	1	2	3	4
8. Performs minor repair and maintance in his/her owm environment (for example, changes light bulbs, hangs pitcure).	0	1	2	3	4
9. Shops for and purchases his/her own groceries.	0	1	2	3	4
10. Responds to his/her own medical emergency by calling parent.	0	1	2	3	4
11. Responds to his/her own medical emergency by calling doctor or hospital.	0	1	2	3	4
12. Does designated household maintenance chores involving family living areas (for example, cleans, takes out trash, does simple yard work).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

13. Performs routine daily personal care for another family member. (for example, dresses, feeds).	0	1	2	3	4
14. Keeps personal items and belongings of another family member in order (for example, makes bed, puts away clothing and belongings).	0	1	2	3	4
15. Prepares meals for other family member(s).	0	1	2	3	4
16. Transports (or arranges for transport of) another family member to and from daily activities.	0	1	2	3	4
17. Purchases clothing and personal items (that are used on a daily basis) for other family members.	0	1	2	3	4
18. Shops for and purchases family groceries.	0	1	2	3	4
19. Performs minor repairs and maintenance in family living areas (for example, changes light bulbs, hangs picture).	0	1	2	3	4
20. Repairs and maintains (or makes arrangement for repair and maintenance of) major household needs (for example, plumbing, yard work, electrical wiring).	0	1	2	3	4
21. Responds to household emergency (for example, stove fire, plumbing problem) by calling parent or neighbor.	0	1	2	3	4
22. Reponds to household emergency (for example, stove fire, plumbing problem) by calling fire department, using fire extinguisher, or calling repair service or shuting off water.	0	1	2	3	4
My teenager:					
23. Uses the telphone and telephone directories.	0	1	2	3	4
24. Carries out transactions with sales people (for example, listens to information, asks questions, gives payment, receives change).	0	1	2	3	4
25. Uses postal services (for example, uses postage, mails letters. packages).	0	1	2	3	4
26. Uses bank (for example, fills out deposit or withdrawal slips, uses passbook).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

27.	Uses travel-related services for short trips (for example, taxi, bus subway).	0	1	2	3	4
28.	Uses travel-related services for long trips (for example, airline, train, bus).	0	1	2	3	4
29.	Uses library services (for example, checks out books or uses Xerox machine).	0	1	2	3	4
30.	Maintains and uses his/her own savings account.	0	1	2	3	4
31.	Maintains and uses his/her own checking or charge account.	0	1	2	3	4
32.	Maintains adequate personal care and grooming (for example, bathes, trims fingernails and toenails when needed)	0	1	2	3	4
33.	Maintains his/her routine general health and fitness (for example, has adequate eating, sleeping and exercise habits).	0	1	2	3	4
34.	Selects clothing that is suited to weather (for example, raincoat if raining, warm clothes in winter).	0	1	2	3	4
35.	Plans and initiates activity for himself/herself in everday unscheduled free time (for example, chooses to watch television or work on a hobby if bored).	0	1	2	3	4
36.	Plans activity for his/her long-term free time (for example, makes plans for summer vacation, mid-semester vacation).	0	1	2	3	4
37.	Initiates friendships with peers (for example, plans or attends parties, outings, games, club meetings).	0	1	2	3	4
38.	Meets nonacademic social obligations or commitments (for example, keeps appointments for family and peer related social events arranged by self or others).	0	1	2	3	4
39.	Meets academic obligations amd commitments (for example, completes homework assignments on time, brings necessary supplies to class).	0	1	2	3	4
40.	Plan transportation to and from special activities (for example arranges for rides with friends or family or plans care or bus route and schedule).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

41. Manage his/her own budget from allowance or income (for example, saves money for large purchases, pays for routine expenses throughout week without running out of money).	0	1	2	3	4
42. Make long-term educational and/or career plans (for example, selects courses, investigates colleges or technical schools).	0	1	2	3	4

When my teenager is free to choose how he/she will spend his/her unscheduled free time. He/she chooses to:

43. Listen to music (for example, radio or stereo).	0	1	2	3	4
44. Read for relaxation (for example, books, newspapers)	0	1	2	3	4
45. Play games or puzzles (for example, cards, crossword puzzles, jigsaw puzzles, computer games).	0	1	2	3	4
46. Write letters to friends, relatives, aquaintances.	0	1	2	3	4
47. Work on or take lessons in crafts or hobbies (for example cooking, collections, pet care, sewing, model building, car repair).	0	1	2	3	4
48. Practice or take lessons that involve a trained artistic or academic skill (for example, piano or other musical instrument, ballet, singing, creative writing, foreign languages).	0	1	2	3	4
49. Go to the movies, rock concerts, dances.					
50. Go to plays, theater, lectures.	0	1	2	3	4
51. Pursue activities that are related to his or her career interest(s) (for example, runs a business, works on a computer, practices piano for professional preparation).	0	1	2	3	4
52. Go for walks.	0	1	2	3	4
53. Go shopping, or spend time at shopping centers or in shopping areas.	0	1	2	3	4
54. Attend club meetings or other organized social group meetings.	0	1	2	3	4
55. Work for pay (for example, babysit, play in a band, do yard work, walk dogs, work at part-time job, deliver papers).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

56. Clean and/or maintan living environment or belongings (for example, clean house, wash or repair clothes, wash car, make household repairs).	0	1	2	3	4
57. Work on schoolwork (for example, spend extra time on homework, make special preparations for class projects, spend time in library).	0	1	2	3	4
58. Spend time with family (for example, work on family projects, have discussions or casual conversations, attend family gatherings such as picnics or parties).	0	1	2	3	4

On these final items, please check "Yes" or "No" in response to each description. Check "Yes" if the description fits your teenager. Check "No" if it does not.

My teenager:

	Yes	No
59. Has casual friendships with teenagers of opposite sex.	☐	☐
60. Has close friendships with teenagers of opposite sex.	☐	☐
61. Has casual friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders)	☐	☐
62. Has close friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders).	☐	☐
63. Has casual friendships with younger children.	☐	☐
64. Has close friendships with younger children.	☐	☐
65. Is active in casual/recreational groups of teenage friends.	☐	☐
66. Has many friendships.	☐	☐
67. Is active in one or more organized extracurricular group (for example, French club, student council, sports team).	☐	☐
68. Has leadership position in one or more organized extracurricular group (for example, president of the student council, captain of the sports team).	☐	☐
69. Has close friendship with adult member of the extended family (for example, an uncle, aunt, grandparent).	☐	☐
70. Works or has worked either for pay or volunteer in an area of particular career interest.	☐	☐

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AUTONOMOUS FUNCTIONING CHECKLIST

		Yes	No
71.	Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)	☐	☐
72.	Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).	☐	☐
73.	Works or has worked to earn money in a self-or-peer-run organization or business.	☐	☐
74.	Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).	☐	☐
75.	Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.	☐	☐
76.	Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).	☐	☐
77.	Has explored career interest by visiting work sites or interviewing people in that job or career.	☐	☐
78.	Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.	☐	☐

Comments:

If you have any additional information about your teenager's everyday independent or self-sufficient behavior, use the space below to write your comments. Thank you.

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

WHAT AM I LIKE

Sample Sentence

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
a.	☐	☐	Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.	☐	☐
1.	☐	☐	Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.	☐	☐
2.	☐	☐	Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.	☐	☐
3.	☐	☐	Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.	☐	☐
4.	☐	☐	Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.	☐	☐
5.	☐	☐	Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.	☐	☐
6.	☐	☐	Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.	☐	☐
7.	☐	☐	Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is right.	☐	☐
8.	☐	☐	Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.	☐	☐
9.	☐	☐	Some teenagers are often disappointed with themselves	BUT	Other teenagers are pretty pleased with themselves.	☐	☐
10.	☐	☐	Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
11.	☐	☐	Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.	☐	☐
12.	☐	☐	Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.	☐	☐
13.	☐	☐	Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.	☐	☐
14.	☐	☐	Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.	☐	☐
15.	☐	☐	Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to	☐	☐
16.	☐	☐	Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.	☐	☐
17.	☐	☐	Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a hard time keeping secrets that their friends tell them.	☐	☐
18.	☐	☐	Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.	☐	☐
19.	☐	☐	Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their class-work.	☐	☐
20.	☐	☐	Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.	☐	☐
21.	☐	☐	Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.	☐	☐
22.	☐	☐	Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
23.	☐	☐	Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they do.	☐	☐
24.	☐	☐	Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age will be attacted to them.	☐	☐
25.	☐	☐	Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.	☐	☐
26.	☐	☐	Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.	☐	☐
27.	☐	☐	Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.	☐	☐
28.	☐	☐	Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.	☐	☐
29.	☐	☐	Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.	☐	☐
30.	☐	☐	Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games right away.	☐	☐
31.	☐	☐	Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.	☐	☐
32.	☐	☐	Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.	☐	☐
33.	☐	☐	Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder about how fun and interesting they are on a date.	☐	☐
34.	☐	☐	Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
35.	☐	☐	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	☐	☐
36.	☐	☐	Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.	☐	☐
37.	☐	☐	Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent.	☐	☐
38.	☐	☐	Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.	☐	☐
39.	☐	☐	Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.	☐	☐
40.	☐	☐	Some teenagers really like their looks	BUT	Other teenagers wished they looked different.	☐	☐
41.	☐	☐	Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.	☐	☐
42.	☐	☐	Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get asked out by people they really want to date.	☐	☐
43.	☐	☐	Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.	☐	☐
44.	☐	☐	Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts and feelings with.	☐	☐
45.	☐	☐	Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

Introduction

On the next few pages are statements which describe things people often do when they are not well.

As you read them, think of yourself today:

- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).

- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).

For Example:

"I am not doing any of the shopping that I would usually do."

- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).

- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).

Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Please mark your answers by placing an "X" in the appropriate box like this. ☒

Thank you for your time and help.

How would you describe your present health

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

How would you describe you present quality of life (how things are going for you generally)?

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

A. These statements describe your sleep and rest this week.

	Yes	No
1. I spend much of the day lying down in order to rest.	☐	☐
2. I sit for much of the day.	☐	☐
3. I am sleeping or dozing much of the time - day and night.	☐	☐
4. I lie down more often than my friends during the day in order to rest.	☐	☐
5. I sit around half asleep.	☐	☐
6. I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	☐	☐
7. I sleep or doze more during the day.	☐	☐

B. These statements describe your daily work around the house.

	Yes	No
1. I only do work that I need to do around the house for short periods of time or I rest often.	☐	☐
2. I am doing less of the daily household chores that I would usually do.	☐	☐
3. I am not doing any of the daily household chores that I would usually do.	☐	☐
4. I am not doing any of the shopping that I would usually do.	☐	☐
5. I am not doing any of the cleaning that I would usually do.	☐	☐
6. I am not doing any of the clothes washing that I would usually do.	☐	☐

C. These statements describe your contact with your family and friends today.

	Yes	No
1. I am going out less to visit people.	☐	☐
2. I am not going out to visit people at all.	☐	☐
3. I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.	☐	☐
4. I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5. I show less affection.	☐	☐
6. I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

	Yes	No
7. I am cutting down the length of visits to friends.	☐	☐
8. I avoid having visitors.	☐	☐
9. My sexual activity is decreased.	☐	☐
10. I talk less with those around me.	☐	☐
11. I make demands on other people that they find irritating, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
12. I stay alone much of the time.	☐	☐
13. I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
14. I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
15. I isolate myself as much as I can from the rest of my family.	☐	☐
16. I refuse contact with my family, for example, I turn away from them.	☐	☐
17. I am not joking with my family members as I usually do.	☐	☐

D. These statements describe your feelings.

	Yes	No
1. I am confused and start to do more than one thing at a time.	☐	☐
2. I have more minor accidents, for example, I drop things, I trip and fall or bump into things.	☐	☐
3. I react slowly to things that are said or done.	☐	☐
4. I do not finish things I start.	☐	☐
5. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
6. I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
7. I forget a lot, for example, things that happened recently, where I put things, or to keep appointments.	☐	☐
8. I do not keep my attention on any activity for long.	☐	☐
9. I make more mistakes than usual.	☐	☐
10. I have difficulty doing things which involve thought and concentration, for example, paying attention in school or at my job.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

E. These statements are about how you talk to other people and write.

	Yes	No
1. I am having trouble writing or typing.	☐	☐
2. I am having trouble talking to people.	☐	☐
3. I am not comfortable in most social situations like parties.	☐	☐
4. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
5. I do not speak clearly when I am under stress.	☐	☐

F. The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.

	Yes	No
1. I spend shorter periods of time on my hobbies and recreation.	☐	☐
2. I am going out and enjoying myself less often.	☐	☐
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
5. I am doing more inactive pastimes in place of my other usual activities.	☐	☐
6. I am taking part in fewer activities with my friends.	☐	☐
7. I am cutting down on some of my usual physical recreation or more active pastimes.	☐	☐
8. I am not doing any of my usual physical recreation or more active pastimes.	☐	☐

Now please look through this questionnaire and make sure that you have read every question.

Thank you once again for your help.

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

Subject Version

1. ***Family Members***

Please tell me the first names and ages of your biological mother and father.

Now tell me the names, ages and sexes of all the children born to (Mother's first name) and (Father's first name). Please start with the first born (the oldest) and include yourself in the list.

Now please tell me the names of your children, if any. Please start with the first born (the oldest).

	Name	*Member ID#*	*Age (or age at death) 00=<1*	*Sex*	*Deceased*	*Correct Birth Order?*
Biologic Mother:		1	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	
Biologic Father:		2	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	
Sibling #1:		3	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Sibling #2:		4	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Sibling #3:		5	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Sibling #4:		6	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Sibling #5:		7	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Child #1:		8	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Child #2:		9	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

Now I'd like you to take a pencil or pen and a piece of paper and write down the names as I read them off. ***(Do so.)*** Could you read the list back to me? ***(Check to make sure the list matches yours.)*** Now I'm going to ask you questions about these people. Looking at the list, can you tell me...

2. Has anyone on the list ever had a serious mental illness, emotional problem, or nervous breakdown? 0 1 9

If no or don't know, go to Q.3

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

3. Has anyone on the list ever seen a psychiatrist, psychologist, social worker, doctor or other health professional for a psychological or emotional problem? 0 1 9

If no or don't know, go to Q.4

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

4. Has anyone on the list ever stayed overnight or longer in a hospital or treatment facility because of any mental or emotional problem? 0 1 9

If no or don't know, go to Q.5

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

5. Has anyone on the list ever stayed overnight or longer in a hospital or treatment facility because of a drug or alcohol problem? 0 1 9

If no or don't know, go to Q.6

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

6. Has a doctor ever given anyone on the list any medicine for a psychological or emotional problem? 0 1 9

If no or don't know, go to Q.7

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

7. Has anyone on the list ever had difficulty carrying out their usual responsibilities, such as working, going to school, or taking care of the family or household? 0 1 9

If no or don't know, go to Q.8

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. I don't mean because (you/NAME) were physically ill. Other than that, was anyone UNABLE to carry out their usual responsibilities for a WEEK OR MORE? 0 1 9

If no or don't know, go to Q.8

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

8. Did anyone on the list ever feel sad, blue, or depressed for most of the time for two days or more? 0 1 9

If no or don't know, go to Q.9

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Without including times of physical illness, or mourning after a death, did anyone have a period during which they felt sad, blue or depressed that lasted TWO WEEKS OR MORE? 0 1 9

If no or don't know, go to Q.9

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

9. Did anyone on the list ever have a period of feeling quite tired, having less energy, or not caring about their usual activities? 0 1 9

If no or don't know, go to Note 1

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Do not include times of physical illness, or mourning after a death. Other than that, did anyone feel VERY tired MOST of the time, have no energy, or not care about their usual activities, for at least TWO WEEKS? 0 1 9

If no or don't know, go to Note 1

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

Note 1: Say: "I know you know this, but I'm supposed to remind you that ALL of these questions are about whether ANY of these people listed on the page have had any these problems; that is; (names on template)."

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

10. Did anyone on the list ever have sleep problems, like trouble falling asleep, or waking up too early, or sleeping too much? 0 1 9

If no or don't know, go to Q.11

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Was it as much as an hour a night for TWO WEEKS OR MORE, and not because of a physical illness? 0 1 9

If no or don't know, go to Q.11

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

11. Has anyone on the list ever had a period of feeling extremely happy or high? 0 1 9

If no or don't know, go to Q.12

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. I mean "high as a kite," so that other people worried about them, or so that it interfered with carrying out normal responsibilities. Has anyone been unusually happy or high, not because of drugs or alcohol, for TWO DAYS OR MORE? 0 1 9

If no or don't know, go to Q.12

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

12. Has anyone on the list ever had a period in which they were more active or talkative than normal? 0 1 9

If no or don't know, go to Q.13

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. I mean EXTREMELY over-active or talkative, so that people WORRIED about them, or so that it interfered with carrying out their usual responsibilities. Has anyone been like that, without being under the influence of drugs or alcohol, for at least TWO DAYS? 0 1 9

If no or don't know, go to Q.13

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib..#5***	***Child#1***	***Child#2***

13. Has anyone on the list ever had a sudden spell or attack in which they felt frightened or panicked? 0 1 9

If no or don't know, go to Q.14

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib..#5***	***Child#1***	***Child#2***

B. Has anyone had SEVERAL attacks of EXTREME fear or panic, even though there was nothing to be afraid of? 0 1 9

If no or don't know, go to Q.14

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

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0 = NO; 1 = YES; 9 = DON'T KNOW

14. Has anyone on the list ever had a sudden spell or attack of difficulty breathing or of a rapid heartbeat? 0 1 9

If no or don't know, go to Q.15

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Did the person have SEVERAL such attacks, NOT caused by heart problems, exercise, or something that would have terrified most people? 0 1 9

If no or don't know, go to Q.15

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

15. Has anyone on the list ever had a period of at least one month when they were very tense or nervous and worried? 0 1 9

If no or don't know, go to Q.16

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Did anyone worry ALMOST EVERY DAY FOR SIX MONTHS OR MORE, about things that other people wouldn't have worried about that much? 0 1 9

If no or don't know, go to Q.16

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

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0 = NO; 1 = YES; 9 = DON'T KNOW

16. Has anyone on the list ever been frightened of going out of the house alone, being in a crowd, standing in lines, going over bridges, or travelling by bus, train or car? 0 1 9

If no or don't know, go to Q.17

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib..#5*	*Child#1*	*Child#2*

B. Do not include children who were too young to do these things. Other than that was anyone so frightened that they either COULDN'T do something, or really had to force themselves to do it? 0 1 9

If no or don't know, go to Q.17

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib..#5*	*Child#1*	*Child#2*

17. Has anyone on the list ever been very frightened of heights, animals, insects, or blood? 0 1 9

If no or don't know, go to Q.18

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib..#5*	*Child#1*	*Child#2*

B. Was anyone more frightened than others at their age -- so frightened of something that they tried very hard to AVOID IT? 0 1 9

If no or don't know, go to Q.18

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib..#5*	*Child#1*	*Child#2*

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0 = NO; 1 = YES; 9 = DON'T KNOW

18. Has anyone on the list ever gotten very embarrassed when they had to do something that involved other people, such as attend parties or social gatherings, or speak or eat in public? 0 1 9

If no or don't know, go to Note 2

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Was anyone so EXTREMELY embarrassed that they COULDN'T DO the things that bothered them, for at least TWO MONTHS? 0 1 9

If no or don't know, go to Note 2

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

Note 2: Say: "I want to remind you that all of these questions are about all of the people on the list; that is; (names on template)."

19. Did anyone on the list ever have a habit of checking, counting or cleaning things? 0 1 9

If no or don't know, go to Q.20

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Did the person do this over and over again, so much that it interfered with their usual activities? 0 1 9

If no or don't know, go to Q.20

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

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0 = NO; 1 = YES; 9 = DON'T KNOW

20. Has anyone on the list ever had unpleasant, nagging thoughts, such as that they hadn't locked the door, when they really had, or that things were dirty, when they were really clean? 0 1 9

If no or don't know, go to Q.21

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Did these thoughts keep coming back, no matter how hard the person tried to get rid of them? 0 1 9

If no or don't know, go to Q.21

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

21. Has anyone on the list ever heard voices, or seen visions, that other people could not see or hear? 0 1 9

If no or don't know, go to Q.22

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Don't include experiences caused by alcohol or drugs, or religious experiences that are common in their religion, or a younger child who had an imaginary playmate. Other than that, did the person clearly and frequently hear voices or see visions? 0 1 9

If no or don't know, go to Q.22

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

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0 = NO; 1 = YES; 9 = DON'T KNOW

22. Has anyone on the list ever believed in things that were very unusual and not true, for example, that people were plotting against them, or that TV programs were sending special messages just to them? 0 1 9

If no or don't know, go to Q.23

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Don't include beliefs caused by alcohol or drugs, or shared religious beliefs. Other than that, did the person believe things that were very unusual and not true? 0 1 9

If no or don't know, go to Q.23

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

23. Did anyone on the list ever have a period in his or her life when they drank a lot? 0 1 9

If no or don't know, go to Q.24

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Did the person have a drinking problem, or did people think they had a drinking problem? 0 1 9

If no or don't know, go to Q.24

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

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0 = NO; 1 = YES; 9 = DON'T KNOW

24. Did anyone on the list ever have a period in his or her life when they used illegal drugs regularly? 0 1 9

If no or don't know, go to Q.25

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Did the person have a drug problem, or did people think they had a drug problem? 0 1 9

If no or don't know, go to Q.25

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

25. Has anyone on the list ever been fired from a job, or laid off? 0 1 9

If no or don't know, go to Q.26

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Was it because their supervisor was not happy with their work, behavior, or attitude? 0 1 9

If no or don't know, go to Q.26

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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0 = NO; 1 = YES; 9 = DON'T KNOW

26. Has anyone on the list ever been put in jail, or arrested or convicted of a crime, other than drunk driving? 0 1 9

If no or don't know, go to Note 3

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

Note 3: ***Say:*** "The next few questions are about problems children and teenagers sometimes have. Since we want to know whether anyone on the list ever had the problem in their whole life, please remember to think about whether the adults had the problems when they were young, as well as thinking about whether the youngsters have had it."

27. When they were young, did anyone on the list get upset or frightened when they had to go to school, sleep away from home, or be away from their parents? 0 1 9

If no or don't know, go to Q.28

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Was it much more than most children their age? 0 1 9

If no or don't know, go to Q.28

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

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28. When they were children, did anyone on the list steal property, skip school, run away from home, or break rules? 0 1 9

If no or don't know, go to Q.29

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Did the person steal valuable property, skip school a lot, or break a lot of rules, more than other children their age? 0 1 9

If no or don't know, go to Q.29

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

29. In grade school, did anyone on the list fidget, leave their seats when they weren't supposed to, not finish their schoolwork, or not pay attention to the teacher? 0 1 9

If no or don't know, go to Q.30

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. Was the person really doing those things all the time, more than other (boys/girls) (his/her) age? 0 1 9

If no or don't know, go to Q.30

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

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0 = NO; 1 = YES; 9 = DON'T KNOW

30. Has anyone on the list EVER been suspended or expelled from school? 0 1 9

If no or don't know, go to Q.31

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

31. Has anyone on the list EVER tried to kill him or herself, or made a suicide attempt? 0 1 9

If no or don't know, go to Note 4

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

B. This may be a painful question, but did the person actually kill him or herself? 0 1 9

If no or don't know, go to Note 4

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***
I'm sorry. That must be hard to think about.

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	*Father*	*Sib.#1*	*Sib.#2*	*Sib.#3*	*Sib.#4*	*Sib.#5*	*Child #1*	*Child #2*

Note 4: Say: "Thank you very much for giving me so much information about your relatives."

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SADS-L

Using the scale below, mark the appropriate box for each term listed below. Complete Onset and Offset dates as applicable.

1 = Not present (screen denied)
2 = Possible (screen and 1 symptom)
3 = Probable (1 criterion short)
4 = Definite (meets DSM III criteria)
5 = Unknown (no information available)
6 = Not Applicable

	Current							Past							
	1	2	3	4	5	6	Onset Date (day/mth/yr)	1	2	3	4	5	6	Onset Date (day/mth/yr)	Offset Date (day/mth/yr)
Schizophrenia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Schizo-affective-manic	☐	☐	☐	☐	☐	☐									
Schizo-affective-depressed	☐	☐	☐	☐	☐	☐									
Other functional psychosis	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Major depression	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
W psychotic features	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Dysthymia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Mania	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
W psychotic features	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Hypomania	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Cyclothymia	☐	☐	☐	☐	☐	☐									
Recurrent Unipolar	☐	☐	☐	☐	☐	☐									
Bipolar I	☐	☐	☐	☐	☐	☐									
Bipolar II	☐	☐	☐	☐	☐	☐									
Other affective disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Simple phobia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Social phobia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Agoraphobia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Generalized anxiety	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		

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SADS-L

Using the scale below, mark the appropriate box for each term listed below. Complete Onset and Offset dates as applicable.

1 = Not present (screen denied)
2 = Possible (screen and 1 symptom)
3 = Probable (1 criterion short)
4 = Definite (meets DSM III criteria)
5 = Unknown (no information available)
6 = Not Applicable

	Current							Past							
	1	2	3	4	5	6	Onset Date (day/mth/yr)	1	2	3	4	5	6	Onset Date (day/mth/yr)	Offset Date (day/mth/yr)
Panic disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Obsessive-compulsive	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Alcohol abuse	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Drug abuse	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Conduct disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Antisocial personality disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Attention deficit disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Anorexia nervosa	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Bulimia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Separation anxiety	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Post traumatic stress disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Mental retardation	☐	☐	☐	☐	☐	☐									
Learning disability	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Organic brain disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Other psychiatric disorder - specify: _____	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		

Current Psychiatric Disorder		Past Psychiatric Disorder		Direct Interview		Number of Informants
Yes	No	Yes	No	Yes	No	
☐	☐	☐	☐	☐	☐	

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SADS-L

	None (1)	Threat (2)	Assault (3)	Homicide (4)	No information (5)	Age of earliest behavior	Age of earliest assault	Number of assaultive acts
Assaultive Behavior	☐	☐	☐	☐	☐			

	Never hospitalized (1)	Less than 5 days (2)	Less than 3 months (3)	Less than 6 months (4)	6 months or more (5)	No information (6)	Age of 1st hospitalization	Number of hospitalizations
Total Psychiatric Hospitalizations	☐	☐	☐	☐	☐	☐		

	No contact (1)	Consultation or brief period of treatment (2)	6 months to 2 years (3)	2 years or more (4)	No information (5)	Age of 1st outpatient contact
Total Outpatient Treatment	☐	☐	☐	☐	☐	

	None (1)	Ideation (2)	Threat (3)	Gesture (4)	Attempt (5)	Completion (6)	No information (7)	Age of earliest behavior	Age of earliest attempt	Number of attempts
Suicidal Behavior	☐	☐	☐	☐	☐	☐	☐			

	Not applicable (living) (1)	Natural death (2)	Accidental death (3)	Possible suicide (4)	Definite suicide (5)	No information (6)
Circumstances of Death	☐	☐	☐	☐	☐	☐

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KIDDIE-SADS-LIFETIME - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28. Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: __ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: __ Days/Week

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

56. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

58. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Increased pauses before answering

59. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

60. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Low or monotonous speech

61. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

62. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Mute or markedly decreased amount of speech

63. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

64. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Slowed body movements

65. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

66. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Depressive stupor

67. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

68. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

70. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

REJECTION SENSITIVITY

71. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

72. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

73. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

74. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

83. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

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KIDDIE-SADS-LIFETIME - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

85. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

87. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Middle Insomnia

88. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

89. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

91. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Circadian Reversal

92. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

93. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

95. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

97. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - MAJOR DEPRESSIVE EPISODE

Onset and Course

118. Number of Episodes

Ages of onset and offset of each episode

119. Onset
Offset
Weeks

120. Onset
Offset
Weeks

121. Onset
Offset
Weeks

122. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - HYPOMANIC EPISODE

Onset and Course

36. Number of Episodes

Ages of onset and offset of each episode

37. Onset
Offset
Weeks

38. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - MANIC EPISODE

39. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

40. Onset
Offset
Weeks

41. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

EATING DISORDERS

REFUSAL TO MAINTAIN BODY WEIGHT

1. Lifetime: (0) NI (1) NP (2) (3) (4) (5) (6)

METHODS OF WEIGHT LOSS

2. ***Restriction*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
3. ***Only Liquids*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
4. ***Vomiting*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
5. ***Supressants*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
6. ***Laxatives*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
7. ***Diurectics*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU

BODY IMAGE DISTURBANCE

8. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

INTENSE AND PERSISTENT FEAR OF GAINING WEIGHT

9. Lifetime: (0) NI (1) NO (2) (3) (4) (5) (6)

INTENSE PREOCCUPATION WITH FOOD AND EATING

10. Lifetime: (0) NI (1) NO (2) (3) (4) (5) (6)

AMENORRHEA

11. Age of Menarche: ___
12. (0) NI (1) NO (2) YES
13. (0) NI (1) NO (2) YES

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KIDDIE-SADS-LIFETIME - SCORING FORM

14. Weeks: ___

15. Weeks: ___

16. (0) NI (1) NO (2) YES

BULIMIA

17. Lifetime: (0) NI (1) NO (2) (3) (4) (5) (6)

18. ***Eats faster*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

19. ***Uncontrollable*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

20. ***Eats alone*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

21. ***Abdominal Pain*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

22. ***Vomiting*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

23. ***Sleep*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

24. ***Interruption*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

25. ***Depression*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

26. Binges: ___ hours

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - ANOREXIA NERVOSA

Onset and Course

27. Number of Episodes

Ages of onset and offset of each episode

28. Onset
Offset
Weeks

29. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - BULIMIA NERVOSA

Onset and Course

30. Number of Episodes

Ages of onset and offset of each episode

31. Onset
Offset
Weeks

32. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANXIETY DISORDERS

SPECIFIC PHOBIAS

1.	***Overall*** Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	***Flying*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
3.	***Elevators*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
4.	***Small Spaces*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
5.	***Heights*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
6.	***Dark*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
7.	***Swimming*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
8.	***Dogs/animals*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
9.	***Insects*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
10.	***Thunderstorms*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
11.	***Cars/Buses/Trains*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
12.	***Dentist/Doctors*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
13.	***Other*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	

DIAGNOSTIC CRITERIA - SPECIFIC PHOBIA

Onset and Course

14. Number of Episodes ___

Ages of onset and offset of each episode

15. Onset ___ Offset ___ Weeks ___

16. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

SEPARATION ANXIETY

PREOCCUPATION WITH THOUGHTS OF HARM TO PARENTS

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PREOCCUPATION WITH HARM BEFALLING SELF

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FEAR OF BEING HOME ALONE

3. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

EXCESSIVE REACTION TO SEPARATION

4. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIFFICULTY BEING AWAY FROM HOME

5. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

HOMESICKNESS

6. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FEAR OF SLEEPING AWAY FROM HOME

7. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

NIGHTMARES

8. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

SCHOOL REFUSAL/RELUCTANCE

9. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PHYSICAL SYMPTOMS DURING SEPARATION

10. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - SEPARATION ANXIETY DISORDER

Onset and Course

11. Number of Episodes [ ]

Ages of onset and offset of each episode

12. Onset [ ]
Offset [ ]
Weeks [ ]

13. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

PANIC DISORDER AND AGORAPHOBIA

1. Lifetime: (0) NI | (1) NP | (2) DBT | (3) DPR | (4) 6 | (5) 3X | (6) DLY

SPONTANEOUS ATTACKS

2. Lifetime: (0) NI | (1) NO | (2) 1 | (3) 2-3 | (4) 4 | (5) 4+

DURATION OF SPONTANEOUS ATTACKS

3. Lifetime: (0) NI | (1) 20 | (2) 10 | (3) SOM | (4) MST | (5) ALL

SITUATIONALLY PREDISPOSED ATTACKS

4. Lifetime: (0) NI | (1) NO | (2) -4 | (3) | (4) | (5) 4+

PHOBIA RELATED ATTACKS

5. Lifetime: (0) NI | (1) NO | (2) | (3)

6. ***Shortness of Breath*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

7. ***Palpitations*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

8. ***Chest Pains*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

9. ***Choking*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

10. ***Dizziness*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

11. ***Numbness*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

12. ***Sweating*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

13. ***Trembling*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

14. ***Dying*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

15. ***Losing Control*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

16. ***Nausea*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

17. ***Depersonalization*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

18. ***Flashes/Chills*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

19. Most Number of Attacks: [ ] in a 4 week period

20. Lifetime: (0) NI | (1) NP | (2) VM | (3) MLD | (4) MO | (5) SVR | (6) EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

AGORAPHOBIA WITH PANIC DISORDER

21. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

AGORAPHOBIA WITHOUT PANIC DISORDER

22. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - PANIC DISORDER WITHOUT AGORAPHOBIA

Onset and Course

23. Number of Episodes

Ages of onset and offset of each episode

24. Onset / Offset / Weeks

25. Onset / Offset / Weeks

DIAGNOSTIC CRITERIA - PANIC DISORDER WITH AGORAPHOBIA

26. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

27. Onset / Offset / Weeks

28. Onset / Offset / Weeks

DIAGNOSTIC CRITERIA - AGORAPHOBIA WITHOUT HISTORY OF PANIC DISORDER

29. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

30. Onset / Offset / Weeks

31. Onset / Offset / Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

SOCIAL PHOBIA

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - SOCIAL PHOBIA

2. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

3. Onset

Offset

Weeks

4. Onset

Offset

Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSESSIONS OR COMPULSIONS

OBSESSIONS

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

COMPULSIONS

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX
3. ***Touching*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
4. ***Counting*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
5. ***Washing*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
6. ***Checking*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
7. ***Collecting*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
8. ***Arranging*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
9. ***Other*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD

DEPERSONALIZATION OR DEREALIZATION

10. Lifetime: (0) NI (1) NO (2) FLT (3) OCC (4) SVL (5) MRK (6) FQT

DIAGNOSTIC CRITERIA - OBSESSIVE-COMPULSIVE DISORDER

11. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

12. Onset ___ Offset ___ Weeks ___

13. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

GENERALIZED ANXIETY DISORDER

WORRY

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

2. Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD

DIFFICULTY CONTROLLING WORRIES

3. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

SYMPTOMS ASSOCIATED WITH WORRY

4. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - GENERALIZED ANXIETY DISORDER

5. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

6. Onset ___ Offset ___ Weeks ___

7. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

POST-TRAUMATIC STRESS DISORDER

TRAUMA TO OTHERS

1. Lifetime: (0) NI (1) NO (2) (3) (4) (5) (6)

TRAUMATIC TO SELF

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR

INTRUSIVE RECOLLECTIONS OF TRAUMA

3. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

RECURRENT DISTRESSING DREAMS

4. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

SENSE OF RELIVING TRAUMA AND INTENSE DISTRESS AT RE-EXPERIENCE

5. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

PHYSIOLOGICAL REACTION UPON EXPOSURE

6. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

THOUGHTS, FEELINGS, CONVERSATIONS, ACTIVITIES, PLACES OF PEOPLE

7. Lifetime: (0) NI (1) NO (2) YES

NO RECALL OF IMPORTANT ASPECTS OF TRAUMA

8. Lifetime: (0) NI (1) NO (2) YES

MARKEDLY REDUCED ACTIVITIES/INTEREST

9. Lifetime: (0) NI (1) NO (2) YES

DETACHMENT, ENSTRANGEMENT, RESTRICTED AFFECT

10. Lifetime: (0) NI (1) NO (2) YES

SENSE OF FORESHORTENED FUTURE

11. Lifetime: (0) NI (1) NO (2) YES

SLEEP PROBLEMS

12. Lifetime: (0) NI (1) NO (2) YES

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KIDDIE-SADS-LIFETIME - SCORING FORM

IRRITABILITY

13. Lifetime: (0) NI (1) NO (2) YES

DIFFICULTY CONCENTRATING

14. Lifetime: (0) NI (1) NO (2) YES

HYPERVIGILENCE

15. Lifetime: (0) NI (1) NO (2) YES

EXAGGERATED STARTLED RESPONSE

16. Lifetime: (0) NI (1) NO (2) YES

OVERALL SEVERITY OF POST-TRAUMATIC STRESS DISORDER

17. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

DIAGNOSTIC CRITERIA - POST-TRAUMATIC STRESS DISORDER

18. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

19. Onset ___ Offset ___ Weeks ___

20. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

INATTENTION

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

HYPERACTIVITY

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IMPULSIVITY

3. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

4. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

5. Onset ___ Offset ___ Weeks ___

6. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

CONDUCT DISORDER/ANTISOCIAL PERSONALITY

CHRONIC VIOLATION OF RULES AT HOME AND/OR SCHOOL

1. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

SCHOOL SUSPENSION/EXPULSION

2. Lifetime: (0) NI | (1) NO | (2) -1 | (3) 1+ | (4) EXP

TRUANCY

3. Lifetime: (0) NI | (1) NO | (2) OCC | (3) FQT | (4) 50%

PATHOLOGICAL LYING

4. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

STAYING OUT AT NIGHT

5. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

RUNAWAY OVERNIGHT

6. Lifetime: (0) NI | (1) NO | (2) 1 | (3) 1+ | (4) FQT

NONAGGRESIVE STEALING

7. Lifetime: (0) NI | (1) NO | (2) | (3) $10 | (4) $50

BULLYING

8. Lifetime: (0) NI | (1) NO | (2) | (3) FQT | (4) DLY

PERSISTENT PHYSICAL FIGHTING

9. Lifetime: (0) NI | (1) NO | (2) | (3) FQT | (4)

USE OF A WEAPON

10. Lifetime: (0) NI | (1) NVR | (2) CON | (3) 1 | (4) 1+

VANDALISM

11. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

FIRESETTING

12. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

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KIDDIE-SADS-LIFETIME - SCORING FORM

BREAKING AND ENTERING

13. Lifetime: (0) NI | (1) NO | (2) -1 | (3) 2 | (4) 2+

AGGRESSIVE STEALING

14. Lifetime: (0) NI | (1) NO | (2) -1 | (3) 2 | (4) 2+

CRUELTY TO ANIMALS

15. Lifetime: (0) NI | (1) NO | (2) OCC | (3) | (4)

PHYSICAL CRUELTY TO PERSONS

16. Lifetime: (0) NI | (1) NO | (2) -1 | (3) 2 | (4) 2+

HOMICIDAL ACTS

17. Lifetime: (0) NI | (1) NO | (2) GTR | (3) ATT | (4) COM

FORCED SEX

18. Lifetime: (0) NI | (1) NO | (2) | (3) | (4) | (5) RAP

GANG ACTIVITIES

19. Lifetime: (0) NI | (1) NO | (2) PER | (3) MEM | (4) LDR

DELINQUENCY

20. Lifetime: (0) NI | (1) NO | (2) ARR | (3) CHA | (4) CON

INCARCERATION

21. Lifetime: (0) NI | (1) NO | (2) HLD | (3) REF | (4) JAL

SUMMARY RATING

22. Lifetime: (0) NI | (1) NO | (2) SLT | (3) MLD | (4) MO | (5) SVR | (6) EX

DIAGNOSTIC CRITERIA - CONDUCT DISORDER

23. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

24. Onset ___ Offset ___ Weeks ___

25. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANTISOCIAL PERSONALITY DISORDER

WORK

1. Lifetime: (0) NI (1) NO (2) MLD (3) MOD (4) SVR (5) EX

FINANCIAL RESPONSIBILITY

2. Lifetime: (0) NI (1) NO (2) MLD (3) MOD (4) SVR (5) EX

CONNING

3. Lifetime: (0) NI (1) MLD (2) MOD (3) SVR (4) EX

DISREGARD FOR SAFETY OF SELF/OTHERS

4. Lifetime: (0) NI (1) MLD (2) MOD (3) EX

LACK OF REMORSE

5. Lifetime: (0) NI (1) MLD (2) MOD (3) EX

DIAGNOSTIC CRITERIA - ANTISOCIAL PERSONALITY DISORDER

6. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

7. Onset

Offset

Weeks

8. Onset

Offset

Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

OPPOSITIONAL DEFIANT DISORDER

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - OPPOSITIONAL DEFIANT DISORDER

2. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

3. Onset

Offset

Weeks

4. Onset

Offset

Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

ALCOHOL

ALCOHOL ABUSE

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

ALCOHOL DEPENDENCE

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - ALCOHOL DEPENDENCE

3. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

4. Onset
Offset
Weeks

5. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - ALCOHOL ABUSE

6. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

7. Onset
Offset
Weeks

8. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

DRUGS

DRUG ABUSE

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DRUG DEPENDENCE

2. Lifetime: (0) NI (1) NO (2) MLD (3) MOD (4) SVR (5) EX

DIAGNOSTIC CRITERIA - SUBSTANCE DEPENDENCE

3. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

4. Onset
Offset
Weeks

5. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - SUBSTANCE ABUSE

6. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

7. Onset
Offset
Weeks

8. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

TIC DISORDERS

MOTOR TICS

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

VOCAL TICS

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - TIC DISORDERS

3. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

4. Onset
   Offset
   Weeks

5. Onset
   Offset
   Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

PSYCHOTIC SYMPTOMOLOGY

COMMAND HALLUCINATIONS

1. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

CONVERSING VOICES

2. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

PERSECUTORY HALLUCINATIONS

3. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

COMMENTING VOICE

4. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

RELIGIOUS HALLUCINATIONS

5. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

THOUGHTS ALOUD

6. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

OTHER VERBAL HALLUCINATIONS

7. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

LOCATION OF AUDITORY HALLUCINATIONS

8. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

9. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

10. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

VISUAL HALLUCINATIONS

11. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

TACTILE HALLUCINATIONS

12. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

OLFACTORY HALLUCINATIONS

13. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

14. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

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KIDDIE-SADS-LIFETIME - SCORING FORM

OTHER PERCEPTUAL CHILDHOOD PHENOMENA

HYPNAGOGIC OR HYPNAPOMPIC HALLUCINATIONS

1. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF
2. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF
3. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

ILLUSIONS

4. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

EIDETIC IMAGERY

5. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

ELABORATED FANTASIES

6. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

IMAGINARY COMPANIONS

7. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

CHARACTERISTICS OF PSYCHOPATHOLOGICALLY MEANINGFUL HALLUCINATIONS

FREQUENCY

8. Lifetime: (0) NI (1) NO (2) SUS (3) -5 (4) SOM (5) LOT (6) DLY

SEVERITY

9. Lifetime: (0) NI (1) NO (2) SUS (3) DEF (4) GEN (5) CNV (6) ACT

THEMATIC CONSISTENCY WITH MOOD DISORDER

DEPRESSION

10. Lifetime: (0) NI (1) NO (2) POS (3) COM

MANIA

11. Lifetime: (0) NI (1) NO (2) POS (3) COM

TEMPORAL CONSISTENCY WITH MOOD DISORDER

DEPRESSION

12. Lifetime: (0) NI (1) NO (2) SUS (3) POS

MANIA

13. Lifetime: (0) NI (1) NO (2) SUS (3) POS

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KIDDIE-SADS-LIFETIME - SCORING FORM

DELUSIONS

DELUSIONS OF REFERENCE

1. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

DELUSIONS OF BEING CONTROLLED OR INFLUENCED

2. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

DELUSIONS THAT PEOPLE CAN READ HIS MIND

3. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

THOUGHT BROADCASTING

4. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

THOUGHT INSERTION

5. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

THOUGHT WITHDRAWAL

6. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

DELUSIONS OF GUILT OR SIN

7. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

DELUSIONS OF INFLUENCE

8. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

PERSECUTORY DELUSIONS

9. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

GUILT RELATED PERSECUTORY DELUSIONS

10. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

SOMATIC DELUSIONS

11. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

GUILT RELATED SOMATIC DELUSIONS

12. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

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KIDDIE-SADS-LIFETIME - SCORING FORM

NIHILISTIC DELUSIONS

13. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

GUILT RELATED NIHILISTIC DELUSIONS

14. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

GRANDIOSE DELUSIONS

15. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

SUBCULTURAL OR FAMILY DELUSIONS

16. Lifetime: (0) NI (1) DEF (2) LIK (3) ALL

SEVERITY OF DELUSIONS OF ANY TYPE

17. Lifetime: (0) NI (1) NO (2) SUS (3) PST (4) GEN (5) SIG (6) ACT

SENSORIUM WHILE DELUDED

18. Lifetime: (0) NI (1) DEL (2) PLX (3) ALW

THEMATIC CONSISTENCY WITH MOOD DISORDER

DEPRESSION

19. Lifetime: (0) NI (1) NO (2) POSS (3) COM

MANIA

20. Lifetime: (0) NI (1) NO (2) POSS (3) COM

TEMPORAL CONSISTENCY WITH MOOD DISORDER

DEPRESSION

21. Lifetime: (0) NI (1) NO (2) SUS (3) POS

MANIA

22. Lifetime: (0) NI (1) NO (2) SUS (3) POS

BIZARRENESS OF DELUSIONAL CONTENT

23. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

MULTIPLE DELUSIONS

24. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

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KIDDIE-SADS-LIFETIME - SCORING FORM

FORMAL THOUGHT DISORDER

SENTENCE INCOHERENCE

1.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
2.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

DERAILMENT

3.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
4.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

ILLOGICAL THINKING

5.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
6.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

POVERTY OF CONTENT OF SPEECH

7.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
8.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

NEOLOGISMS

9.	Lifetime:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR
10.	Observed:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR

PRESSURE OF SPEECH

11.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
12.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSERVATIONAL ITEMS

INAPPROPRIATE AFFECT

1. Observed: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

BLUNTED AFFECT

2. Observed: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

CATATONIC MOTOR BEHAVIOR

3. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR
4. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR
5. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR
6. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR
7. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR

BIZARRENESS

8. Observed: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX
9. Observed: (0) NI (1) ABS (2) DBT (3) PST (4) SVR
10. Observed: (0) NI (1) ABS (2) DBT (3) PST (4) SVR
11. Observed: (0) NI (1) ABS (2) DBT (3) PST (4) SVR
12. Observed: (0) VG (1) G (2) OF (3) P (4) VP

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - SCHIZOPHRENIA

1. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

2. Onset
Offset
Weeks

3. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - SCHIZOAFFECTIVE DISORDER

4. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

5. Onset
Offset
Weeks

6. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - BRIEF PSYCHOTIC DISORDER

7. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

8. Onset
Offset
Weeks

9. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - DELUSIONAL DISORDER

10. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

11. Onset

Offset

Weeks

12. Onset

Offset

Weeks

KIDDY-GAS (C-GAS)

1. Current Episode:	100-91	90-81	80-71	70-61	60-51	50-41	40-31	30-21	20-11	10-1
2. Last Two Weeks:	100-91	90-81	80-71	70-61	60-51	50-41	40-31	30-21	20-11	10-1

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section, page

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section, page

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27.	Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28.	Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: __ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: __ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

56. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

58. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Increased pauses before answering

59. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

60. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Low or monotonous speech

61. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

62. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Mute or markedly decreased amount of speech

63. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

64. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Slowed body movements

65. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

66. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Depressive stupor

67. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

68. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

70. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

REJECTION SENSITIVITY

71. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

72. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

73. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

74. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

83. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

85. Last Two Weeks: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

Frequency: [ ] Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

87. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Middle Insomnia

88. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

89. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

91. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Circadian Reversal

92. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

93. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

95. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

97. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIAGNOSTIC CRITERIA - MAJOR DEPRESSIVE EPISODE

Onset and Course

118. Number of Episodes

Ages of onset and offset of each episode

119. Onset
Offset
Weeks

120. Onset
Offset
Weeks

121. Onset
Offset
Weeks

122. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIAGNOSTIC CRITERIA - HYPOMANIC EPISODE

Onset and Course

36. Number of Episodes

Ages of onset and offset of each episode

37. Onset
Offset
Weeks

38. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - MANIC EPISODE

39. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

40. Onset
Offset
Weeks

41. Onset
Offset
Weeks

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ELIGIBILITY CHECKLIST

Answer the following statements by marking the appropriate box.

Inclusion criteria

If any of the following statements are answered 'No', the patient is not eligible for the study.

		Yes	No
1.	Has the patient and legal guardian signed an informed consent?	☐	☐
2.	Is the patient an adolescent between the ages of 12 years 0 month and 18 years 11 months inclusive?	☐	☐
3.	Is the patient currently in an episode of major depression (DSM-III-R) for at least 8 weeks?	☐	☐
4.	Does the patient have a score of ≥ 12 on the 17-item Hamilton Depression Scale (Screening visit ***and*** Eligibility Determination visit, pages 8 and 88)?	☐	☐
5.	Is the patient medically healthy as determined by physical examination, medical history and laboratory screening (pages 3 and 5)?	☐	☐
6.	Does the patient have an IQ ≥ 80 by Peabody Picture Vocabulary Test?	☐	☐
7.	Is the patient male, or if female and sexually active, is the patient using a reliable method of contraception (oral contraception, surgical sterilization, I.U.D., diaphragm in conjunction with spermicidal foam amd condom on partners)?	☐	☐

Exclusion criteria

If any of the following statements are answered 'Yes', the patient is not eligible for the study.

		Yes	No
1.	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder?	☐	☐
2.	Does the patient have a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R)?	☐	☐
3.	Has the patient been adequately treated with anti-depressants within 6 months prior to beginning this study (page 4)?	☐	☐
4.	Has the patient ever had suicidal ideation with a definite plan, or made a suicide attempt within the current episode, or ever made a suicide attempt by medication overdose?	☐	☐
5.	Has the patient any medical illness which would contraindicate the use of heterocyclic antidepressants (e.g., cardiovascular disease)?	☐	☐
6.	Is the patient currently using (1) psychotropic medications including anticonvulsants, anxiolytics, neuroleptics, lithium carbonate, (2) illicit drugs as documented by a drug screen with two weeks of starting the study (page 4)?	☐	☐
7.	Does the patient have evidence of organic brain disease, epilepsy or mental retardation?	☐	☐
8.	Is the patient pregnant or lactating?	☐	☐
9.	Has the patient been treated with any investigational drug within 30 days of entry into the study or within 5 half lives of the investigation drug (the longer period will apply)(page 4)?	☐	☐

SmithKline Beecham Pharmaceuticals

Tracking Number

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Eligibility Determination	02		105

QUALIFICATION FOR ENTRY TO DOUBLE-BLIND PHASE

Does the patient qualify to enter the double-blind phase of the study, i.e., are the inclusion and exclusion criteria listed on page 104 satisfied?

☐ No - the patient does not qualify for entry

1. Complete page 106 (concomitant medication) and page 107 (adverse experience) if the patient has taken any medication or reported an adverse experience during the screening phase.

   Note: These pages are to be completed only for patients who ***will not*** enter the double-blind phase.

☐ Yes - the patient does qualify for entry

1. Dispense the Week 1 study medication card.

2. Detach the tear off label from the Week 1 card and affix the label to the Week 1 Label page (page 113) in Binder 2. Also record the start date in the Study Medication Record on page 112 in Binder 2.

   Important: The drug code on the randomization label ***must be identical*** to the Patient Number preprinted in the Patient Number box atop of pages 108-232 in Binder 2.
   To ensure that this Patient Number is properly referenced to the Tracking Number of the Screening/Eligibility pages of this case report form record the pre-printed Patient Number from the top of page 108 (Binder 2) in the space below and again on page 1 (Binder 1-in the page header) of the case report form.

   Patient Number

3. If the patient is entering the double-blind phase and had an adverse experience during the screening procedures, the experience must be recorded in the adverse experience section (pages 226-231). Additionally, if the patient has taken any medication, either over the counter or prescription, during the screening procedures, these must be recorded in the concomitant medication section (pages 224-225).

I certify that I have reviewed the screening/eligiblity data in the case report form (pages 1-107) and that all information is complete and accurate.

Investigator's Signature _____ _____ Date

SmithKline Beecham Pharmaceuticals

Tracking Number

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Eligibility Determination	02	106

CONCOMITANT MEDICATION → SCREENING FAILURES ONLY

- Record all concomitant medication taken as corrective therapy for Baseline Adverse Experience.
- Where appropriate, medical conditions should be recorded on the Adverse Experiences form utilizing the same terminology.

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						

★ State dates as precisely as possible.

SmithKline Beecham Pharmaceuticals

Tracking Number

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Eligibility Determination	02	107

ADVERSE EXPERIENCE ⟶ SCREENING FAILURES ONLY

➧ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
➧ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				➧ If patient died, complete Form D

Table of Contents

Tab 1

Page 1 - Demography
Page 2 - Personal History
Page 3 - Significant Medical History and Physical Exam
Page 4 - Prior Medication
Page 5 - Laboratory Tests & Plasma Sample

Tab 2

Page 6 - Hamilton Depression Scale
Page 9 - Autonomous Functioning Checklist
Page 16 - Self-Perception for Adolescents
Page 20 - Sickness Impact Profile
Page 24 - Family History

Tab 3

Page 39 - SADS-L
Page 42 - Kiddie SADS Lifetime
Page 84 - Kiddle GAS (C-GAS)

SCREENING
TAB 2

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SCREENING
TAB 3

ELIGIBILITY
DETERMINATION

QUALIFICATION FOR
ENTRY INTO
DOUBLE-BLIND-PHASE

Project	Protocol	Center	Patient Number
29060	329	0	

SmithKline Beecham
Pharmaceuticals

CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

ACUTE PHASE - BINDER 2

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials ___ **Country** _____

GENERAL INSTRUCTIONS

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

Important: Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

DATE

Use the following three-letter abbreviations for month:

January	=	JAN
February	=	FEB
March	=	MAR
April	=	APR
May	=	MAY
June	=	JUN
July	=	JUL
August	=	AUG
September	=	SEP
October	=	OCT
November	=	NOV
December	=	DEC

Example: | 0 | 1 | J | A | N | 9 | 4 | = 1st January 1994

day month year

TIME

Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example: | 1 | 5 | 3 | 0 | = 3:30 p.m.

24 hr. clock

SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

Assessments	Baseline		Acute Phase								Continuation Phase					
Time (weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	●															
Medical History and Physical Exam	●															
Clinical Laboratory Studies	● [1]									●			●			●
Serum Pregnancy	●		● [2]	----	----	----	----	----	----	----	----	----	----	----	----	----
ECG	●			●		●		●		●			●			●
Vital Signs	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hamilton Depression Scale	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Full K-SADS-L	●															●
Affect Section of K-SADS-L		●		●		●		●		●	●	●	●	●	●	
C-GAS	●															
CGI		●	●	●	●	●	●	●	●	●	●	●	●		●	●
SADS-L	●															
FH-FHE	●															
Autonomous Functioning Checklist	●									●						●
Self Perception Profile	●									●						●
Sickness Impact Scale	●									●						●
Randomization		●														
Adverse Experiences		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Supportive Psychotherapy		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Plasma Sampling for Drug Analysis	●					●				●				●		●
Study Medication Record			●	●	●	●	●	●	●	●	●	●	●	●	●	●
Concomitant Medication	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

[1] - Clinical laboratory studies should include a Urine Drug Screen
[2] - On suspicion of pregnancy

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - SCREENING/ELIGIBILITY

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0117*

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 1

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 2 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 1	day month year	108

TRACKING NUMBER

Enter the Tracking Number from the top of page 107. Tracking Number

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 1		109

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 1	01		110

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 1	03		111

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 1	01		112

STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily
		1	2

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No

☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance
20				

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(2 \times \text{days since last visit})} \times 100$$

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

STUDY MEDICATION DISPENSING

Record study medication information for Week 2 in the Study Medication Record, page 131. Attach label to page 132. Record number of capsules dispensed on page 131.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 2

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 3 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 2	day month year	114

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

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Record in the Adverse Experience section

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☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 2	14	115

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
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SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
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(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
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SmithKline Beecham
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15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27.	Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28.	Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: __ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: __ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

56. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

58. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Increased pauses before answering

59. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

60. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Low or monotonous speech

61. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

62. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Mute or markedly decreased amount of speech

63. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

64. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Slowed body movements

65. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

66. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Depressive stupor

67. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

68. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

70. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

REJECTION SENSITIVITY

71. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

72. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

73. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

74. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

83. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

85. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

87. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Middle Insomnia

88. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

89. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

91. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Circadian Reversal

92. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

93. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

95. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

97. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts – Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts – Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3. Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4. Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily
		2	

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance
20				

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(2 \times \text{days since last visit})} \times 100$$

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year)

STUDY MEDICATION DISPENSING

Record study medication information for Week 3 in the Study Medication Record, page 137. Attach label to page 138. Record number of capsules dispensed on page 137.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 3

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 4 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 3	day month year	133

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 3		134

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 3	04		135

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 3	03		136

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 3	05		137

STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily
		3	

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance
30				

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(3 \times \text{days since last visit})} \times 100$$

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 3		138

STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

STUDY MEDICATION DISPENSING

Record study medication information for Week 4 in the Study Medication Record, page 156. Attach label to page 157. Record number of capsules dispensed on page 156.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 4

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 5 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 4	day month year	139

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

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Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

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PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ Yes ☐ No

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 4	06		140

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
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SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
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SmithKline Beecham
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Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 4	00		142

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

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    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 4			143

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27.	Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28.	Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

56. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

58. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Increased pauses before answering

59. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

60. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Low or monotonous speech

61. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

62. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Mute or markedly decreased amount of speech

63. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

64. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Slowed body movements

65. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

66. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Depressive stupor

67. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

68. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

70. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

REJECTION SENSITIVITY

71. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

72. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

73. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

74. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

83. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

85. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

87. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Middle Insomnia

88. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

89. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

91. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Circadian Reversal

92. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

93. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

95. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

97. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily
		4	

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance
40				

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(4 \times \text{days since last visit})} \times 100$$

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year)

STUDY MEDICATION DISPENSING

Record study medication information for Week 5 in the Study Medication Record, page 162. Attach label to page 163. Record number of capsules dispensed on page 162.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 5

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 6 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 5	day month year	158

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 5	07		159

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 5	07	162

STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

STUDY MEDICATION DISPENSING

Record study medication information for Week 6 in the Study Medication Record, page 181. Attach label to page 182. Record number of capsules dispensed on page 181.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0		Acute Phase	

MODULE PARAMETERS - WEEK 6

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0717*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 6	day month year	164

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 6		165

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week ☐

NEGATIVE SELF IMAGE

21.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week ☐

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27.	Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28.	Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: ___ Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

70. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

REJECTION SENSITIVITY

71. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

72. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

73. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

74. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

SLEEP PROBLEMS

75. [ ][ ] Hours slept before onset of depression

76. [ ][ ] Hours slept during the current episode

77. [ ][ ] Hours slept during the last two weeks

HYPERSOMNIA

78. [ ][ ] Hours slept in daytime of current episode

79. [ ][ ] Hours slept in daytime in the last two weeks

80. [ ][ ] Hours lying down in current episode

81. [ ][ ] Hours lying down in last two weeks

82. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

83. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

85. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

87. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Middle Insomnia

88. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

89. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

91. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Circadian Reversal

92. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

93. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

95. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

97. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

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Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 6	06		182

STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year)

STUDY MEDICATION DISPENSING

Record study medication information for Week 7 in the Study Medication Record, page 187. Attach label to page 188. Record number of capsules dispensed on page 187.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 7

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 8 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Visit Date	Page
29060	329	0 0		Acute Phase Week 7	09	day month year	183

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 7	00		184

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 7	00		185

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 7	00		186

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 7	09	187

STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No

☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 7	00		188

STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

STUDY MEDICATION DISPENSING

Record study medication information for Week 8 in the Study Medication Record, page 222. Attach label to page 223. Record number of capsules dispensed on page 222.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 8

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 9 1 7 *

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 8	day month year	189

VITAL SIGNS

Weight	Sitting			Standing		
☐ lbs ☐ kg	Blood Pressure (mmHg) systolic	diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic	diastolic	Pulse (beats/ min)
.	/			/		

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

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PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ Yes ☐ No

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
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   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
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   - ☐ 4 = Stopped working because of present illness.

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Project	Protocol	Center	Patient Number	Visit			Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
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10. Anxiety Psychic
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11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
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- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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AUTONOMOUS FUNCTIONING CHECKLIST

Grade in School [ ]

Informant _____
(mother, father, guardian, other)

Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you ***believe*** or ***think*** he or she ***could*** do or ***could not*** do.

Second, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4
Does Not Do	**Does Only Rarely**	**Does About Half the Time There is an Opportunity**	**Does Most of the Time There is an Opportunity**	**Does Every Time There is an Opportunity**

Sample Item. Pick up trash in the yard. 0 1 2 3 4

0 - Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)

1 - Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.

2 - Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.

3 - Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.

4 - Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has ***never had the chance*** to do.

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AUTONOMOUS FUNCTIONING CHECKLIST

Some questions describe things that your teenager may do with help from others. Answer these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

My teenager:

1. Keeps own personal items and belongings in order (for example makes bed, puts away own clothing and belongings).	0	1	2	3	4
2. Prepares food that does not require cooking for himself/herself (for example, cereal, sandwich).	0	1	2	3	4
3. Care for his/her own clothing (for example, laundry, simple repair, shoe cleaning)	0	1	2	3	4
4. Travels to and from daily activities (for example, rides bike or walks, takes bus, arranges for transportation, drives car).	0	1	2	3	4
5. Prepares food that requires cooking for himself/herself (for example, hamburger, soup).	0	1	2	3	4
6. Performs simple first aid or medical care for himself/herself (for example, bandages, takes own temperature).	0	1	2	3	4
7. Purchases his/her own clothing and personal items that are used on a daily basis (for example, underwear, toiletries).	0	1	2	3	4
8. Performs minor repair and maintance in his/her owm environment (for example, changes light bulbs, hangs pitcure).	0	1	2	3	4
9. Shops for and purchases his/her own groceries.	0	1	2	3	4
10. Responds to his/her own medical emergency by calling parent.	0	1	2	3	4
11. Responds to his/her own medical emergency by calling doctor or hospital.	0	1	2	3	4
12. Does designated household maintenance chores involving family living areas (for example, cleans, takes out trash, does simple yard work).	0	1	2	3	4

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

13. Performs routine daily personal care for another family member. (for example, dresses, feeds).	0	1	2	3	4
14. Keeps personal items and belongings of another family member in order (for example, makes bed, puts away clothing and belongings).	0	1	2	3	4
15. Prepares meals for other family member(s).	0	1	2	3	4
16. Transports (or arranges for transport of) another family member to and from daily activities.	0	1	2	3	4
17. Purchases clothing and personal items (that are used on a daily basis) for other family members.	0	1	2	3	4
18. Shops for and purchases family groceries.	0	1	2	3	4
19. Performs minor repairs and maintenance in family living areas (for example, changes light bulbs, hangs picture).	0	1	2	3	4
20. Repairs and maintains (or makes arrangement for repair and maintenance of) major household needs (for example, plumbing, yard work, electrical wiring).	0	1	2	3	4
21. Responds to household emergency (for example, stove fire, plumbing problem) by calling parent or neighbor.	0	1	2	3	4
22. Reponds to household emergency (for example, stove fire, plumbing problem) by calling fire department, using fire extinguisher, or calling repair service or shuting off water.	0	1	2	3	4
My teenager:					
23. Uses the telphone and telephone directories.	0	1	2	3	4
24. Carries out transactions with sales people (for example, listens to information, asks questions, gives payment, receives change).	0	1	2	3	4
25. Uses postal services (for example, uses postage, mails letters. packages).	0	1	2	3	4
26. Uses bank (for example, fills out deposit or withdrawal slips, uses passbook).	0	1	2	3	4

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 8	0		196

AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

27.	Uses travel-related services for short trips (for example, taxi, bus subway).	0	1	2	3	4
28.	Uses travel-related services for long trips (for example, airline, train, bus).	0	1	2	3	4
29.	Uses library services (for example, checks out books or uses Xerox machine).	0	1	2	3	4
30.	Maintains and uses his/her own savings account.	0	1	2	3	4
31.	Maintains and uses his/her own checking or charge account.	0	1	2	3	4
32.	Maintains adequate personal care and grooming (for example, bathes, trims fingernails and toenails when needed)	0	1	2	3	4
33.	Maintains his/her routine general health and fitness (for example, has adequate eating, sleeping and exercise habits).	0	1	2	3	4
34.	Selects clothing that is suited to weather (for example, raincoat if raining, warm clothes in winter).	0	1	2	3	4
35.	Plans and initiates activity for himself/herself in everday unscheduled free time (for example, chooses to watch television or work on a hobby if bored).	0	1	2	3	4
36.	Plans activity for his/her long-term free time (for example, makes plans for summer vacation, mid-semester vacation).	0	1	2	3	4
37.	Initiates friendships with peers (for example, plans or attends parties, outings, games, club meetings).	0	1	2	3	4
38.	Meets nonacademic social obligations or commitments (for example, keeps appointments for family and peer related social events arranged by self or others).	0	1	2	3	4
39.	Meets academic obligations amd commitments (for example, completes homework assignments on time, brings necessary supplies to class).	0	1	2	3	4
40.	Plan transportation to and from special activities (for example arranges for rides with friends or family or plans care or bus route and schedule).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

41. Manage his/her own budget from allowance or income (for example, saves money for large purchases, pays for routine expenses throughout week without running out of money).	0	1	2	3	4
42. Make long-term educational and/or career plans (for example, selects courses, investigates colleges or technical schools).	0	1	2	3	4

When my teenager is free to choose how he/she will spend his/her unscheduled free time. He/she chooses to:

43. Listen to music (for example, radio or stereo).	0	1	2	3	4
44. Read for relaxation (for example, books, newspapers)	0	1	2	3	4
45. Play games or puzzles (for example, cards, crossword puzzles, jigsaw puzzles, computer games).	0	1	2	3	4
46. Write letters to friends, relatives, aquaintances.	0	1	2	3	4
47. Work on or take lessons in crafts or hobbies (for example cooking, collections, pet care, sewing, model building, car repair).	0	1	2	3	4
48. Practice or take lessons that involve a trained artistic or academic skill (for example, piano or other musical instrument, ballet, singing, creative writing, foreign languages).	0	1	2	3	4
49. Go to the movies, rock concerts, dances.					
50. Go to plays, theater, lectures.	0	1	2	3	4
51. Pursue activities that are related to his or her career interest(s) (for example, runs a business, works on a computer, practices piano for professional preparation).	0	1	2	3	4
52. Go for walks.	0	1	2	3	4
53. Go shopping, or spend time at shopping centers or in shopping areas.	0	1	2	3	4
54. Attend club meetings or other organized social group meetings.	0	1	2	3	4
55. Work for pay (for example, babysit, play in a band, do yard work, walk dogs, work at part-time job, deliver papers).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

56. Clean and/or maintan living environment or belongings (for example, clean house, wash or repair clothes, wash car, make household repairs).	0	1	2	3	4
57. Work on schoolwork (for example, spend extra time on homework, make special preparations for class projects, spend time in library).	0	1	2	3	4
58. Spend time with family (for example, work on family projects, have discussions or casual conversations, attend family gatherings such as picnics or parties).	0	1	2	3	4

On these final items, please check "Yes" or "No" in response to each description. Check "Yes" if the description fits your teenager. Check "No" if it does not.

My teenager:

	Yes	No
59. Has casual friendships with teenagers of opposite sex.	☐	☐
60. Has close friendships with teenagers of opposite sex.	☐	☐
61. Has casual friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders)	☐	☐
62. Has close friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders).	☐	☐
63. Has casual friendships with younger children.	☐	☐
64. Has close friendships with younger children.	☐	☐
65. Is active in casual/recreational groups of teenage friends.	☐	☐
66. Has many friendships.	☐	☐
67. Is active in one or more organized extracurricular group (for example, French club, student council, sports team).	☐	☐
68. Has leadership position in one or more organized extracurricular group (for example, president of the student council, captain of the sports team).	☐	☐
69. Has close friendship with adult member of the extended family (for example, an uncle, aunt, grandparent).	☐	☐
70. Works or has worked either for pay or volunteer in an area of particular career interest.	☐	☐

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AUTONOMOUS FUNCTIONING CHECKLIST

		Yes	No
71.	Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)	☐	☐
72.	Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).	☐	☐
73.	Works or has worked to earn money in a self-or-peer-run organization or business.	☐	☐
74.	Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).	☐	☐
75.	Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.	☐	☐
76.	Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).	☐	☐
77.	Has explored career interest by visiting work sites or interviewing people in that job or career.	☐	☐
78.	Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.	☐	☐

Comments:

If you have any additional information about your teenager's everyday independent or self-sufficient behavior, use the space below to write your comments. Thank you.

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

WHAT AM I LIKE

Sample Sentence

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
a.	☐	☐	Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.	☐	☐
1.	☐	☐	Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.	☐	☐
2.	☐	☐	Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.	☐	☐
3.	☐	☐	Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.	☐	☐
4.	☐	☐	Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.	☐	☐
5.	☐	☐	Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.	☐	☐
6.	☐	☐	Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.	☐	☐
7.	☐	☐	Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is right.	☐	☐
8.	☐	☐	Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.	☐	☐
9.	☐	☐	Some teenagers are often disappointed with themselves	BUT	Other teenagers are pretty pleased with themselves.	☐	☐
10.	☐	☐	Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
11.	☐	☐	Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.	☐	☐
12.	☐	☐	Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.	☐	☐
13.	☐	☐	Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.	☐	☐
14.	☐	☐	Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.	☐	☐
15.	☐	☐	Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to	☐	☐
16.	☐	☐	Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.	☐	☐
17.	☐	☐	Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a hard time keeping secrets that their friends tell them.	☐	☐
18.	☐	☐	Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.	☐	☐
19.	☐	☐	Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their class-work.	☐	☐
20.	☐	☐	Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.	☐	☐
21.	☐	☐	Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.	☐	☐
22.	☐	☐	Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
23.	☐	☐	Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they do.	☐	☐
24.	☐	☐	Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age will be attacted to them.	☐	☐
25.	☐	☐	Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.	☐	☐
26.	☐	☐	Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.	☐	☐
27.	☐	☐	Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.	☐	☐
28.	☐	☐	Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.	☐	☐
29.	☐	☐	Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.	☐	☐
30.	☐	☐	Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games right away.	☐	☐
31.	☐	☐	Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.	☐	☐
32.	☐	☐	Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.	☐	☐
33.	☐	☐	Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder about how fun and interesting they are on a date.	☐	☐
34.	☐	☐	Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
35.	☐	☐	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	☐	☐
36.	☐	☐	Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.	☐	☐
37.	☐	☐	Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent.	☐	☐
38.	☐	☐	Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.	☐	☐
39.	☐	☐	Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.	☐	☐
40.	☐	☐	Some teenagers really like their looks	BUT	Other teenagers wished they looked different.	☐	☐
41.	☐	☐	Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.	☐	☐
42.	☐	☐	Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get asked out by people they really want to date.	☐	☐
43.	☐	☐	Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.	☐	☐
44.	☐	☐	Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts and feelings with.	☐	☐
45.	☐	☐	Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

Introduction

On the next few pages are statements which describe things people often do when they are not well.

As you read them, think of yourself today:

- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).

- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).

For Example:

"I am not doing any of the shopping that I would usually do."

- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).

- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).

Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Please mark your answers by placing an "X" in the appropriate box like this. ☒

Thank you for your time and help.

How would you describe your present health

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

How would you describe you present quality of life (how things are going for you generally)?

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

A. These statements describe your sleep and rest this week.

	Yes	No
1. I spend much of the day lying down in order to rest.	☐	☐
2. I sit for much of the day.	☐	☐
3. I am sleeping or dozing much of the time - day and night.	☐	☐
4. I lie down more often than my friends during the day in order to rest.	☐	☐
5. I sit around half asleep.	☐	☐
6. I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	☐	☐
7. I sleep or doze more during the day.	☐	☐

B. These statements describe your daily work around the house.

	Yes	No
1. I only do work that I need to do around the house for short periods of time or I rest often.	☐	☐
2. I am doing less of the daily household chores that I would usually do.	☐	☐
3. I am not doing any of the daily household chores that I would usually do.	☐	☐
4. I am not doing any of the shopping that I would usually do.	☐	☐
5. I am not doing any of the cleaning that I would usually do.	☐	☐
6. I am not doing any of the clothes washing that I would usually do.	☐	☐

C. These statements describe your contact with your family and friends today.

	Yes	No
1. I am going out less to visit people.	☐	☐
2. I am not going out to visit people at all.	☐	☐
3. I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.	☐	☐
4. I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5. I show less affection.	☐	☐
6. I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

	Yes	No
7. I am cutting down the length of visits to friends.	☐	☐
8. I avoid having visitors.	☐	☐
9. My sexual activity is decreased.	☐	☐
10. I talk less with those around me.	☐	☐
11. I make demands on other people that they find irritating, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
12. I stay alone much of the time.	☐	☐
13. I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
14. I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
15. I isolate myself as much as I can from the rest of my family.	☐	☐
16. I refuse contact with my family, for example, I turn away from them.	☐	☐
17. I am not joking with my family members as I usually do.	☐	☐

D. These statements describe your feelings.

	Yes	No
1. I am confused and start to do more than one thing at a time.	☐	☐
2. I have more minor accidents, for example, I drop things, I trip and fall or bump into things.	☐	☐
3. I react slowly to things that are said or done.	☐	☐
4. I do not finish things I start.	☐	☐
5. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
6. I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
7. I forget a lot, for example, things that happened recently, where I put things, or to keep appointments.	☐	☐
8. I do not keep my attention on any activity for long.	☐	☐
9. I make more mistakes than usual.	☐	☐
10. I have difficulty doing things which involve thought and concentration, for example, paying attention in school or at my job.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

E. These statements are about how you talk to other people and write.

	Yes	No
1. I am having trouble writing or typing.	☐	☐
2. I am having trouble talking to people.	☐	☐
3. I am not comfortable in most social situations like parties.	☐	☐
4. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
5. I do not speak clearly when I am under stress.	☐	☐

F. The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.

	Yes	No
1. I spend shorter periods of time on my hobbies and recreation.	☐	☐
2. I am going out and enjoying myself less often.	☐	☐
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
5. I am doing more inactive pastimes in place of my other usual activities.	☐	☐
6. I am taking part in fewer activities with my friends.	☐	☐
7. I am cutting down on some of my usual physical recreation or more active pastimes.	☐	☐
8. I am not doing any of my usual physical recreation or more active pastimes.	☐	☐

Now please look through this questionnaire and make sure that you have read every question.

Thank you once again for your help.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28. Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: __ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: __ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

70. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

REJECTION SENSITIVITY

71. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

72. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

73. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

74. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

83. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

85. Last Two Weeks: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

87. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Middle Insomnia

88. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

89. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

91. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Circadian Reversal

92. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

93. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

95. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

97. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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LABORATORY TESTS

For SB	Lab Number Code _____

Sample Date ___ ___ ___
day month year

➧ Attach SBCL laboratory report behind this page.

➧ Are there CLINICALLY SIGNIFICANT ABNORMAL laboratory values?

☐ No
☐ Yes ⟶ Record the findings and/or diagnosis in the Adverse Experiences.

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year)

STUDY MEDICATION DISPENSING

Record study medication information for Weeks 9-12 in the Study Medication Record, page 250 in Binder 3. Attach label to page 251. Record number of capsules dispensed on page 250.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - CONCOMITANT MEDICATION

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 1 0 1 7 *

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CONCOMITANT MEDICATION

- Record all concomitant medication taken since the Eligibility Determination visit (Week 0).
- Where appropriate, medical conditions should be recorded on the Adverse Experiences form utilizing the same terminology.

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						

★ State dates as precisely as possible.

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CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
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For SB						
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For SB						
						☐
For SB						

★ State dates as precisely as possible.

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MODULE PARAMETERS - ADVERSE EXPERIENCES/CONCLUSION

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1117*

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				If patient died, complete Form D

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				If patient died, complete Form D

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
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Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature		_____		If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
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	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

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Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
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	2 Dose decreased	☐	☐	☐
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	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ACUTE PHASE CONCLUSION

Will the patient enter the continuation phase of this study?

☐ Yes - Go to Binder 3 - Ensure the preprinted Patient Number is identical to the Patient Number assigned in this phase.

☐ No

➧ If 'No', mark the ONE most appropriate category

1 ☐ Adverse experience (complete Adverse Experience section)

2 ☐ Lack of efficacy

3 ☐ Deviation from protocol (including non-compliance)

4 ☐ Lost to follow-up

6 ☐ Termination by sponsor

7 ☐ Other

Comments on reason for withdrawal:

Date of Last Visit ___ day ___ month ___ year

Date of Last Dose ___ day ___ month ___ year

I certify that I have reviewed the data on this case report form (pages 108-232) and that all information is complete and accurate.

Investigator's Signature _____ _____ Date

Project	Protocol	Center	Patient Number
29060	329	0	

Ensure Patient Number is identical for Binder 2 and Binder 3

SmithKline Beecham
Pharmaceuticals

CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

CONTINUATION PHASE - BINDER 3

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials ____ Country _____

GENERAL INSTRUCTIONS

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

Important: Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

DATE

Use the following three-letter abbreviations for month:

January	=	JAN
February	=	FEB
March	=	MAR
April	=	APR
May	=	MAY
June	=	JUN
July	=	JUL
August	=	AUG
September	=	SEP
October	=	OCT
November	=	NOV
December	=	DEC

Example: | 0 | 1 | J | A | N | 9 | 3 | = 1st January 1993

day month year

TIME

Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example: | 1 | 5 | 3 | 0 | = 3:30 p.m.

24 hr. clock

ADVERSE EXPERIENCE DEFINITIONS

INTENSITY

Mild	Adverse experience which is easily tolerated.
Moderate	Adverse experience sufficiently discomforting to interfere with daily activity.
Severe	Adverse experience which prevents normal everyday activities.

SUSPECTED RELATIONSHIP TO STUDY MEDICATION

Related	There is a direct cause and effect relationship between the adverse experience and the study drug.
Possibly Related	A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but is possible or likely.
Probably Unrelated	Cause and effect relationship between the drug and the adverse experience has not been demonstrated, is improbable but not impossible.
Unrelated	The adverse experience is definitely not related to the test drug.

SERIOUS ADVERSE EXPERIENCE

A serious adverse experience is any experience which:

- Is fatal
- Is life threatening
- Is permanently or temporarily disabling
- Is incapacitating
- Results in hospitalization
- Prolongs a hospital stay
- Is associated with congenital abnormality, carcinoma or overdose

In addition, any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious experience.

- Use each form for a maximum of three experiences.
- All questions on the Adverse Experience form should be completed.

SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

Assessments	Baseline		Acute Phase								Continuation Phase					
Time (weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	●															
Medical History and Physical Exam	●															
Clinical Laboratory Studies	● [1]									●			●			●
Serum Pregnancy	●		● [2]	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
ECG	●			●		●		●		●			●			●
Vital Signs	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hamilton Depression Scale	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Full K-SADS-L	●															●
Affect Section of K-SADS-L		●		●		●		●		●	●	●	●	●	●	
C-GAS	●															
CGI		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
SADS-L	●															
FH-FHE	●															
Autonomous Functioning Checklist	●									●						●
Self Perception Profile	●									●						●
Sickness Impact Scale	●									●						●
Randomization		●														
Adverse Experiences		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Supportive Psychotherapy		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Plasma Sampling for Drug Analysis	●					●				●				●		●
Study Medication Record			●	●	●	●	●	●	●	●	●	●	●	●	●	●
Concomitant Medication	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

[1] - Clinical laboratory studies should include a Urine Drug Screen
[2] - On suspicion of pregnancy

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Continuation Phase	

MODULE PARAMETERS - WEEK 12

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 1 3 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
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VITAL SIGNS

Weight	Sitting		Standing	
	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
☐ lbs ☐ kg	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

- ☐ 1 = Very much improved
- ☐ 2 = Much improved
- ☐ 3 = Minimally improved
- ☐ 4 = No change
- ☐ 5 = Minimally worse
- ☐ 6 = Much worse
- ☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28. Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: ___ Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

85. Last Two Weeks: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

87. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Middle Insomnia

88. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

89. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

91. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Circadian Reversal

92. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

93. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

95. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

97. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3. Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4. Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

Enter patient number (drug code as listed on clinical supplies)

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STUDY MEDICATION DISPENSING

Record study medication information for Weeks 13-16 in the Study Medication Record, page 270. Attach label(s) to page 271. Record number of capsules dispensed on page 270.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 16

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting			Standing		
	Blood Pressure (mmHg) systolic	diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic	diastolic	Pulse (beats/ min)
.	/			/		

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27.	Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28.	Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

56. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

58. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Increased pauses before answering

59. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

60. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Low or monotonous speech

61. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

62. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Mute or markedly decreased amount of speech

63. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

64. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Slowed body movements

65. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

66. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Depressive stupor

67. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

68. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

85. Last Two Weeks: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

87. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Middle Insomnia

88. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

89. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

91. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Circadian Reversal

92. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

93. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

95. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

97. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

109. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode: (0) NI (1) NO (2) MIN (3) DEF (4) SER (5) VS (6) EXT

113. Last Two Weeks: (0) NI (1) NO (2) MIN (3) DEF (4) SER (5) VS (6) EXT

Medical Lethality

114. Current Episode (0) NI (1) NO (2) MIN (3) MLD (4) MO (5) SVR (6) EXT

115. Last Two Weeks: (0) NI (1) NO (2) MIN (3) MLD (4) MO (5) SVR (6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) ACT

117. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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Pharmaceuticals

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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STUDY MEDICATION DISPENSING

Record study medication information for Weeks 17-20 in the Study Medication Record, page 291. Attach label(s) to page 292. Record number of capsules dispensed on page 291.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 20

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1517*

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28. Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

PSYCHOMOTOR AGITATION

43.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Pacing

47.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Hand wringing

49.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Pulling or rubbing on hair, clothing, skin

51.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
52.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Can't stop talking, talks on and on

53.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
54.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

56. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

58. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Increased pauses before answering

59. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

60. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Low or monotonous speech

61. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

62. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Mute or markedly decreased amount of speech

63. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

64. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Slowed body movements

65. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

66. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Depressive stupor

67. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

68. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

70. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

REJECTION SENSITIVITY

71. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

72. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

73. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

74. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

83. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

85. Last Two Weeks: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

87. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Middle Insomnia

88. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

89. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

91. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Circadian Reversal

92. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

93. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

95. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

97. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

109. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Suicidal Acts – Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts – Seriousness

112. Current Episode: (0) NI (1) NO (2) MIN (3) DEF (4) SER (5) VS (6) EXT

113. Last Two Weeks: (0) NI (1) NO (2) MIN (3) DEF (4) SER (5) VS (6) EXT

Medical Lethality

114. Current Episode (0) NI (1) NO (2) MIN (3) MLD (4) MO (5) SVR (6) EXT

115. Last Two Weeks: (0) NI (1) NO (2) MIN (3) MLD (4) MO (5) SVR (6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) ACT

117. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3. Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4. Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode: (0) NI (1) NO (2) DBT (3) MLD (4) MO (5) SVR (6) EX

14. Last Two Weeks: (0) NI (1) NO (2) DBT (3) MLD (4) MO (5) SVR (6) EX

FLIGHT OF IDEAS

15. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

16. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

POOR JUDGEMENT

17. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) VS

18. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) VS

DISTRACTABILITY

19. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR

20. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR

MOTOR HYPERACTIVITY

21. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) MKD (6) EX

22. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) MKD (6) EX

Inappropriate laughing, joking or punning

23. Current Episode: (0) NI (1) NO (2) DBT (3) MLD (4) MOD

24. Last Two Weeks: (0) NI (1) NO (2) DBT (3) MLD (4) MOD

Uninhibited people seeking, gregarious

25. Current Episode: (0) NI (1) NO (2) DBT (3) MLD (4) MOD

26. Last Two Weeks: (0) NI (1) NO (2) DBT (3) MLD (4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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LABORATORY TESTS

For SB	Lab Number Code

Sample Date ___ day ___ month ___ year

- Attach SBCL laboratory report behind this page.
- Are there CLINICALLY SIGNIFICANT ABNORMAL laboratory values?

☐ No
☐ Yes ⟶ Record the findings and/or diagnosis in the Adverse Experiences.

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year)

STUDY MEDICATION DISPENSING

Record study medication information for Weeks 21-24 in the Study Medication Record, page 311. Attach label(s) to page 312. Record number of capsules dispensed on page 311.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 24

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 1 6 1 7 *

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VITAL SIGNS

Weight	Sitting			Standing		
	Blood Pressure (mmHg) systolic	diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic	diastolic	Pulse (beats/ min)
☐ lbs ☐ kg	/			/		

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

- ☐ 1 = Very much improved
- ☐ 2 = Much improved
- ☐ 3 = Minimally improved
- ☐ 4 = No change
- ☐ 5 = Minimally worse
- ☐ 6 = Much worse
- ☐ 7 = Very much worse

PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ Yes ☐ No

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28. Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

85. Last Two Weeks: (0) NI | (1) NO | (2) | (3) | (4) | (5) | (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

87. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Middle Insomnia

88. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

89. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

91. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Circadian Reversal

92. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

93. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

95. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

97. Last Two Weeks: (0) NI | (1) NPR | (2) DBT | (3) MLD | (4) MOD | (5) SVR

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ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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STUDY MEDICATION DISPENSING

Record study medication information for Weeks 25-28 in the Study Medication Record, page 331. Attach label(s) to page 332. Record number of capsules dispensed on page 331.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 28

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting			Standing		
	Blood Pressure (mmHg) systolic	diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic	diastolic	Pulse (beats/ min)
.	/			/		

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week ☐

NEGATIVE SELF IMAGE

21.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week ☐

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27.	Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28.	Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

70. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

REJECTION SENSITIVITY

71. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

72. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

73. Last Year: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

74. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

83. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

85. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

Frequency: ☐ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

87. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Middle Insomnia

88. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

89. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

91. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Circadian Reversal

92. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

93. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

95. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

97. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3. Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4. Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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STUDY MEDICATION DISPENSING

Record study medication information for Weeks 29-32 in the Study Medication Record, page 397. Attach label(s) to page 398. Record number of capsules dispensed on page 397.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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Ensure Patient Number is identical for Binder 3 and Binder 4

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CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

CONTINUATION PHASE - BINDER 4

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials _____ Country _____

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MODULE PARAMETERS - WEEK 32

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1817*

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ Yes ☐ No

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
    - ☐ 0 = Not present
    - ☐ 1 = Self-absorption (bodily)
    - ☐ 2 = Preoccupation with health
    - ☐ 3 = Frequent complaints, requests for help, etc.
    - ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
    - ☐ 0 = No weight loss
    - ☐ 1 = Slight or doubtful loss of weight
    - ☐ 2 = Obvious or severe loss of weight

17. Insight
    - ☐ 0 = Acknowledges being depressed and ill
    - ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
    - ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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AUTONOMOUS FUNCTIONING CHECKLIST

Grade in School ___

Informant _____
(mother, father, guardian, other)

Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you ***believe*** or ***think*** he or she ***could*** do or ***could not*** do.

Second, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4
Does Not Do	**Does Only Rarely**	**Does About Half the Time There is an Opportunity**	**Does Most of the Time There is an Opportunity**	**Does Every Time There is an Opportunity**

Sample Item. Pick up trash in the yard. 0 1 2 3 4

0 - Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)

1 - Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.

2 - Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.

3 - Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.

4 - Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has ***never had the chance*** to do.

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AUTONOMOUS FUNCTIONING CHECKLIST

Some questions describe things that your teenager may do with help from others. Answer these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

My teenager:

1. Keeps own personal items and belongings in order (for example makes bed, puts away own clothing and belongings).	0	1	2	3	4
2. Prepares food that does not require cooking for himself/ herself (for example, cereal, sandwich).	0	1	2	3	4
3. Care for his/her own clothing (for example, laundry, simple repair, shoe cleaning)	0	1	2	3	4
4. Travels to and from daily activities (for example, rides bike or walks, takes bus, arranges for transportation, drives car).	0	1	2	3	4
5. Prepares food that requires cooking for himself/herself (for example, hamburger, soup).	0	1	2	3	4
6. Performs simple first aid or medical care for himself/ herself (for example, bandages, takes own temperature).	0	1	2	3	4
7. Purchases his/her own clothing and personal items that are used on a daily basis (for example, underwear, toiletries).	0	1	2	3	4
8. Performs minor repair and maintance in his/her owm environment (for example, changes light bulbs, hangs pitcure).	0	1	2	3	4
9. Shops for and purchases his/her own groceries.	0	1	2	3	4
10. Responds to his/her own medical emergency by calling parent.	0	1	2	3	4
11. Responds to his/her own medical emergency by calling doctor or hospital.	0	1	2	3	4
12. Does designated household maintenance chores involving family living areas (for example, cleans, takes out trash, does simple yard work).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

13. Performs routine daily personal care for another family member. (for example, dresses, feeds).	0	1	2	3	4
14. Keeps personal items and belongings of another family member in order (for example, makes bed, puts away clothing and belongings).	0	1	2	3	4
15. Prepares meals for other family member(s).	0	1	2	3	4
16. Transports (or arranges for transport of) another family member to and from daily activities.	0	1	2	3	4
17. Purchases clothing and personal items (that are used on a daily basis) for other family members.	0	1	2	3	4
18. Shops for and purchases family groceries.	0	1	2	3	4
19. Performs minor repairs and maintenance in family living areas (for example, changes light bulbs, hangs picture).	0	1	2	3	4
20. Repairs and maintains (or makes arrangement for repair and maintenance of) major household needs (for example, plumbing, yard work, electrical wiring).	0	1	2	3	4
21. Responds to household emergency (for example, stove fire, plumbing problem) by calling parent or neighbor.	0	1	2	3	4
22. Reponds to household emergency (for example, stove fire, plumbing problem) by calling fire department, using fire extinguisher, or calling repair service or shuting off water.	0	1	2	3	4
My teenager:					
23. Uses the telphone and telephone directories.	0	1	2	3	4
24. Carries out transactions with sales people (for example, listens to information, asks questions, gives payment, receives change).	0	1	2	3	4
25. Uses postal services (for example, uses postage, mails letters. packages).	0	1	2	3	4
26. Uses bank (for example, fills out deposit or withdrawal slips, uses passbook).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

27.	Uses travel-related services for short trips (for example, taxi, bus subway).	0	1	2	3	4
28.	Uses travel-related services for long trips (for example, airline, train, bus).	0	1	2	3	4
29.	Uses library services (for example, checks out books or uses Xerox machine).	0	1	2	3	4
30.	Maintains and uses his/her own savings account.	0	1	2	3	4
31.	Maintains and uses his/her own checking or charge account.	0	1	2	3	4
32.	Maintains adequate personal care and grooming (for example, bathes, trims fingernails and toenails when needed)	0	1	2	3	4
33.	Maintains his/her routine general health and fitness (for example, has adequate eating, sleeping and exercise habits).	0	1	2	3	4
34.	Selects clothing that is suited to weather (for example, raincoat if raining, warm clothes in winter).	0	1	2	3	4
35.	Plans and initiates activity for himself/herself in everday unscheduled free time (for example, chooses to watch television or work on a hobby if bored).	0	1	2	3	4
36.	Plans activity for his/her long-term free time (for example, makes plans for summer vacation, mid-semester vacation).	0	1	2	3	4
37.	Initiates friendships with peers (for example, plans or attends parties, outings, games, club meetings).	0	1	2	3	4
38.	Meets nonacademic social obligations or commitments (for example, keeps appointments for family and peer related social events arranged by self or others).	0	1	2	3	4
39.	Meets academic obligations amd commitments (for example, completes homework assignments on time, brings necessary supplies to class).	0	1	2	3	4
40.	Plan transportation to and from special activities (for example arranges for rides with friends or family or plans care or bus route and schedule).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

41. Manage his/her own budget from allowance or income (for example, saves money for large purchases, pays for routine expenses throughout week without running out of money).	0	1	2	3	4
42. Make long-term educational and/or career plans (for example, selects courses, investigates colleges or technical schools).	0	1	2	3	4

When my teenager is free to choose how he/she will spend his/her unscheduled free time. He/she chooses to:

43. Listen to music (for example, radio or stereo).	0	1	2	3	4
44. Read for relaxation (for example, books, newspapers)	0	1	2	3	4
45. Play games or puzzles (for example, cards, crossword puzzles, jigsaw puzzles, computer games).	0	1	2	3	4
46. Write letters to friends, relatives, aquaintances.	0	1	2	3	4
47. Work on or take lessons in crafts or hobbies (for example cooking, collections, pet care, sewing, model building, car repair).	0	1	2	3	4
48. Practice or take lessons that involve a trained artistic or academic skill (for example, piano or other musical instrument, ballet, singing, creative writing, foreign languages).	0	1	2	3	4
49. Go to the movies, rock concerts, dances.					
50. Go to plays, theater, lectures.	0	1	2	3	4
51. Pursue activities that are related to his or her career interest(s) (for example, runs a business, works on a computer, practices piano for professional preparation).	0	1	2	3	4
52. Go for walks.	0	1	2	3	4
53. Go shopping, or spend time at shopping centers or in shopping areas.	0	1	2	3	4
54. Attend club meetings or other organized social group meetings.	0	1	2	3	4
55. Work for pay (for example, babysit, play in a band, do yard work, walk dogs, work at part-time job, deliver papers).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

56. Clean and/or maintan living environment or belongings (for example, clean house, wash or repair clothes, wash car, make household repairs).	0	1	2	3	4
57. Work on schoolwork (for example, spend extra time on homework, make special preparations for class projects, spend time in library).	0	1	2	3	4
58. Spend time with family (for example, work on family projects, have discussions or casual conversations, attend family gatherings such as picnics or parties).	0	1	2	3	4

On these final items, please check "Yes" or "No" in response to each description. Check "Yes" if the description fits your teenager. Check "No" if it does not.

My teenager:

	Yes	No
59. Has casual friendships with teenagers of opposite sex.	☐	☐
60. Has close friendships with teenagers of opposite sex.	☐	☐
61. Has casual friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders)	☐	☐
62. Has close friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders).	☐	☐
63. Has casual friendships with younger children.	☐	☐
64. Has close friendships with younger children.	☐	☐
65. Is active in casual/recreational groups of teenage friends.	☐	☐
66. Has many friendships.	☐	☐
67. Is active in one or more organized extracurricular group (for example, French club, student council, sports team).	☐	☐
68. Has leadership position in one or more organized extracurricular group (for example, president of the student council, captain of the sports team).	☐	☐
69. Has close friendship with adult member of the extended family (for example, an uncle, aunt, grandparent).	☐	☐
70. Works or has worked either for pay or volunteer in an area of particular career interest.	☐	☐

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AUTONOMOUS FUNCTIONING CHECKLIST

	Yes	No
71. Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)	☐	☐
72. Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).	☐	☐
73. Works or has worked to earn money in a self-or-peer-run organization or business.	☐	☐
74. Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).	☐	☐
75. Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.	☐	☐
76. Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).	☐	☐
77. Has explored career interest by visiting work sites or interviewing people in that job or career.	☐	☐
78. Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.	☐	☐

Comments:

If you have any additional information about your teenager's everyday independent or self-sufficient behavior, use the space below to write your comments. Thank you.

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

WHAT AM I LIKE

Sample Sentence

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
a.	☐	☐	Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.	☐	☐
1.	☐	☐	Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.	☐	☐
2.	☐	☐	Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.	☐	☐
3.	☐	☐	Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.	☐	☐
4.	☐	☐	Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.	☐	☐
5.	☐	☐	Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.	☐	☐
6.	☐	☐	Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.	☐	☐
7.	☐	☐	Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is right.	☐	☐
8.	☐	☐	Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.	☐	☐
9.	☐	☐	Some teenagers are often disappointed with themselves	BUT	Other teenagers are pretty pleased with themselves.	☐	☐
10.	☐	☐	Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
11.	☐	☐	Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.	☐	☐
12.	☐	☐	Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.	☐	☐
13.	☐	☐	Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.	☐	☐
14.	☐	☐	Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.	☐	☐
15.	☐	☐	Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to	☐	☐
16.	☐	☐	Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.	☐	☐
17.	☐	☐	Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a hard time keeping secrets that their friends tell them.	☐	☐
18.	☐	☐	Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.	☐	☐
19.	☐	☐	Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their class-work.	☐	☐
20.	☐	☐	Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.	☐	☐
21.	☐	☐	Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.	☐	☐
22.	☐	☐	Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
23.	☐	☐	Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they do.	☐	☐
24.	☐	☐	Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age will be attacted to them.	☐	☐
25.	☐	☐	Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.	☐	☐
26.	☐	☐	Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.	☐	☐
27.	☐	☐	Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.	☐	☐
28.	☐	☐	Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.	☐	☐
29.	☐	☐	Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.	☐	☐
30.	☐	☐	Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games right away.	☐	☐
31.	☐	☐	Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.	☐	☐
32.	☐	☐	Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.	☐	☐
33.	☐	☐	Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder about how fun and interesting they are on a date.	☐	☐
34.	☐	☐	Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
35.	☐	☐	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	☐	☐
36.	☐	☐	Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.	☐	☐
37.	☐	☐	Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent.	☐	☐
38.	☐	☐	Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.	☐	☐
39.	☐	☐	Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.	☐	☐
40.	☐	☐	Some teenagers really like their looks	BUT	Other teenagers wished they looked different.	☐	☐
41.	☐	☐	Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.	☐	☐
42.	☐	☐	Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get asked out by people they really want to date.	☐	☐
43.	☐	☐	Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.	☐	☐
44.	☐	☐	Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts and feelings with.	☐	☐
45.	☐	☐	Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

Introduction

On the next few pages are statements which describe things people often do when they are not well.

As you read them, think of yourself today:

- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).

- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).

For Example:

"I am not doing any of the shopping that I would usually do."

- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).

- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).

Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Please mark your answers by placing an "X" in the appropriate box like this. ☒

Thank you for your time and help.

How would you describe your present health

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

How would you describe you present quality of life (how things are going for you generally)?

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

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PATIENT LOG - CONTINUATION PHASE

Investigator _____

Directions: Enter ALL patients who have been considered for the study and who have been interviewed. For patients not entering the Continuation Phase, note the reason for exclusion in the designated column.

Patient Initials	Initial Interview (day month year)	Reason for Exclusion

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PATIENT ASSIGNMENT SHEET - CONTINUATION PHASE

Investigator _____ For SB Date day month year

Directions: Do not enter the patient on the patient assignment sheet until he/she starts continuation phase medication.

Final Dose Status: C = Completed all treatment visits
W = Withdrawn prior to completing all treatment visits

	Patient Initials	Patient Number	Date of First Dose of Continuation Phase (day month year)	Date of Last Dose (day month year)	Status (C/W)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

A. These statements describe your sleep and rest this week.

	Yes	No
1. I spend much of the day lying down in order to rest.	☐	☐
2. I sit for much of the day.	☐	☐
3. I am sleeping or dozing much of the time - day and night.	☐	☐
4. I lie down more often than my friends during the day in order to rest.	☐	☐
5. I sit around half asleep.	☐	☐
6. I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	☐	☐
7. I sleep or doze more during the day.	☐	☐

B. These statements describe your daily work around the house.

	Yes	No
1. I only do work that I need to do around the house for short periods of time or I rest often.	☐	☐
2. I am doing less of the daily household chores that I would usually do.	☐	☐
3. I am not doing any of the daily household chores that I would usually do.	☐	☐
4. I am not doing any of the shopping that I would usually do.	☐	☐
5. I am not doing any of the cleaning that I would usually do.	☐	☐
6. I am not doing any of the clothes washing that I would usually do.	☐	☐

C. These statements describe your contact with your family and friends today.

	Yes	No
1. I am going out less to visit people.	☐	☐
2. I am not going out to visit people at all.	☐	☐
3. I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.	☐	☐
4. I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5. I show less affection.	☐	☐
6. I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

	Yes	No
7. I am cutting down the length of visits to friends.	☐	☐
8. I avoid having visitors.	☐	☐
9. My sexual activity is decreased.	☐	☐
10. I talk less with those around me.	☐	☐
11. I make demands on other people that they find irritating, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
12. I stay alone much of the time.	☐	☐
13. I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
14. I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
15. I isolate myself as much as I can from the rest of my family.	☐	☐
16. I refuse contact with my family, for example, I turn away from them.	☐	☐
17. I am not joking with my family members as I usually do.	☐	☐

D. These statements describe your feelings.

	Yes	No
1. I am confused and start to do more than one thing at a time.	☐	☐
2. I have more minor accidents, for example, I drop things, I trip and fall or bump into things.	☐	☐
3. I react slowly to things that are said or done.	☐	☐
4. I do not finish things I start.	☐	☐
5. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
6. I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
7. I forget a lot, for example, things that happened recently, where I put things, or to keep appointments.	☐	☐
8. I do not keep my attention on any activity for long.	☐	☐
9. I make more mistakes than usual.	☐	☐
10. I have difficulty doing things which involve thought and concentration, for example, paying attention in school or at my job.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

E. These statements are about how you talk to other people and write.

	Yes	No
1. I am having trouble writing or typing.	☐	☐
2. I am having trouble talking to people.	☐	☐
3. I am not comfortable in most social situations like parties.	☐	☐
4. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
5. I do not speak clearly when I am under stress.	☐	☐

F. The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.

	Yes	No
1. I spend shorter periods of time on my hobbies and recreation.	☐	☐
2. I am going out and enjoying myself less often.	☐	☐
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
5. I am doing more inactive pastimes in place of my other usual activities.	☐	☐
6. I am taking part in fewer activities with my friends.	☐	☐
7. I am cutting down on some of my usual physical recreation or more active pastimes.	☐	☐
8. I am not doing any of my usual physical recreation or more active pastimes.	☐	☐

Now please look through this questionnaire and make sure that you have read every question.

Thank you once again for your help.

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KIDDIE-SADS-LIFETIME - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

4. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IRRITABILITY AND ANGER

5. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Duration: ___ # of weeks

6. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX (7) VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: (0) NI (1) NO (2) OCC (3) USL (4) ALW

8. Last Two Weeks: (0) NI (1) NO (2) OCC (3) USL (4) ALW

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KIDDIE-SADS-LIFETIME - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

10. Last Two Weeks: (0) NI (1) ND (2) QUE (3) DDF (4) VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: (0) NI (1) NAL (2) MOT (3) UN (4) PN

12. Last Two Weeks: (0) NI (1) NAL (2) MOT (3) UN (4) PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

14. Last Two Weeks: (0) NI (1) VR (2) FUL (3) RES (4) MLD (5) SLT (6) UNR

___ % Usual % of Normal

___ % Maximum % of Normal

___ Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

16. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

Worse in Afternoon and/or Evening

17. Current Episode: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

18. Last Two Weeks: (0) NI (1) NW (2) MIN (3) MLD (4) CW (5) EXT

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KIDDIE-SADS-LIFETIME - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

NEGATIVE SELF IMAGE

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28. Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

32. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Duration: ___ # of weeks

34. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

36. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Anhedonia

37. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

38. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

40. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

42. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PSYCHOMOTOR AGITATION

43. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

44. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

46. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) MOD (5) SVR

Pacing

47. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

48. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Hand wringing

49. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

50. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

52. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

Can't stop talking, talks on and on

53. Current Episode: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

54. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) PR (4) SVR (5) SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME - SCORING FORM

INSOMNIA

84. Current Episode: (0) NI (1) NO (2) (3) (4) (5) (6)

85. Last Two Weeks: (0) NI (1) NO (2) (3) (4) (5) (6)

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

87. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Middle Insomnia

88. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

89. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Terminal Insomnia

90. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

91. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Circadian Reversal

92. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

93. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Non-restorative sleep

94. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

95. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

Daytime sleepiness

96. Current Episode: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

97. Last Two Weeks: (0) NI (1) NPR (2) DBT (3) MLD (4) MOD (5) SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANOREXIA

98. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

99. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) RAR (6) NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

103. Last Two Weeks: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

105. Last Two Weeks: (0) NI (1) ABS (2) DBT (3) MLD (4) MOD (5) SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME - SCORING FORM

SUICIDAL IDEATION

108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT

Medical Lethality

114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - MAJOR DEPRESSIVE EPISODE

Onset and Course

118. Number of Episodes [ ]

Ages of onset and offset of each episode

119. Onset [ ]
Offset [ ]
Weeks [ ]

120. Onset [ ]
Offset [ ]
Weeks [ ]

121. Onset [ ]
Offset [ ]
Weeks [ ]

122. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3. Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4. Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

RACING THOUGHTS

13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX

FLIGHT OF IDEAS

15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

POOR JUDGEMENT

17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS

DISTRACTABILITY

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR

MOTOR HYPERACTIVITY

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

Inappropriate laughing, joking or punning

23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

Uninhibited people seeking, gregarious

25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD
26. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD

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KIDDIE-SADS-LIFETIME - SCORING FORM

Increased Productivity

27. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

28. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Sharpened and unusually creative thinking

29. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

30. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

Hypersexuality

31. Current Episode: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

32. Last Two Weeks: (0) NI (1) NO (2) DBT (3) PRS (4) SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: (0) NA (1) NVR (2) SMT (3) ONL

34. Last Two Weeks: (0) NA (1) NVR (2) SMT (3) ONL

NUMBER OF MANIC PERIODS

35. ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - HYPOMANIC EPISODE

Onset and Course

36. Number of Episodes [ ]

Ages of onset and offset of each episode

37. Onset [ ] Offset [ ] Weeks [ ]

38. Onset [ ] Offset [ ] Weeks [ ]

DIAGNOSTIC CRITERIA - MANIC EPISODE

39. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

40. Onset [ ] Offset [ ] Weeks [ ]

41. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

EATING DISORDERS

REFUSAL TO MAINTAIN BODY WEIGHT

1. Lifetime: (0) NI (1) NP (2) (3) (4) (5) (6)

METHODS OF WEIGHT LOSS

2. ***Restriction*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
3. ***Only Liquids*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
4. ***Vomiting*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
5. ***Supressants*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
6. ***Laxatives*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU
7. ***Diurectics*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) ROU

BODY IMAGE DISTURBANCE

8. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

INTENSE AND PERSISTENT FEAR OF GAINING WEIGHT

9. Lifetime: (0) NI (1) NO (2) (3) (4) (5) (6)

INTENSE PREOCCUPATION WITH FOOD AND EATING

10. Lifetime: (0) NI (1) NO (2) (3) (4) (5) (6)

AMENORRHEA

11. Age of Menarche: ___
12. (0) NI (1) NO (2) YES
13. (0) NI (1) NO (2) YES

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KIDDIE-SADS-LIFETIME - SCORING FORM

14. Weeks: [ ]

15. Weeks: [ ]

16. (0) NI (1) NO (2) YES

BULIMIA

17. Lifetime: (0) NI (1) NO (2) (3) (4) (5) (6)

18. ***Eats faster*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

19. ***Uncontrollable*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

20. ***Eats alone*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

21. ***Abdominal Pain*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

22. ***Vomiting*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

23. ***Sleep*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

24. ***Interruption*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

25. ***Depression*** Lifetime: (0) NI (1) NVR (2) SMT (3) OFT (4) AS

26. Binges: [ ] hours

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - ANOREXIA NERVOSA

Onset and Course

27. Number of Episodes

Ages of onset and offset of each episode

28. Onset
Offset
Weeks

29. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - BULIMIA NERVOSA

Onset and Course

30. Number of Episodes

Ages of onset and offset of each episode

31. Onset
Offset
Weeks

32. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANXIETY DISORDERS

SPECIFIC PHOBIAS

1.	***Overall*** Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	***Flying*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
3.	***Elevators*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
4.	***Small Spaces*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
5.	***Heights*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
6.	***Dark*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
7.	***Swimming*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
8.	***Dogs/animals*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
9.	***Insects*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
10.	***Thunderstorms*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
11.	***Cars/Buses/Trains*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
12.	***Dentist/Doctors*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
13.	***Other*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	

DIAGNOSTIC CRITERIA - SPECIFIC PHOBIA

Onset and Course

14. Number of Episodes [ ]

Ages of onset and offset of each episode

15. Onset [ ] Offset [ ] Weeks [ ]

16. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

SEPARATION ANXIETY

PREOCCUPATION WITH THOUGHTS OF HARM TO PARENTS

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PREOCCUPATION WITH HARM BEFALLING SELF

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FEAR OF BEING HOME ALONE

3. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

EXCESSIVE REACTION TO SEPARATION

4. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIFFICULTY BEING AWAY FROM HOME

5. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

HOMESICKNESS

6. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

FEAR OF SLEEPING AWAY FROM HOME

7. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

NIGHTMARES

8. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

SCHOOL REFUSAL/RELUCTANCE

9. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

PHYSICAL SYMPTOMS DURING SEPARATION

10. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - SEPARATION ANXIETY DISORDER

Onset and Course

11. Number of Episodes ___

Ages of onset and offset of each episode

12. Onset ___ Offset ___ Weeks ___

13. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

PANIC DISORDER AND AGORAPHOBIA

1. Lifetime: (0) NI | (1) NP | (2) DBT | (3) DPR | (4) 6 | (5) 3X | (6) DLY

SPONTANEOUS ATTACKS

2. Lifetime: (0) NI | (1) NO | (2) 1 | (3) 2-3 | (4) 4 | (5) 4+

DURATION OF SPONTANEOUS ATTACKS

3. Lifetime: (0) NI | (1) 20 | (2) 10 | (3) SOM | (4) MST | (5) ALL

SITUATIONALLY PREDISPOSED ATTACKS

4. Lifetime: (0) NI | (1) NO | (2) -4 | (3) | (4) | (5) 4+

PHOBIA RELATED ATTACKS

5. Lifetime: (0) NI | (1) NO | (2) | (3)

6. ***Shortness of Breath*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

7. ***Palpitations*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

8. ***Chest Pains*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

9. ***Choking*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

10. ***Dizziness*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

11. ***Numbness*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

12. ***Sweating*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

13. ***Trembling*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

14. ***Dying*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

15. ***Losing Control*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

16. ***Nausea*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

17. ***Depersonalization*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

18. ***Flashes/Chills*** Lifetime: (0) NI | (1) NO | (2) DBT | (3) MLD | (4) MOD

19. Most Number of Attacks: ___ in a 4 week period

20. Lifetime: (0) NI | (1) NP | (2) VM | (3) MLD | (4) MO | (5) SVR | (6) EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

AGORAPHOBIA WITH PANIC DISORDER

21. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

AGORAPHOBIA WITHOUT PANIC DISORDER

22. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - PANIC DISORDER WITHOUT AGORAPHOBIA

Onset and Course

23. Number of Episodes ___

Ages of onset and offset of each episode

24. Onset ___ Offset ___ Weeks ___

25. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - PANIC DISORDER WITH AGORAPHOBIA

26. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

27. Onset ___ Offset ___ Weeks ___

28. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - AGORAPHOBIA WITHOUT HISTORY OF PANIC DISORDER

29. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

30. Onset ___ Offset ___ Weeks ___

31. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

SOCIAL PHOBIA

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - SOCIAL PHOBIA

2. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

3. Onset ___ Offset ___ Weeks ___

4. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSESSIONS OR COMPULSIONS

OBSESSIONS

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

COMPULSIONS

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX
3. ***Touching*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
4. ***Counting*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
5. ***Washing*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
6. ***Checking*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
7. ***Collecting*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
8. ***Arranging*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD
9. ***Other*** Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD

DEPERSONALIZATION OR DEREALIZATION

10. Lifetime: (0) NI (1) NO (2) FLT (3) OCC (4) SVL (5) MRK (6) FQT

DIAGNOSTIC CRITERIA - OBSESSIVE-COMPULSIVE DISORDER

11. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

12. Onset ___ Offset ___ Weeks ___

13. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

GENERALIZED ANXIETY DISORDER

WORRY

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

2. Lifetime: (0) NI (1) NO (2) DBT (3) MLD (4) MOD

DIFFICULTY CONTROLLING WORRIES

3. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

SYMPTOMS ASSOCIATED WITH WORRY

4. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - GENERALIZED ANXIETY DISORDER

5. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

6. Onset ___ Offset ___ Weeks ___

7. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

POST-TRAUMATIC STRESS DISORDER

TRAUMA TO OTHERS

1. Lifetime: (0) NI (1) NO (2) (3) (4) (5) (6)

TRAUMATIC TO SELF

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR

INTRUSIVE RECOLLECTIONS OF TRAUMA

3. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

RECURRENT DISTRESSING DREAMS

4. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

SENSE OF RELIVING TRAUMA AND INTENSE DISTRESS AT RE-EXPERIENCE

5. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

PHYSIOLOGICAL REACTION UPON EXPOSURE

6. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

THOUGHTS, FEELINGS, CONVERSATIONS, ACTIVITIES, PLACES OF PEOPLE

7. Lifetime: (0) NI (1) NO (2) YES

NO RECALL OF IMPORTANT ASPECTS OF TRAUMA

8. Lifetime: (0) NI (1) NO (2) YES

MARKEDLY REDUCED ACTIVITIES/INTEREST

9. Lifetime: (0) NI (1) NO (2) YES

DETACHMENT, ENSTRANGEMENT, RESTRICTED AFFECT

10. Lifetime: (0) NI (1) NO (2) YES

SENSE OF FORESHORTENED FUTURE

11. Lifetime: (0) NI (1) NO (2) YES

SLEEP PROBLEMS

12. Lifetime: (0) NI (1) NO (2) YES

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KIDDIE-SADS-LIFETIME - SCORING FORM

IRRITABILITY

13. Lifetime: (0) NI (1) NO (2) YES

DIFFICULTY CONCENTRATING

14. Lifetime: (0) NI (1) NO (2) YES

HYPERVIGILENCE

15. Lifetime: (0) NI (1) NO (2) YES

EXAGGERATED STARTLED RESPONSE

16. Lifetime: (0) NI (1) NO (2) YES

OVERALL SEVERITY OF POST-TRAUMATIC STRESS DISORDER

17. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EXT

DIAGNOSTIC CRITERIA - POST-TRAUMATIC STRESS DISORDER

18. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

19. Onset ___ Offset ___ Weeks ___

20. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

INATTENTION

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

HYPERACTIVITY

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

IMPULSIVITY

3. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

4. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

5. Onset ___ Offset ___ Weeks ___

6. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

CONDUCT DISORDER/ANTISOCIAL PERSONALITY

CHRONIC VIOLATION OF RULES AT HOME AND/OR SCHOOL

1. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

SCHOOL SUSPENSION/EXPULSION

2. Lifetime: (0) NI | (1) NO | (2) -1 | (3) 1+ | (4) EXP

TRUANCY

3. Lifetime: (0) NI | (1) NO | (2) OCC | (3) FQT | (4) 50%

PATHOLOGICAL LYING

4. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

STAYING OUT AT NIGHT

5. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

RUNAWAY OVERNIGHT

6. Lifetime: (0) NI | (1) NO | (2) 1 | (3) 1+ | (4) FQT

NONAGGRESIVE STEALING

7. Lifetime: (0) NI | (1) NO | (2) | (3) $10 | (4) $50

BULLYING

8. Lifetime: (0) NI | (1) NO | (2) | (3) FQT | (4) DLY

PERSISTENT PHYSICAL FIGHTING

9. Lifetime: (0) NI | (1) NO | (2) | (3) FQT | (4)

USE OF A WEAPON

10. Lifetime: (0) NI | (1) NVR | (2) CON | (3) 1 | (4) 1+

VANDALISM

11. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

FIRESETTING

12. Lifetime: (0) NI | (1) NO | (2) | (3) | (4)

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KIDDIE-SADS-LIFETIME - SCORING FORM

BREAKING AND ENTERING

13. Lifetime: (0) NI (1) NO (2) -1 (3) 2 (4) 2+

AGGRESSIVE STEALING

14. Lifetime: (0) NI (1) NO (2) -1 (3) 2 (4) 2+

CRUELTY TO ANIMALS

15. Lifetime: (0) NI (1) NO (2) OCC (3) (4)

PHYSICAL CRUELTY TO PERSONS

16. Lifetime: (0) NI (1) NO (2) -1 (3) 2 (4) 2+

HOMICIDAL ACTS

17. Lifetime: (0) NI (1) NO (2) GTR (3) ATT (4) COM

FORCED SEX

18. Lifetime: (0) NI (1) NO (2) (3) (4) (5) RAP

GANG ACTIVITIES

19. Lifetime: (0) NI (1) NO (2) PER (3) MEM (4) LDR

DELINQUENCY

20. Lifetime: (0) NI (1) NO (2) ARR (3) CHA (4) CON

INCARCERATION

21. Lifetime: (0) NI (1) NO (2) HLD (3) REF (4) JAL

SUMMARY RATING

22. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - CONDUCT DISORDER

23. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

24. Onset ___ Offset ___ Weeks ___

25. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANTISOCIAL PERSONALITY DISORDER

WORK

1. Lifetime: (0) NI (1) NO (2) MLD (3) MOD (4) SVR (5) EX

FINANCIAL RESPONSIBILITY

2. Lifetime: (0) NI (1) NO (2) MLD (3) MOD (4) SVR (5) EX

CONNING

3. Lifetime: (0) NI (1) MLD (2) MOD (3) SVR (4) EX

DISREGARD FOR SAFETY OF SELF/OTHERS

4. Lifetime: (0) NI (1) MLD (2) MOD (3) EX

LACK OF REMORSE

5. Lifetime: (0) NI (1) MLD (2) MOD (3) EX

DIAGNOSTIC CRITERIA - ANTISOCIAL PERSONALITY DISORDER

6. Onset and Course

Number of Episodes ____

Ages of onset and offset of each episode

7. Onset ____ Offset ____ Weeks ____

8. Onset ____ Offset ____ Weeks ____

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KIDDIE-SADS-LIFETIME - SCORING FORM

OPPOSITIONAL DEFIANT DISORDER

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - OPPOSITIONAL DEFIANT DISORDER

2. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

3. Onset

Offset

Weeks

4. Onset

Offset

Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

ALCOHOL

ALCOHOL ABUSE

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

ALCOHOL DEPENDENCE

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - ALCOHOL DEPENDENCE

3. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

4. Onset ___ Offset ___ Weeks ___

5. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - ALCOHOL ABUSE

6. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

7. Onset ___ Offset ___ Weeks ___

8. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

DRUGS

DRUG ABUSE

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DRUG DEPENDENCE

2. Lifetime: (0) NI (1) NO (2) MLD (3) MOD (4) SVR (5) EX

DIAGNOSTIC CRITERIA - SUBSTANCE DEPENDENCE

3. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

4. Onset ___ Offset ___ Weeks ___

5. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - SUBSTANCE ABUSE

6. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

7. Onset ___ Offset ___ Weeks ___

8. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

TIC DISORDERS

MOTOR TICS

1. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

VOCAL TICS

2. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MO (5) SVR (6) EX

DIAGNOSTIC CRITERIA - TIC DISORDERS

3. Onset and Course

Number of Episodes

Ages of onset and offset of each episode

4. Onset
Offset
Weeks

5. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

PSYCHOTIC SYMPTOMOLOGY

COMMAND HALLUCINATIONS

1. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

CONVERSING VOICES

2. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

PERSECUTORY HALLUCINATIONS

3. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

COMMENTING VOICE

4. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

RELIGIOUS HALLUCINATIONS

5. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

THOUGHTS ALOUD

6. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

OTHER VERBAL HALLUCINATIONS

7. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

LOCATION OF AUDITORY HALLUCINATIONS

8. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

9. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

10. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

VISUAL HALLUCINATIONS

11. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

TACTILE HALLUCINATIONS

12. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

OLFACTORY HALLUCINATIONS

13. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

14. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

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KIDDIE-SADS-LIFETIME - SCORING FORM

OTHER PERCEPTUAL CHILDHOOD PHENOMENA

HYPNAGOGIC OR HYPNAPOMPIC HALLUCINATIONS

1. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF
2. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF
3. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

ILLUSIONS

4. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

EIDETIC IMAGERY

5. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

ELABORATED FANTASIES

6. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

IMAGINARY COMPANIONS

7. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

CHARACTERISTICS OF PSYCHOPATHOLOGICALLY MEANINGFUL HALLUCINATIONS

FREQUENCY

8. Lifetime: (0) NI (1) NO (2) SUS (3) -5 (4) SOM (5) LOT (6) DLY

SEVERITY

9. Lifetime: (0) NI (1) NO (2) SUS (3) DEF (4) GEN (5) CNV (6) ACT

THEMATIC CONSISTENCY WITH MOOD DISORDER

DEPRESSION

10. Lifetime: (0) NI (1) NO (2) POS (3) COM

MANIA

11. Lifetime: (0) NI (1) NO (2) POS (3) COM

TEMPORAL CONSISTENCY WITH MOOD DISORDER

DEPRESSION

12. Lifetime: (0) NI (1) NO (2) SUS (3) POS

MANIA

13. Lifetime: (0) NI (1) NO (2) SUS (3) POS

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KIDDIE-SADS-LIFETIME - SCORING FORM

DELUSIONS

DELUSIONS OF REFERENCE

1. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

DELUSIONS OF BEING CONTROLLED OR INFLUENCED

2. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

DELUSIONS THAT PEOPLE CAN READ HIS MIND

3. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

THOUGHT BROADCASTING

4. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

THOUGHT INSERTION

5. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

THOUGHT WITHDRAWAL

6. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

DELUSIONS OF GUILT OR SIN

7. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

DELUSIONS OF INFLUENCE

8. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

PERSECUTORY DELUSIONS

9. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

GUILT RELATED PERSECUTORY DELUSIONS

10. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

SOMATIC DELUSIONS

11. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

GUILT RELATED SOMATIC DELUSIONS

12. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

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KIDDIE-SADS-LIFETIME - SCORING FORM

NIHILISTIC DELUSIONS

13. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

GUILT RELATED NIHILISTIC DELUSIONS

14. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

GRANDIOSE DELUSIONS

15. Lifetime: (0) NI (1) ABS (2) NON (3) SUS (4) DEF

SUBCULTURAL OR FAMILY DELUSIONS

16. Lifetime: (0) NI (1) DEF (2) LIK (3) ALL

SEVERITY OF DELUSIONS OF ANY TYPE

17. Lifetime: (0) NI (1) NO (2) SUS (3) PST (4) GEN (5) SIG (6) ACT

SENSORIUM WHILE DELUDED

18. Lifetime: (0) NI (1) DEL (2) PLX (3) ALW

THEMATIC CONSISTENCY WITH MOOD DISORDER

DEPRESSION

19. Lifetime: (0) NI (1) NO (2) POSS (3) COM

MANIA

20. Lifetime: (0) NI (1) NO (2) POSS (3) COM

TEMPORAL CONSISTENCY WITH MOOD DISORDER

DEPRESSION

21. Lifetime: (0) NI (1) NO (2) SUS (3) POS

MANIA

22. Lifetime: (0) NI (1) NO (2) SUS (3) POS

BIZARRENESS OF DELUSIONAL CONTENT

23. Lifetime: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

MULTIPLE DELUSIONS

24. Lifetime: (0) NI (1) ABS (2) SUS (3) DEF

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KIDDIE-SADS-LIFETIME - SCORING FORM

FORMAL THOUGHT DISORDER

SENTENCE INCOHERENCE

1.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
2.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

DERAILMENT

3.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
4.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

ILLOGICAL THINKING

5.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
6.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

POVERTY OF CONTENT OF SPEECH

7.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
8.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

NEOLOGISMS

9.	Lifetime:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR
10.	Observed:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR

PRESSURE OF SPEECH

11.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
12.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSERVATIONAL ITEMS

INAPPROPRIATE AFFECT

1. Observed: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

BLUNTED AFFECT

2. Observed: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX

CATATONIC MOTOR BEHAVIOR

3. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR
4. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR
5. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR
6. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR
7. Observed: (0) NI (1) ABS (2) DBT (3) MM (4) SVR

BIZARRENESS

8. Observed: (0) NI (1) NO (2) SLT (3) MLD (4) MOD (5) SVR (6) EX
9. Observed: (0) NI (1) ABS (2) DBT (3) PST (4) SVR
10. Observed: (0) NI (1) ABS (2) DBT (3) PST (4) SVR
11. Observed: (0) NI (1) ABS (2) DBT (3) PST (4) SVR
12. Observed: (0) VG (1) G (2) OF (3) P (4) VP

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - SCHIZOPHRENIA

1. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

2. Onset [ ] Offset [ ] Weeks [ ]

3. Onset [ ] Offset [ ] Weeks [ ]

DIAGNOSTIC CRITERIA - SCHIZOAFFECTIVE DISORDER

4. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

5. Onset [ ] Offset [ ] Weeks [ ]

6. Onset [ ] Offset [ ] Weeks [ ]

DIAGNOSTIC CRITERIA - BRIEF PSYCHOTIC DISORDER

7. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

8. Onset [ ] Offset [ ] Weeks [ ]

9. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - DELUSIONAL DISORDER

10. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

11. Onset ___ Offset ___ Weeks ___

12. Onset ___ Offset ___ Weeks ___

KIDDY-GAS (C-GAS)

1. Current Episode:	100-91	90-81	80-71	70-61	60-51	50-41	40-31	30-21	20-11	10-1
2. Last Two Weeks:	100-91	90-81	80-71	70-61	60-51	50-41	40-31	30-21	20-11	10-1

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LABORATORY TESTS

For SB	Lab Number Code

Sample Date ___ day ___ month ___ year

- Attach SBCL laboratory report behind this page.
- Are there CLINICALLY SIGNIFICANT ABNORMAL laboratory values?

☐ No
☐ Yes ⟶ Record the findings and/or diagnosis in the Adverse Experiences.

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year)

STUDY MEDICATION DISPENSING

Record study medication information for Down Titration in the Study Medication Record, page 401. Attach label to page 400. Record number of capsules dispensed on page 401.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - DOWN TITRATION

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 1 9 1 7 *

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Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Down Titration	day month year	400

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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STUDY MEDICATION RECORD

Record the start and end date of each dose level as the patient is down titrated.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

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MODULE PARAMETERS - CONCOMITANT MEDICATION

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 2 0 1 7 *

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CONCOMITANT MEDICATION

- Record all concomitant medication taken since the Week 8 visit.
- Where appropriate, medical conditions should be recorded on the Adverse Experiences form utilizing the same terminology.

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						

★ State dates as precisely as possible.

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CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
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For SB						
						☐
For SB						

★ State dates as precisely as possible.

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CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
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For SB						
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For SB						
						☐
For SB						
						☐
For SB						

★ State dates as precisely as possible.

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CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
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For SB						
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For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						

★ State dates as precisely as possible.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
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For SB						
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For SB						
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For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						

★ State dates as precisely as possible.

SmithKline Beecham Pharmaceuticals

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CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
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For SB						
						☐
For SB						

★ State dates as precisely as possible.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Continuation Phase	

MODULE PARAMETERS-ADVERSE EXPERIENCE

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V2117*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			409

ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
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Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
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If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
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If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
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	2 Moderate	☐	☐	☐
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If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
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Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
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Experience continuing		☐	☐	☐
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Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
	Duration if less than 24 hours	hours minutes	hours minutes	hours minutes
	Experience continuing	☐	☐	☐
	Experience continuing at end of study	☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
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	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
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Suspected Relationship To Study Medication	1 Related	☐	☐	☐
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Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number _____	AE Number _____	AE Number _____
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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STUDY CONCLUSION

Did the patient complete the study as planned?

☐ Yes
☐ No

➧ If 'No', mark the ONE most appropriate category

1 ☐ Adverse experience (complete Adverse Experience section)
2 ☐ Lack of efficacy
3 ☐ Deviation from protocol (including non-compliance)
4 ☐ Lost to follow-up
6 ☐ Termination by sponsor
7 ☐ Other

Comments on reason for withdrawal:

Date of Last Visit ____ day month year

Date of Last Dose ____ day month year

I certify that I have reviewed the data on this case report form (pages 233-418) and that all information is complete and accurate.

Investigator's Signature _____ _____ Date

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Continuation Phase	

MODULE PARAMETERS - STUDY CONCLUSION

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 2 2 1 7 *

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center		Page
29060	329	0 0		D

PATIENT LOG - CONTINUATION PHASE

Investigator _____

Directions: Enter ALL patients who have been considered for the study and who have been interviewed. For patients not entering the Continuation Phase, note the reason for exclusion in the designated column.

Patient Initials	Initial Interview (day month year)	Reason for Exclusion

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center		Page
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PATIENT ASSIGNMENT SHEET - CONTINUATION PHASE

Investigator _____ For SB Date day month year

Directions: Do not enter the patient on the patient assignment sheet until he/she starts continuation phase medication.

Final Dose Status: C = Completed all treatment visits
W = Withdrawn prior to completing all treatment visits

	Patient Initials	Patient Number	Date of First Dose of Continuation Phase (day month year)	Date of Last Dose (day month year)	Status (C/W)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
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18					
19					
20					
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22					
23					
24					
25					

Investigator CVs

CURRICULUM VITAE - [redacted]

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[redacted]

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Randomisation Code

CODING MEMO Page - 1
PROJECT - 29060 PROTOCOL - 329I
Coding Memo Creator - OAKESR8
Date Printed: August 12, 1993 Date Created: August 12, 1993
Seed: 8570387 Block Size: 6

TREATMENT GROUP - PLACEBO
Interval Number 1 Named PHASE 1
Drug: PLACEBO

00001	00005	00010	00012	00016	00018
00020	00024	00027	00028	00031	00033
00037	00042	00047	00048	00049	00053
00059	00060	00062	00064	00069	00071
00074	00078	00080	00084	00085	00086
00094	00095	00097	00101	00107	00108
00111	00114	00115	00120	00123	00125
00128	00129	00135	00136	00141	00144
00148	00150	00155	00156	00158	00162
00164	00168	00169	00174	00176	00177
00183	00184	00189	00191	00197	00198
00200	00202	00207	00210	00213	00216
00217	00218	00224	00225	00229	00232
00237	00238	00241	00246	00251	00252
00253	00254	00259	00263	00266	00267
00274	00276	00277	00282	00285	00287
00291	00293	00296	00298	00302	00306
00311	00312	00315	00316	00320	00323
00327	00330	00331	00334	00337	00342
00343	00345	00349	00353	00357	00359

TREATMENT GROUP - IMIPRAMINE PO
Interval Number 1 Named PHASE 1
Drug: PO IMIPRAMINE

00003	00006	00007	00009	00013	00014
00022	00023	00026	00030	00035	00036
00040	00041	00044	00045	00050	00054
00056	00057	00061	00066	00067	00070
00073	00076	00079	00082	00088	00090
00092	00093	00098	00100	00103	00104
00110	00113	00117	00118	00122	00126
00127	00132	00134	00137	00139	00143
00146	00149	00153	00154	00159	00161
00163	00166	00171	00172	00175	00180
00185	00186	00187	00192	00194	00195
00199	00203	00208	00209	00211	00215
00219	00221	00223	00227	00230	00233
00236	00239	00243	00244	00247	00249
00255	00256	00262	00264	00269	00270
00272	00273	00279	00281	00284	00286
00289	00290	00295	00297	00301	00305
00307	00308	00314	00317	00321	00322
00325	00326	00332	00335	00339	00341
00346	00347	00351	00352	00356	00360

TREATMENT GROUP - PAROXETINE PO
Interval Number 1 Named PHASE 1
Drug: PO PAROXETINE

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PROJECT - 29060 PROTOCOL - 329II
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TREATMENT GROUP - PLACEBO
Interval Number 1 Named PHASE 2
Drug: PLACEBO

00003	00007	00009	00016	00018	00020
00026	00029	00038	00039	00043	00046
00050	00055	00058	00063	00065	00066
00077	00080	00083	00087	00090	00096
00098	00101	00107	00111	00115	00117
00122	00126	00129	00135	00139	00141
00145	00146	00156	00160	00161	00165
00175	00176	00177	00182	00185	00186

TREATMENT GROUP - IMIPRAMINE PO
Interval Number 1 Named PHASE 2
Drug: PO IMIPRAMINE

00001	00006	00008	00013	00014	00015
00017	00019	00022	00027	00028	00032
00035	00036	00037	00045	00047	00048
00049	00052	00053	00059	00061	00062
00067	00069	00072	00074	00076	00078
00082	00084	00085	00089	00092	00094
00097	00099	00103	00105	00106	00112
00114	00116	00120	00121	00125	00128
00131	00133	00134	00138	00140	00142
00147	00150	00151	00153	00154	00158
00166	00167	00168	00171	00173	00174
00178	00183	00184	00188	00189	00191

TREATMENT GROUP - PAROXETINE PO
Interval Number 1 Named PHASE 2
Drug: PO PAROXETINE

00002	00004	00005	00010	00011	00012
00021	00023	00024	00025	00030	00031
00033	00034	00040	00041	00042	00044
00051	00054	00056	00057	00060	00064
00068	00070	00071	00073	00075	00079
00081	00086	00088	00091	00093	00095
00100	00102	00104	00108	00109	00110
00113	00118	00119	00123	00124	00127
00130	00132	00136	00137	00143	00144
00148	00149	00152	00155	00157	00159
00162	00163	00164	00169	00170	00172
00179	00180	00181	00187	00190	00192

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PROJECT - 29060 PROTOCOL - 329I
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Date Printed: August 12, 1993 Date Created: August 12, 1993
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TREATMENT GROUP - PAROXETINE PO (CONT.)

00002	00004	00008	00011	00015	00017
00019	00021	00025	00029	00032	00034
00038	00039	00043	00046	00051	00052
00055	00058	00063	00065	00068	00072
00075	00077	00081	00083	00087	00089
00091	00096	00099	00102	00105	00106
00109	00112	00116	00119	00121	00124
00130	00131	00133	00138	00140	00142
00145	00147	00151	00152	00157	00160
00165	00167	00170	00173	00178	00179
00181	00182	00188	00190	00193	00196
00201	00204	00205	00206	00212	00214
00220	00222	00226	00228	00231	00234
00235	00240	00242	00245	00248	00250
00257	00258	00260	00261	00265	00268
00271	00275	00278	00280	00283	00288
00292	00294	00299	00300	00303	00304
00309	00310	00313	00318	00319	00324
00328	00329	00333	00336	00338	00340
00344	00348	00350	00354	00355	00358

Certificates of Analysis

SmithKline Beecham
Pharmaceuticals

Drug Product Certificate of Analysis

Product:	Overencapsulated Paxil Tablets		
Batch Number:	U95085	**Formula Code:**	AM
Date of Manufacture:	08-May-1995	**Strength:**	10 mg
Sample Log Number:	9500258	**Use-by Date:**	31-Jul-1999

Test	**Result**
General Appearance	Passes Bluish green opaque Supro B capsules containing a yellow capsule shaped, film coated tablet.
Identification (HPLC)	Passes
Assay - Paroxetine (HPLC)	100.8% LC (n=2)
Dissolution (HPLC)	Avg = 99% dissolved (n=6) L = 93% H = 102% RSD% = 3.2

This product conforms with Product Specification CPSC/PDSU 0203/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by [redacted] on 01 Jul 1999
Quality Assurance Date

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SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0500
Product:	Overencapsulated Paxil Tablets
Strength:	10 mg
Formula:	N/A
Lot Number:	U-93127
Date of Overencapsulation:	27-Jul-93
Request Log Number:	9300697

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a yellow capsule shaped, film coated tablet.	Passes
Identification (HPLC)	The retention time of the major peak in the sample preparation corresponds with that of the standard preparation as obtained in the assay.	Passes
Assay - Paroxetine (HPLC)	90.0 - 110.0% of claim	99.0% (n=2)
Dissolution (UV)	Not less than 80% (Q) in 60 minutes or Overencapsulated tablet average must not be less than 90% of the tablet average and the commercial tablet must comply with USP of not less than 80% (Q) in 60 minutes	95% (n=6) Low=91% High=99% RSD%=3.2

This product conforms with Product Specification CPSC/PDSU 0203/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

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Pharmaceuticals

Drug Product Certificate of Analysis

Product:	Overencapsulated Paxil Tablets		
Batch Number:	U95086	**Formula Code:**	AN
Date of Manufacture:	08-May-1995	**Strength:**	20 mg
Sample Log Number:	9500257	**Use-by Date:**	31-Jul-1999

Test	Result
General Appearance	Passes Bluish green opaque Supro B capsules containing a pink capsule shaped, film coated tablet.
Identification (HPLC)	Passes
Assay - Paroxetine (HPLC)	101.7% LC (n=2)
Dissolution (HPLC)	Avg = 102% dissolved (n=6) L = 96% H = 108% RSD% = 4.5

This product conforms with Product Specification CPSC/PDSU 0204/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by [redacted] on 01 Jul 1997
Quality Assurance Date

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SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0501
Product:	Overencapsulated Paxil Tablets
Strength:	20 mg
Formula:	N/A
Lot Number:	U-93128
Date of Overencapsulation:	03-Aug-93
Request Log Number:	9300696

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a pink capsule shaped, bisected film coated tablet.	Passes
Identification (HPLC)	The retention time of the major peak in the sample preparation corresponds with that of the standard preparation as obtained in the assay.	Passes
Assay - Paroxetine (HPLC)	90.0 - 110.0% of claim	100.4% (n=2)
Dissolution (UV)	Not less than 80% (Q) in 60 minutes or Overencapsulated tablet average must not be less than 90% of the tablet average and the commercial tablet must comply with USP of not less than 80% (Q) in 60 minutes	96% (n=6) Low=89% High=102% RSD%=4.7

This product conforms with Product Specification CPSC/PDSU 0204/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

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Pharmaceuticals

Drug Product Certificate of Analysis

Product:	Overencapsulated Placebo for Paxil Tablets, 20 mg		
Batch Number:	U95084	**Formula Code:**	ER
Date of Manufacture:	02-May-1995	**Strength:**	placebo
Sample Log Number:	9500256	**Use-by Date:**	31-Jul-1999

Test	Specification
General Appearance	Passes Bluish green opaque Supro B capsules containing a pink capsule shaped, bisected film coated tablet.
Paroxetine Content (HPLC)	Passes Absence of Active

This product conforms with Product Specification CPSC/PDSU 0207/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by [redacted] on 01 Jul 1997
Quality Assurance Date

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SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0497
Product:	Overencapsulated Placebo for Paxil Tablets, 20 mg
Strength:	Placebo
Formula:	N/A
Lot Number:	U-93126
Date of Overencapsulation:	21-Jul-93
Request Log Number:	9300634

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a pink capsule shaped, bisected film coated tablet.	Passes
Paroxetine Content (HPLC)	Absence of Active	Passes

This product conforms with Product Specification CPSC/PDSU 0207/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

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Pharmaceutical Technologies

Drug Product Analytical Report

Analytical Report:	PDRU 0915
Product:	Overencapsulated Imipramine HCl Tablets
Strength:	50 mg
Formula:	AA
Lot Number:	U 9 5 1 2 1
Date of Overencapsulation:	07-Jun-95
Commercial Lot Number:	22763 (Biocraft Laboratories)
Use by Date:	01-Feb-98
Request Log Number:	9 5 0 0 2 9 8

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with BL on one side and 21 on the other side.	Passes
Identification (UV)	The ultraviolet spectrum for the sample closely matches that of the standard similarly prepared in the Assay or dissolution procedure for Imipramine HCl tablets.	Passes
Assay - Imipramine HCl (UV)	93.0 - 107.0% of claim	101.9% (n=2)
Dissolution (UV)	Not less than 75% (Q) in 45 minutes or Overencapsulated tablet average must not be less than 90% of the tablet average and the commercial tablet must comply with USP of not less than 75% (Q) in 45 minutes	Avg = 100% (n=6) L = 83% H = 106% RSD% = 8.5

This product conforms with Product Specification CPSC/PDSU 0209/01.

Approved by: [redacted] Date: 27 JUL 95

Prepared by: CAG [redacted]

LNB Reference: SLM-24857 pp. 22-27.

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Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0499
Product:	Overencapsulated Imipramine Hydrochloride USP Tablets
Strength:	50 mg
Formula:	commercial
Lot Number:	U-93135
Date of Overencapsulation:	30-Jun-1993
Request Log Number:	9300596

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with BL on one side and 21 on the other side.	Passes
Identification (UV)	The ultraviolet spectrum for the sample closely matches that of the standard similarly prepared in the Assay or dissolution procedure for Imipramine HCl tablets.	Passes
Assay - Imipramine HCl (UV)	93.0 - 107.0% of claim	100.5% (n=2)
Dissolution (UV)	Not less than 75% (Q) in 45 minutes or Overencapsulated tablet average must not be less than 90% of the commercial tablet average and the commercial tablet must comply with USP of not less than 75% (Q) in 45 minutes	102% (n=6) Low=100% High=104%

This product conforms with Product Specification CPSC/PDSU 0209/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

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SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0498
Product:	Overencapsulated Imipramine Hydrochloride USP Tablets
Strength:	50 mg
Formula:	commercial
Lot Number:	U-93139
Date of Overencapsulation:	16-Aug-93
Request Log Number:	9300695

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with BL on one side and 21 on the other side.	Passes
Identification (UV)	The ultraviolet spectrum for the sample closely matches that of the standard similarly prepared in the Assay or dissolution procedure for Imipramine HCl tablets.	Passes
Assay - Imipramine HCl (UV)	93.0 - 107.0% of claim	100.3% (n=2)
Dissolution (UV)	Not less than 75% (Q) in 45 minutes or Overencapsulated tablet average must not be less than 90% of the commercial tablet average and the commercial tablet must comply with USP of not less than 75% (Q) in 45 minutes	102% (n=6) Low=101% High=103%

This product conforms with Product Specification CPSC/PDSU 0209/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

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SmithKline Beecham
Pharmaceuticals

Drug Product Certificate of Analysis

Product:	Overencapsulated Placebo for Imipramine Tablets		
Batch Number:	U 9 5 0 8 7	**Formula Code:**	BF
Date of Manufacture:	11-May-1995	**Strength:**	placebo
Sample Log Number:	9 5 0 0 2 6 8	**Use-by Date:**	30-Apr-1998

Test	**Specification**
General Appearance	Passes Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with RL on one side and 71 on the other side.
Imipramine Content (UV)	Passes Absence of Active

This product conforms with Product Specification CPSC/PDSU 0210/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by [redacted] on 01 Jul 1997
Quality Assurance Date

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SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0493
Product:	Overencapsulated Placebo for Imipramine HCl Tablets, 50 mg
Strength:	Placebo
Formula:	N/A
Lot Number:	U-93178
Date of Overencapsulation:	07-Sep-93
Request Log Number:	9300771

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with RL on one side and 71 on the other side.	Passes
Imipramine Content (UV)	Absence of Active as per dissolution procedure for Imipraimine HCl tablets.	Passes

This product conforms with Product Specification CPSC/PDSU 0210/01

Approved by: [redacted] Date: 06 DEC 93

Prepared by: [redacted]

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Statistical Report

Confidential

SmithKline Beecham

Paroxetine

BRL-029060

Statistical Report

329

SB Document Number: BRL-029060/RSD-100V2V/1

Statistical TOC

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1 Introduction

The purpose of this appendix is to describe the statistical methodology used to analyze results presented in the clinical report. Summaries for the clinical report were provided for the double-blind acute and continuation phases. The focus of this appendix will be on methodology for the acute phase. Analysis for the continuation phase was performed similarly as the acute phase. All model testing was performed on acute phase data.

The primary efficacy parameters of consideration were HAMD Total (17 item) mean change from baseline at endpoint, K-SADS-L Depression subscale mean change from baseline at endpoint and percentage of responders at endpoint, where response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Endpoint of the acute phase was defined as the last observation carried forward to week 8.

The following results from the acute phase endpoint (last observation carried forward) statistical analyses are presented for the primary efficacy parameters: parametric ANOVA tables from analysis of variance of mean change from baseline for full and reduced models, and p-values for responders at endpoint, patients in remission at endpoint, patients with sustained response, and patients withdrawing due to lack of efficacy.

Covariate analyses which were performed to determine the importance of prognostic variables in predicting a patients' response at endpoint and to determine the effect of various covariates on the HAMD Total and K-SADS-L Depression subscale at endpoint are also presented.

1.1 Patient Populations

The primary population of interest was the Intent-to-Treat (ITT) population. The acute phase was of primary interest in this study. Two hundred seventy-five (275) patients were included in acute phase of the ITT population. Only 271 randomized patients having at least one post-dose assessment during the acute phase were included in the efficacy analyses and only this subset of patients was included in calculations of baseline scores presented in acute phase efficacy tables. One hundred ninety (190) patients completed the acute phase of the study. Of these 190 patients, 125 patients entered the continuation phase. One hundred eighteen (118) patients had at least one efficacy assessment during the

continuation phase and only this subset of patients was included in continuation phase tables.

Also of interest was the Per Protocol population for the acute phase. This population does not include patients having significant protocol violations during the acute phase as specified by the inclusion/exclusion criteria of the protocol. There were 30 patients determined to be protocol violators during the acute phase. Since more than 5% of the ITT patients were protocol violators, the primary efficacy variables were analyzed for the per protocol population, as well as for the intent-to-treat population. Protocol violators were identified prior to the breaking of the blind. No patients were identified with significant protocol violations during the continuation phase. The acute phase protocol violators and reason for violation are provided in Table 1.

Table 1 Summary of Patients Identified as Acute Phase Protocol Violators and Reason for Violation

Has C-GAS score □ 60 at screening:			
329.002.00099	329.002.00241	329.002.00323	329.005.00006
329.005.00012	329.005.00109	329.005.00112	329.005.00116
329.005.00335	329.005.00336	329.006.00037	329.006.00038
329.006.00041	329.006.00042	329.008.00273	329.012.00227
Is non-compliant:			
329.003.00075	329.003.00092	329.003.00093	329.003.00248
329.003.00292	329.003.00314	329.008.00157	329.009.00131
329.009.00199			
Received prohibited concomitant medication(s):			
329.005.00002			
Does not meet age requirement:			
329.007.00140			
Has severe or uncontrolled medical condition(s):			
329.009.00203			
Has received prohibited medication(s) prior to screening and/or baseline:			
329.007.00311			
Has no previous episodes of major depression as specified in the protocol:			
329.009.00237			

2 Statistical Methodology

2.1 Efficacy Variables at Baseline

The general linear model procedure, PROC GLM, in SAS version 6.08 was used to analyze data at baseline to demonstrate comparability. A model with effects for treatment and investigator was used. If the treatment effect was found to be significant (p □ 0.05), then the baseline score was included in the model. SAS type III sums of squares were used.

2.2 Change from Baseline

The calculation of change from baseline (change = score - baseline score) required a baseline value. Therefore, if a patient was missing a baseline evaluation for a variable, the screening visit evaluation was used, if available. If no screening or baseline data were available for a patient, then treatment period data for that patient were not included in the analysis of change from baseline. Means presented in the study report summary tables are least squares (adjusted) means.

The change from baseline of efficacy variables, was analyzed by the general linear models procedure, PROC GLM, in SAS version 6.08 for each of the treatment groups. SAS type III sums of squares were used.

Comparisons between paroxetine and placebo and between imipramine and placebo were made using the CONTRAST statement. Treatment comparisons were made at a significance level of 0.05.

The statistical model was determined by analyzing data at endpoint. A full model was tested using effects for treatment, investigator, and treatment by investigator interaction. If the interaction was not found to be significant ($p > 0.10$), then a reduced model was used in the analyses including effects for treatment and investigator.

Data were analyzed at each week of the acute phase using the statistical model determined from the endpoint analysis (last observation carried forward to week 8).

The primary efficacy parameters analyzed were HAMD Total (17 item) and K-SADS-L Depression subscale. The K-SADS-L Depression subscale was

computed by summing the scores from the following 9 items: 2, 20, 34, 42, 44, 56, 83, 85, and 109

The mean change from baseline for the following secondary efficacy parameters was analyzed: HAMD depressed mood item (item 1), HAMD anxiety/somatization subfactor (items 10, 11, 12, 13, 15, 17), HAMD sleep subfactor (items 4, 5, 6), HAMD cognitive disturbance subfactor (items 2, 3, 9), HAMD retardation subfactor (items 1, 7, 8, 14), self perception profile (SPP) score, autonomous functioning checklist total (AFC) score, AFC self/family care subscore (items 1-22), AFC management subscore (items 23-42), AFC recreational activity subscore (items 43-58), AFC social/vocational activities subscore (items 59-78), sickness impact profile (SIP) score, SIP present health subscore, SIP present quality of life subscore, SIP sleep/rest subscore (section A), SIP home maintenance subscore (section B), SIP social interaction subscore (section C), SIP alertness behavior subscore (section D), SIP communication subscore (section E) and SIP recreational pastimes subscore (section F) were analyzed in the same manner as the primary change from baseline variables. Variables were analyzed at weekly intervals and at endpoint.

The mean CGI Global Improvement score was analyzed at weekly intervals and at endpoint using the same methodology as that used for mean change from baseline.

2.3 Percent Responders

The percent of responders was analyzed using the categorical modeling procedure, PROC CATMOD, in SAS version 6.08. Response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Patients were classified as being a responder or non-responder. The proportion of responders was then compared among the treatments. A generalized logit model with maximum likelihood parameter estimations was used.

Comparisons between paroxetine and placebo and between imipramine and placebo were made using the CONTRAST statement with a significance level of 0.05

The statistical model was determined by analyzing data at endpoint. A full model was tested using effects for treatment, investigator, and treatment by investigator interaction. If the interaction was not found to be significant (p □ 0.10), then a

reduced model was used in the analyses only including effects for treatment and investigator.

The following secondary variables were analyzed similarly as percent of patients responding: percent of patients withdrawing due to lack of efficacy and percent of patients in remission at weekly intervals and at endpoint. Remission was defined as HAMD total score less than or equal to 8.

2.4 Survival Analysis

Survival analysis was performed for the time to sustained response, defined as response lasting until endpoint of the acute phase. The Cox proportional hazards modeling procedure, PROC PHREG, of SAS version 6.08 was used. Patients who did not achieve sustained respond were censored.

A test of the validity of the proportional hazards model was first considered using a time-dependent variable in the model. If the time-dependent variable was significant (p□0.05), then the hazard ratio changes with time and the proportional hazards model assumption is invalid. If the assumptions were met, the survival analysis was performed comparing treatment groups.

The failure time was considered to be on a continuous scale, thus the default option (*Breslow*) for the handling of ties was used.

2.5 Covariate Analyses

Exploratory analyses were done to determine the effect of various covariates on percentage of responders at endpoint of the acute phase and the mean HAMD Total and K-SADS-L Depression subscale at endpoint of the acute phase. Response was defined as HAMD Total score less than or equal to 8 or a 50% or greater decrease from baseline in HAMD Total. The ten covariates of interest included the following: AFC at endpoint, SPP at endpoint, SIP at endpoint, atypical depression (yes, no), melancholic/ endogenous subtype of depression (yes, no), current anxiety disorder (yes, no), current comorbid disorder other than major depressive disorder (yes, no), age at first onset of depression, number of episodes of major depressive disorder, and family history of major depressive disorder (yes, no).

For responders at endpoint of the acute phase, an analysis via logistic regression was performed for each variable of interest using a model with an effect for the variable. PROC LOGISTIC of the SAS system was used.

For mean HAMD and K-SADS-L at endpoint of the acute phase, an analysis of variance was performed for each covariate via the General Linear Models procedure, PROC GLM of SAS, using type III sums of squares. Each analysis used a model including effects for treatment, covariate, and treatment by covariate interaction.

3 Summary of Statistical Results

All patients randomized with data from at least one post dose assessment were included in the intent-to-treat efficacy analyses. Endpoint was used to determine the statistical model.

3.1 Efficacy Variables at Baseline

No significant differences at baseline were observed.

3.2 Change from Baseline Model Verification

The full model at endpoint was tested. The treatment-by-investigator interaction was found to be nonsignificant for all variables except the HAMD Retardation subscale. All nonsignificant interactions were removed from the model for analysis at all timepoints. For these analyses, a reduced model with effects for treatment and investigator was used.

ANOVA tables are included below which show the results of the full model with interaction and the reduced model without interaction at endpoint for mean change from baseline for the primary efficacy variables.

The treatment-by-investigator interaction p-values at endpoint from the analysis of variance (ANOVA) are provided in Table 2 for each efficacy parameter.

Table 2 Treatment-by-Investigator ANOVA P-values for Efficacy Parameters

Variable	Treatment-by-Investigator P-value
HAMD Total	0.811
K-SADS-L Depression	0.965
HAMD Depressed Mood	
HAMD Anxiety/Somatization	0.706
HAMD Sleep Disturbance	0.796
HAMD Cognitive Disturbance	0.990
HAMD Retardation	0.042
SPP Total	0.962
AFC Total	0.499
AFC Self/Family Care	0.646
AFC Management	0.324
AFC Recreational Activity	0.831
AFC Social/Vocational Activities	0.435
SIP Total	0.939
SIP Present Health	0.180
SIP Present Quality of Life	0.505
SIP Sleep/Rest	0.807
SIP Home Maintenance	0.902
SIP Social Interaction	0.763
SIP Alertness Behavior	0.980
SIP Communication	0.899
SIP Recreational Pastimes	0.765

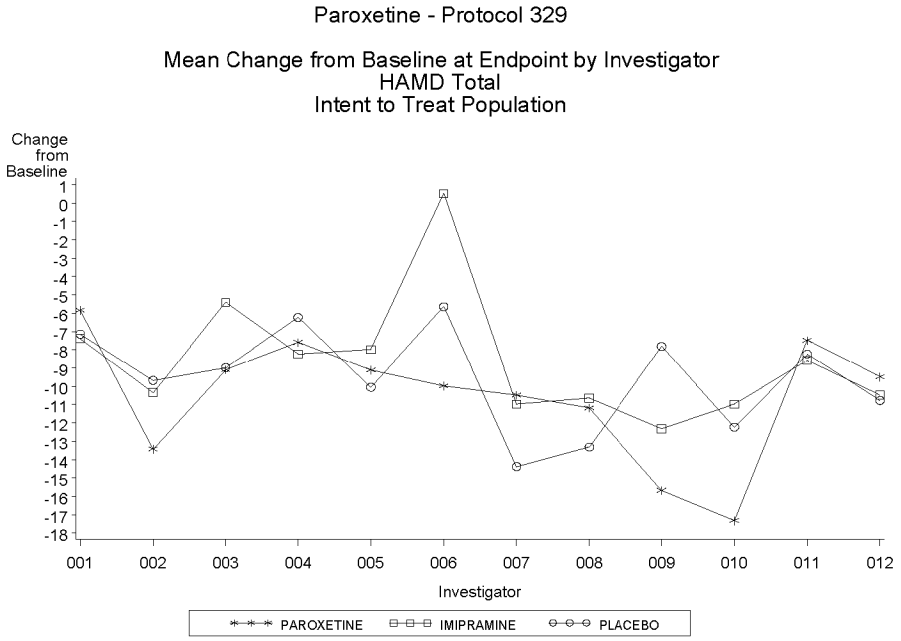
3.2.1 HAMD Total (17 items)

Analysis of the mean change from baseline of the HAMD total yielded no statistically significant treatment by investigator interaction (p=0.811). The baseline treatment effect was also not significant (p=0.220). A reduced model without interaction was used for this analysis. For the calculation of the HAMD score, individual missing results were not replaced. The missing items were allowed for by calculating the total as (S/n)x N, where S was the score recorded for n items and N was the number of items which should have been present.

Table 3 ANOVA Table for HAMD Total Mean Change from Baseline at Endpoint

Analysis of Variance of Improvement from Baseline at Endpoint						
HAMD Total (17 items)						
Intent-to-Treat Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	120.82	1.12	0.329	
	Investigator	11	1145.48	1.93	0.037	
	Treat. by Inv.	22	863.59	0.73	0.811	
	Error	235	12712.23			7.35
Reduced Model	Treatment	2	181.44	1.72	0.182	
	Investigator	11	1090.83	1.88	0.043	
	Error	257	13575.82			7.27
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 1 Plot of Treatment-by-Investigator HAMD Total Mean Change from Baseline at Endpoint



3.2.2 K-SADS-L Depression Subscale

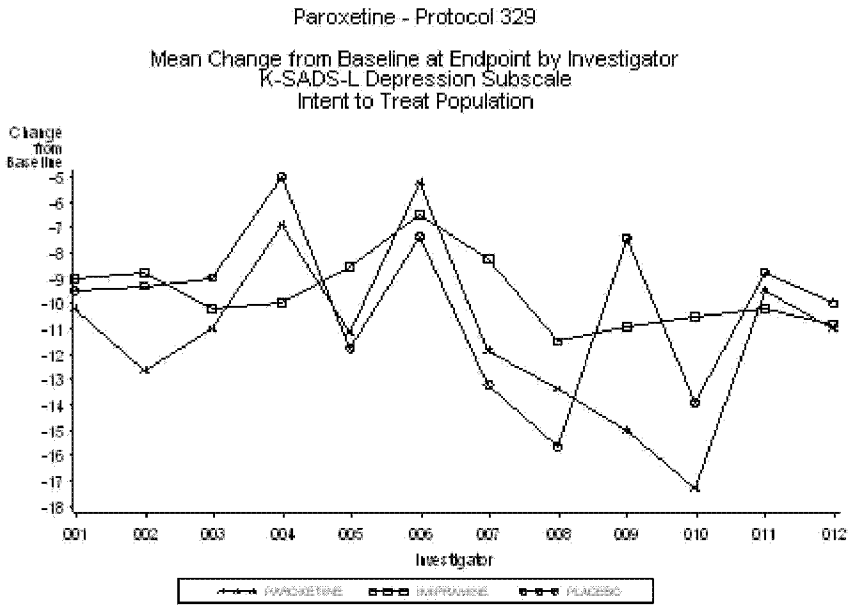
Analysis of the mean change from baseline of the K-SADS-L total yielded no statistically significant treatment by investigator interaction (p=0.965). The baseline treatment effect was also not significant (p=0.164). A reduced model without interaction was used for this analysis. For the calculation of the

K-SADS-L depression subscale, individual missing results were not replaced. The missing items were allowed for by calculating the total as (S/n)x N, where S was the score recorded for n items and N was the number of items which should have been present.

Table 4 ANOVA Table for K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint

Analysis of Variance of Improvement from Baseline at Endpoint						
K-SADS-L Depression Subscale						
Intent-to-Treat Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	87.53	0.79	0.455	
	Investigator	11	542.13	0.89	0.551	
	Treat. by Inv.	22	630.97	0.52	0.965	
	Error	220	12183.12			7.44
Reduced Model	Treatment	2	245.82	2.32	0.100	
	Investigator	11	583.23	1.00	0.446	
	Error	242	12814.09			7.28
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 2 Plot of Treatment-by-Investigator K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint



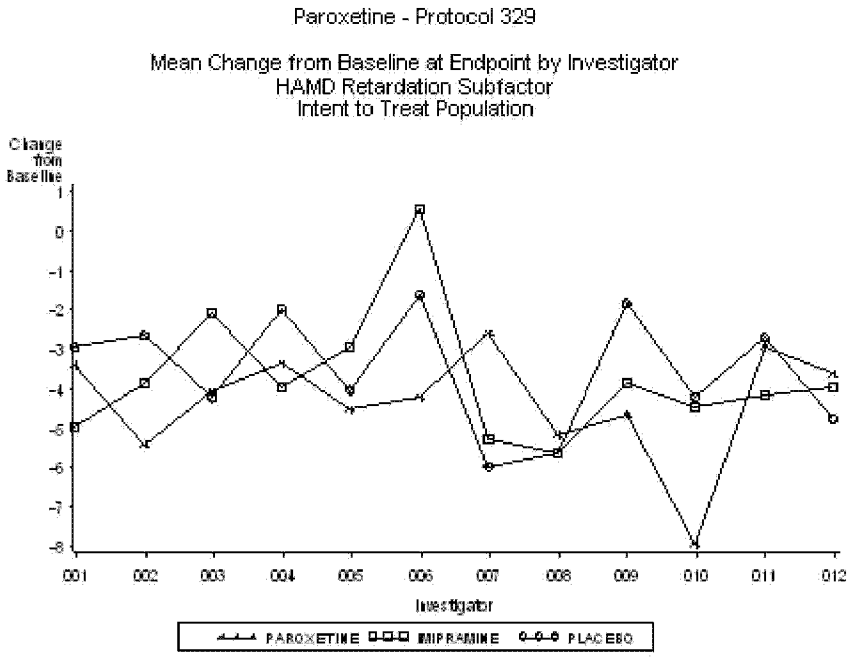
3.2.3 HAMD Retardation Subfactor

The HAMD retardation subfactor was found to have a significant treatment-by-investigator interaction (p=0.042) at endpoint. Treatment by investigator means were plotted. Centers 006, 010, and 007 were investigated for their effect on the interaction. When center 007 was removed, the interaction effect was nonsignificant (p=0.205). There was no reason to believe that the results observed at any center were not accurate. Therefore, the retardation subscale was analyzed with a full model including effects for treatment, investigator, and treatment-by-investigator interaction.

Table 5 ANOVA Table for HAMD Retardation Subfactor Mean Change from Baseline at Endpoint

Analysis of Variance of Improvement from Baseline at Endpoint						
HAMD Retardation Subfactor						
Intent-to-Treat Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	20.89	1.46	0.234	
	Investigator	11	129.34	1.65	0.087	
	Treat. by Inv.	22	255.09	1.62	0.042	
	Error	235	1677.65			2.67
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 3 Plot of Treatment-by-Investigator HAMD Retardation Subfactor Mean Change from Baseline at Endpoint



3.3 Percent Response Model Verification

The percent of patients responding, as defined by HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater was analyzed using categorical modeling methods on a model including treatment and investigator effects.

Due to the small treatment-by-investigator cells by response for some sites, no test of the interaction effect could be made.

3.4 Survival Analysis

Survival analysis was performed for the time to sustained response, defined as response lasting until endpoint of the acute phase. Response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Patients were classified as being a responder or non-responder. Nonresponders were considered as censored values.

Survival analysis was performed for time to sustained response during the acute phase. The test for the model assumptions included effects for treatment and a

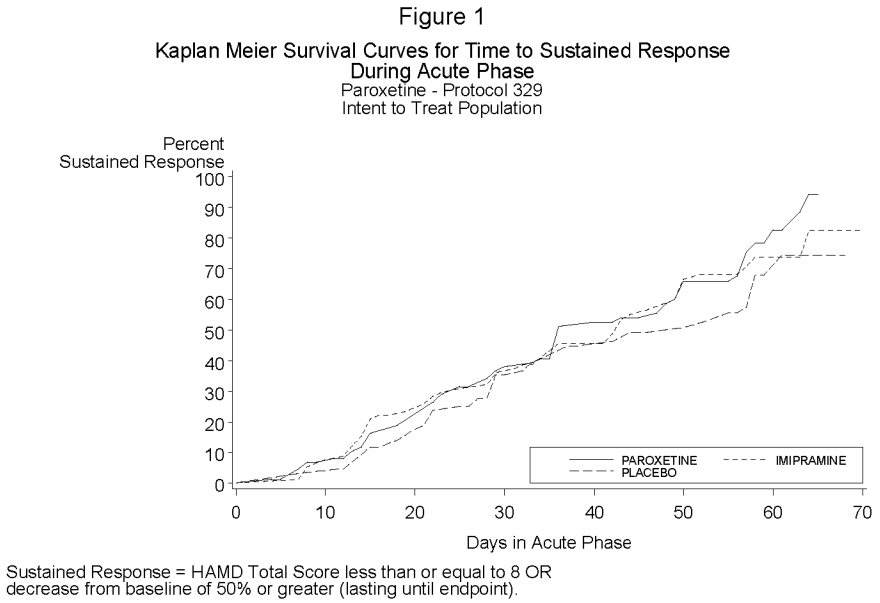
time-dependent variable, *treatment x log(# of days)*. Two treatment effects were included: paroxetine relative to placebo and imipramine relative to placebo. Two time-dependent variables were included similarly. This tests were not significant (p=0.180 and 0.066), thus we conclude that there is no evidence of an increasing or decreasing trend over time in the hazard ratio. Since the model assumptions were met, the analysis was done using a model with the treatment effect.

The results are presented in Table 6. When comparing each active drug to placebo, no significant treatment effect was observed. A plot of the Kaplan Meier curves is also provided below.

Table 6 Survival Analysis of Sustained Response During the Acute Phase

	Par vs Pla	Imp vs Pla
P-value	0.095	0.222
Risk Ratio	1.383	1.273
95% C. I.	(0.946, 2.022)	(0.864, 1.877)

Figure 4 Kaplan Meier Survival Curves for Time to Sustained Response During Acute Phase



3.5 Per Protocol Analyses

An analysis of mean change from baseline in HAMD Total and K-SADS-L Depression subscale at endpoint of the acute phase was performed for the per protocol population.

Similarly to the ITT analyses, the full model at endpoint was tested. The treatment-by-investigator interaction was found to be nonsignificant for both variable. Therefore, for these analyses, a reduced model with effects for treatment and investigator was used.

ANOVA tables are included below which show the results of the full model with interaction and the reduced model without interaction for each variable.

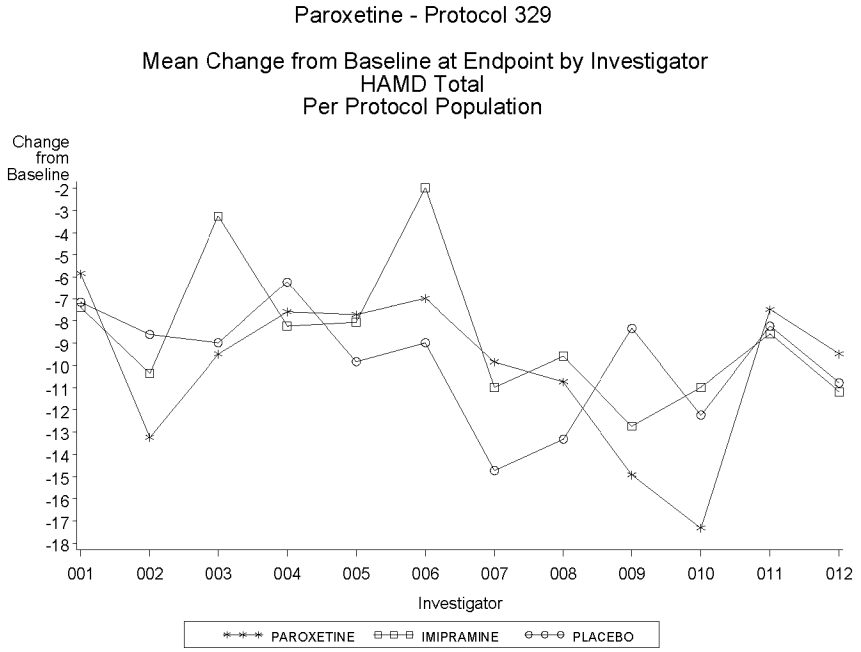
3.5.1 HAMD Total (17 items)

Analysis of the mean change from baseline of the HAMD total yielded no statistically significant treatment by investigator interaction (p=0.850). The baseline treatment effect was also not significant (p=0.290). A reduced model without interaction was used for this analysis.

Table 7 ANOVA Table for HAMD Total Mean Change from Baseline at Endpoint Per Protocol Population

Analysis of Variance of Improvement from Baseline at Endpoint						
HAMD Total (17 items)						
Per Protocol Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	58.73	0.52	0.593	
	Investigator	11	1014.54	1.65	0.088	
	Treat. by Inv.	22	845.99	0.69	0.850	
	Error	205	11479.00			7.48
Reduced Model	Treatment	2	77.29	0.71	0.492	
	Investigator	11	1041.82	1.74	0.065	
	Error	227	12324.98			7.36
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 5 Plot of Treatment-by-Investigator HAMD Total Mean Change from Baseline at Endpoint Per Protocol Population



3.5.2 K-SADS-L Depression Subscale

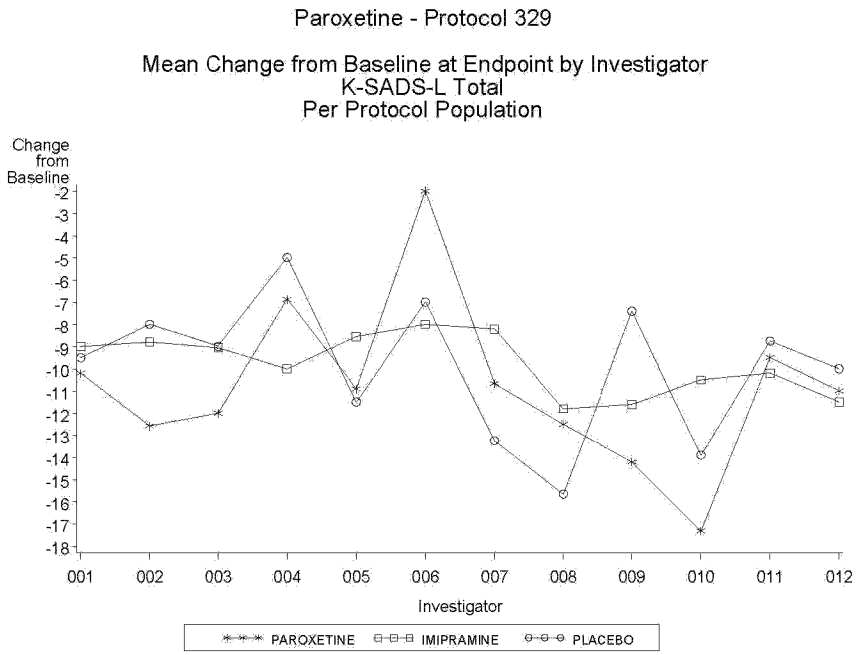
Analysis of the mean change from baseline of the K-SADS-L total yielded no statistically significant treatment by investigator interaction (p=0.975). The

baseline treatment effect was also not significant (p=0.247). A reduced model without interaction was used for this analysis.

Table 8 ANOVA Table for K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint Per Protocol Population

Analysis of Variance of Improvement from Baseline at Endpoint						
K-SADS-L Depression Subscale						
Per Protocol Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	32.77	0.28	0.754	
	Investigator	11	468.09	0.73	0.705	
	Treat. by Inv.	22	622.15	0.49	0.975	
	Error	192	11137.08			7.62
Reduced Model	Treatment	2	185.68	1.69	0.187	
	Investigator	11	619.86	1.03	0.425	
	Error	214	11759.23			4.41
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 6 Plot of Treatment-by-Investigator K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint Per Protocol Population



3.6 Covariate Analyses

3.6.1 Percentage of Responders

The effect of covariates was evaluated using response as defined by the HAMD Total. Logistic analyses were performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. For categorical covariates, analyses were done via the Categorical Modeling (CATMOD) procedure of the SAS system. For continuous covariates (AFC, SPP, SIP, age at first onset, and number of episodes), analyses were done via the Logistic (LOGISTIC) procedure of the SAS system. Given below are the p-values at endpoint for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.28.1). The number and percentage of responders are also presented for each covariate (Table 13.28.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance. Due to the small number of patients without a family history of depression (5-paroxetine, 4-imipramine, 3-placebo), categorical analyses were not performed for this covariate.

To determine the overall treatment effect for logistic analysis of continuous covariates, an indicator variable denoting paroxetine versus placebo and imipramine versus placebo were included as effects. For the interaction effect, each of the treatment comparison indicators was multiplied by the covariate to obtained two interaction effects. The overall interaction p-value was obtained by taking the difference in the log likelihood and degrees of freedom from models with and without the interactions terms and obtaining the p-value from the Chi-Square distribution. The overall treatment effect was obtained in a similar manner by comparing the model without the interaction terms to a model containing only the covariate.

A significant treatment-by-covariate interaction was found for AFC, SIP, age at first onset, and number of episodes. The overall treatment effect was not significant except for the SIP covariate. The overall treatment p-value for each covariate was consistent with the model with no covariate (Table 13.28.1) with the exception of SIP. The significant atypical depression effect should be interpreted as the patients with atypical depression showed more response. The significant melancholic/endogenous subtype effect should be interpreted as the patients not classified as this subtype showed more response.

Table 13.28.1 Summary of Covariate Analysis for Percentage of Responders at Endpoint

Protocol 329

Covariate	Treatment P-value	Covariate P-value	Treatment-by-Covariate P-value
None	0.275	-	-
AFC[2]	0.257	0.101	0.001
SPP[2] excluding interaction	0.129 0.129	0.003 □0.001	0.717
SIP[2]	0.050	□0.001	0.082
Atypical Depression[1] excluding interaction	0.356 0.564	0.023 0.017	0.503
Melancholic/Endogenous Subtype[1] excluding interaction	0.413 0.339	0.025 0.027	0.797
Current Anxiety Disorder[1] excluding interaction	0.116 0.442	0.208 0.068	0.114
Current Comorbid Disorder[1] excluding interaction	0.227 0.352	0.440 0.387	0.436
Age at First Onset of Depression[2]	0.337	0.932	0.034
Number of Major Depressive Episodes[2]	0.352	0.028	0.010

[1] Categorical analysis via logistic analysis (CATMOD) with a model including effects for treatment, covariate, treatment-by-covariate interaction, and study.

[2] Analysis via logistic regression (LOGISTIC) with a model including effects for treatment, covariate, treatment-by-covariate interaction, and study

Table 13.28.2 Summary of Response at Endpoint by Covariate

Covariate		Paroxetine			Imipramine			Placebo		
		n	N	%	n	N	%	n	N	%
None		60	90	66.7	55	94	58.5	48	87	55.2
AFC		48	60	80.0	41	57	71.9	41	62	66.1
SIP		51	63	81.0	42	60	70.0	41	66	62.1
SPP		50	62	80.7	42	60	70.0	41	66	62.1
Atypical Depression	Yes	19	22	86.4	10	15	66.7	6	8	75.0
	No	40	67	59.7	44	77	57.1	42	78	53.9
Melancholic/Endogenous Subtype of Depression	Yes	18	33	54.6	17	33	51.5	17	35	48.6
	No	41	56	73.2	37	60	61.7	31	51	60.8
Current Anxiety Disorder	Yes	9	12	75.0	7	21	33.3	10	21	47.6
	No	50	77	64.9	47	72	65.3	38	65	58.5
Current Comorbid Disorder	Yes	21	30	70.0	20	37	54.1	16	34	47.1
	No	38	59	64.4	34	56	60.7	32	52	61.5
Age at Onset of Depression		59	89	66.3	54	93	58.1	48	86	55.8
Number of Episodes of Major Depressive Disorder		59	89	66.3	54	93	58.1	48	86	55.8
Family History of Major Depressive Disorder	Yes	51	77	66.2	51	84	60.7	44	83	53.0
	No	3	5	60.0	2	4	50.0	3	3	100.0

3.6.2 HAMD Total

An analysis of variance was performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. Analyses were done via the General Linear Models (GLM) procedure of the SAS system. Provided below are the p-values at endpoint for each effect from the type III sums of squares for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.29.1). The sample size, least square means, and standard errors from the analysis of variance are also presented for each covariate (Table 13.29.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance.

As shown in Table 13.29.1, there were two treatment-by-covariate interaction with a p-value □ 0.10. A significant interaction was observed in analyses with the covariate of AFC at endpoint and number of episodes. The significant AFC at endpoint and number of depressive episodes covariates can be interpreted as a significant linear relationship with magnitude of the covariate and magnitude of the HAMD Total at endpoint. The significant atypical depression effect should be interpreted as the patients without atypical depression showed greater improvement. The significant melancholic/ endogenous subtype effect should be interpreted as the patients classified as this subtype showed greater improvement. The significant current anxiety disorder effect should be interpreted as the patients having current anxiety disorder in general showed greater improvement.

Table 13.29.1 Summary of Covariate Analysis for HAMD Total at Endpoint

Protocol 329

Covariate	Treatment P-value	Covariate P-value	Treatment-by-Covariate P-value
None	0.290	-	-
AFC	0.019	0.017	0.013
SPP excluding interaction	0.860 0.327	□0.001 □0.001	0.627
SIP excluding interaction	0.114 0.088	□0.001 □0.001	0.272
Atypical Depression excluding interaction	0.266 0.497	0.010 0.036	0.458
Melancholic/Endogenous Subtype excluding interaction	0.427 0.325	0.014 0.014	0.761
Current Anxiety Disorder excluding interaction	0.094 0.420	0.104 0.040	0.103
Current Comorbid Disorder excluding interaction	0.134 0.333	0.200 0.191	0.107
Age at First Onset of Depression excluding interaction	0.797 0.306	0.229 0.255	0.810
Number of Major Depressive Episodes	0.063	□0.001	0.018
Family History of Major Depressive Disorder excluding interaction	0.897 0.255	0.120 0.160	0.590

Analysis of variance (GLM) with a model including effect for treatment, covariate, treatment-by-covariate interaction, and study.

Table 13.29.2 Summary of HAMD Total at Endpoint by Covariate

Covariate		Paroxetine			Imipramine			Placebo		
		n	mean	s.e.	n	mean	s.e.	n	mean	s.e.
None		90	8.47	0.76	94	9.34	0.75	87	10.18	0.78
AFC		60	6.41	0.82	57	7.46	0.84	62	8.10	0.80
SIP		63	6.42	0.63	60	8.24	0.66	66	7.44	0.63
SPP		62	6.70	0.74	60	7.59	0.75	66	8.26	0.72
Atypical Depression	Yes	22	5.32	1.54	15	8.13	1.86	8	9.50	2.56
	No	67	9.46	0.88	77	9.58	0.82	78	10.21	0.82
Melancholic/Endogenous Subtype of Depression	Yes	33	10.45	1.26	33	10.48	1.26	35	11.26	1.22
	No	56	7.25	0.96	60	8.80	0.93	51	9.37	1.01
Current Anxiety Disorder	Yes	12	7.17	2.08	21	13.00	1.57	21	11.90	1.57
	No	77	8.64	0.82	72	8.35	0.85	65	9.57	0.89
Current Comorbid Disorder	Yes	30	7.60	1.32	37	10.13	1.19	34	12.29	1.24
	No	59	8.86	0.94	56	8.91	0.97	52	8.73	1.00
Age at Onset of Depression		88	8.48	0.78	93	9.39	0.76	86	10.21	0.79
Number of Episodes of Major Depressive Disorder		89	8.62	0.75	93	9.38	0.73	86	10.08	0.76
Family History of Major Depressive Disorder	Yes	77	8.40	0.82	84	9.13	0.79	83	10.43	0.79
	No	5	6.60	3.22	4	7.50	3.61	3	3.67	4.16

3.6.3 KSADS Total

An analysis of variance was also performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. Analyses were done via the General Linear Models (GLM) procedure of the SAS system. Provided below are the p-values at endpoint for each effect from the type III sums of squares for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.30.1). The sample size, least square means, and standard errors from the analysis of variance are also presented for each covariate (Table 13.30.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance.

As shown in Table 13.30.1, there were two treatment-by-covariate interaction with a p-value □ 0.10. A significant interaction was observed in analyses with the covariate of current comorbidity and number of episodes. The significant AFC at endpoint, SPP at endpoint, SIP at endpoint, and number of depressive episodes covariates can be interpreted as a significant linear relationship with magnitude of the covariate and magnitude of the K-SADS-L depressive subscale at endpoint. The significant atypical depression effect should be interpreted as the patients without atypical depression showed greater improvement. The significant melancholic/ endogenous subtype effect should be interpreted as the patients classified as this subtype showed greater improvement.

Table 13.30.1 Summary of Covariate Analysis for KSAD Total at Endpoint

Protocol 329

Covariate	Treatment P-value	Covariate P-value	Treatment-by-Covariate P-value
None	0.058	-	-
AFC excluding interaction	0.212 0.168	0.004 0.006	0.261
SPP excluding interaction	0.670 0.227	□0.001 □0.001	0.359
SIP excluding interaction	0.382 0.097	□0.001 □0.001	0.825
Atypical Depression excluding interaction	0.096 0.182	0.107 0.026	0.452
Melancholic/Endogenous Subtype excluding interaction	0.112 0.092	0.002 0.002	0.833
Current Anxiety Disorder excluding interaction	0.019 0.098	0.540 0.264	0.183
Current Comorbid Disorder	0.014	0.725	0.050
Age at First Onset of Depression excluding interaction	0.580 0.073	0.143 0.153	0.810
Number of Major Depressive Episodes	0.055	0.001	0.010
Family History of Major Depressive Disorder excluding interaction	0.949 0.054	0.104 0.143	0.640

Analysis of variance (GLM) with a model including effect for treatment, covariate, treatment-by-covariate interaction, and study.

Table 13.30.2 Summary of KSAD Total at Endpoint by Covariate

Covariate		Paroxetine			Imipramine			Placebo		
		n	mean	s.e.	n	mean	s.e.	n	mean	s.e.
None		83	16.75	0.85	89	18.00	0.82	85	19.59	0.84
AFC		60	15.39	0.92	57	16.74	0.94	62	17.74	0.91
SIP		63	15.56	0.71	60	17.58	0.75	66	17.08	0.71
SPP		62	15.90	0.84	60	16.72	0.85	66	17.94	0.82
Atypical Depression	Yes	22	13.68	1.64	14	15.43	2.06	7	19.86	2.91
	No	60	17.83	0.99	73	18.51	0.90	77	19.48	0.88
Melancholic/Endogenous Subtype of Depression	Yes	29	18.62	1.42	32	20.50	1.35	35	20.94	1.29
	No	53	15.68	1.05	56	16.63	1.02	49	18.49	1.09
Current Anxiety Disorder	Yes	10	14.3	2.44	19	19.58	1.77	21	21.86	1.68
	No	72	17.06	0.91	69	17.61	0.93	63	18.73	0.97
Current Comorbid Disorder	Yes	25	14.68	1.54	35	17.74	1.06	33	21.48	1.34
	No	57	17.61	1.02	53	18.49	1.30	51	18.24	1.08
Age at Onset of Depression		81	16.80	0.86	88	17.98	0.83	84	19.60	0.85
Number of Episodes of Major Depressive Disorder		82	16.89	0.84	88	18.04	0.81	84	19.45	0.82
Family History of Major Depressive Disorder	Yes	71	16.67	0.93	81	18.16	0.87	81	19.90	0.87
	No	5	15.60	3.49	3	13.33	4.50	3	13.67	4.50

3.7 Confidence Intervals for Efficacy Results at Week 8

The following table provides results for the mean change from baseline in depression related scales and in % responders including the 95% confidence intervals for the treatment difference between active drug and placebo at Week 8 of the observed cases (OC) and last observation carried forward (LOCF) datasets.

Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission

Week 8, ITT Population

	Paroxetine	Imipramine	Placebo	95% Confidence Intervals Paroxetine vs Placebo	Imipramine vs Placebo
Mean Change in HAM-D Total (SEM)					
Wk 8 LOCF	-10.7 □ 0.81	-8.9 □ 0.81	-9.1 □ 0.83	(-3.92, 0.62)	(-2.09, 2.45)
Wk 8 OC	-12.2 □ 0.88	-10.6 □ 0.97	-10.5 □ 0.88	(-4.11, 0.77)	(-2.65, 2.49)
Mean Change HAM-D Depression Item (SEM)					
Wk 8 LOCF	-2.00 □ 0.14	-1.62 □ 0.14	-1.33 □ 0.14	(-1.06, -0.28)	(-0.68, 0.10)
Wk 8 OC	-2.21 □ 0.17	-1.76 □ 0.18	-1.54 □ 0.17	(-1.14, -0.20)	(-0.71, 0.27)
Mean Change in K-SADS-L 9-Item Depression Subscore (SEM)					
Wk 8 LOCF	-11.7 □ 0.84	-9.6 □ 0.83	-9.6 □ 0.83	(-4.40, 0.22)	(-2.28, 2.32)
Wk 8 OC	-12.0 □ 0.93	-10.7 □ 1.02	-10.8 □ 0.93	(-3.74, 1.42)	(-2.52, 2.90)
Mean Change in K-SADS-L Depression Item (SEM)					
Wk 8 LOCF	-2.20 □ 0.18	-1.77 □ 0.18	-1.73 □ 0.19	(-0.97, 0.03)	(-0.54, 0.46)
Wk 8 OC	-2.35 □ 0.20	-2.05 □ 0.22	-1.93 □ 0.20	(-0.97, 0.13)	(-0.70, 0.46)
Mean Clinical Global Improvement Score (SEM)					
Wk 8 LOCF	2.4 □ 0.16	2.7 □ 0.15	2.7 □ 0.16	(-0.80, 0.08)	(-0.46, 0.40)
Wk 8 OC	1.9 □ 0.15	2.2 □ 0.17	2.4 □ 0.16	(-0.88, -0.02)	(-0.66, 0.26)
% Responders (50% □ HAM-D Total or a Score □8)					
Wk 8 LOCF	67% (60/90)	59% (55/94)	55% (48/87)	(-2.8, 25.7)	(-11.1, 17.7)
Wk 8 OC	81% (54/67)	73% (41/56)	65% (43/66)	(0.5, 30.3)	(-8.3, 24.3)
% Responders (CGI Rating of "Very Much Improved" or "Much Improved")					
Wk 8 LOCF	66% (59/90)	52% (49/94)	48% (42/87)	(2.9, 31.7)	(-10.6, 18.4)
Wk 8 OC	79% (53/67)	68% (38/56)	61% (40/66)	(3.2, 33.8)	(-9.7, 24.3)
% Remission (HAM-D Score □ 8)					
Wk 8 LOCF	63% (57/90)	50% (47/94)	46% (40/87)	(2.8, 31.8)	(-10.6, 18.6)
Wk 8 OC	76% (51/67)	64% (36/56)	58% (38/66)	(2.8, 34.2)	(-10.6, 24.0)

Audited Investigator Sites

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SmithKline Beecham

Paroxetine

BRL-029060

List of Audited Investigator Sites

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SB Document Number: BRL-029060/RSD-100V2W/1

Audited Investigator Sites

Worldwide Regulatory Compliance-GCP is an independent function within SmithKline Beecham with responsibility for assuring Company management that clinical trials are organised, performed and reported in compliance with Company protocols and working practices and the requirements of national and international GCP (Good Clinical Practice) guidelines. This is achieved through a combination of study specific audits of investigator sites and audits, at regular intervals, of SmithKline Beecham systems for data handling, reporting and archiving.

Details of the selection of investigators for audit, and the methods of performing and reporting the audits are documented in WRC SOPs.

List of Audited Investigators

Study Number:

Centre No	Investigator	Site Address	Country	Audit Date
005	[redacted]	University of Pittsburgh, Pittsburgh, PA.	USA	16-Sep-97 - 17-Sep-97
009	[redacted]	UT Southwestern at Dallas, TX.	USA	30-July-97 - 1-Aug-97

Appendix B: Patient Data Listings of Demographic

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PAROXETINE - PROTOCOL 329

Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.001.00063	Female	14	No	No	48	20	Adverse event, including intercurrent illness	
329.001.00065	Male	14	No	No	14	20	Adverse event, including intercurrent illness	NEEDED PSYCHIATRIC HOSPITALIZATION FOR INCREASED AGGRESSION AGAINST SELF.
329.001.00068	Female	13	Yes	No	72	40	Lack of Efficacy	
329.001.00072	Male	15	No	No	32	20	Other reason	FAMILY WITHDREW CONSENT.SEE MISCELLANEOUS NOTES.
329.001.00121	Male	15	Yes	No	154	30	Lack of Efficacy	
329.001.00205	Male	12	No	No	8	20	Adverse event, including intercurrent illness	MANIA/HYPOMANIA SYMPTOMS
329.001.00206	Male	16	Yes	No	58	30	Lack of Efficacy	
329.002.00055	Male	13	Yes	No	156	20	Lack of Efficacy	RELAPSE IN CONTINUATION PHASE.
329.002.00058	Female	16	Yes	No	119	40	Adverse event, including intercurrent illness	INTENTIONAL OVERDOSE OF TYLENOL ON 1/19/95.
329.002.00099	Male	15	Yes	Yes	255	20		
329.002.00102	Female	16	Yes	Yes	252	20		
329.002.00105	Male	16	No	No	22	20	Protocol violation, including non-compliance	PATIENT RAN AWAY FROM HOME WITHOUT MEDS. WAS OFF MEDS SEVERAL DAYS BEFORE HE RETURNED HOME. UNABLE TO REACH FAMILY TO RETRIEVE MED PAK/DO WK. 32 VISIT. SEE PROGRESS NOTE FROM WEEK 4
329.002.00106	Female	15	No	No	48	40	Other reason	PT D/C ON OWN -- OPPOSITIONAL DEFIANT DISORDER

* Relative to Start of Study Medication

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.002.00242	Female	15	Yes	No	120	40	Protocol violation, including non-compliance	
329.002.00245	Female	14	No	No	18	20	Adverse event, including intercurrent illness	DOWN TITRATED (PER S. FRITSH, M.D.) 3.A.M. DOSES, LEVEL 1.
329.002.00319	Female	16	Yes	Yes	245	20		
329.003.00075	Female	17	Yes	Yes	240	20		
329.003.00077	Male	16	Yes	No	94	30	Lost to follow-up	JAMES DID NOT ARRIVE FOR MONTH 2VISIT,FAMILY DID NOT RESPOND TO ATTEMPTS TO CONTACT THEM.
329.003.00081	Female	12	Yes	No	59	40	Lack of Efficacy	
329.003.00087	Female	14	No	No	4	20	Other reason	VOLUNTARY WITHDRAWAL
329.003.00089	Female	14	Yes	No	60	20	Adverse event, including intercurrent illness	
329.003.00091	Female	16	Yes	Yes	245	20		
329.003.00248	Female	14	Yes	No	63	30	Lack of Efficacy	
329.003.00250	Female	15	Yes	No	75	30	Adverse event, including intercurrent illness	PT TOOK OVERDOSE & WAS HOSPITALIZED
329.003.00292	Male	16	Yes	No	59	20	Lost to follow-up	
329.003.00313	Male	18	No	No	12	20	Adverse event, including intercurrent illness	PT. WAS DROPPED DUE TO HOSPITALIZATION I.E. ADVERSE EXPERIENCE
329.004.00015	Female	16	Yes	No	203	20	Other reason	CONFLICT BETWEEN SCHOOL AND STUDY
329.004.00017	Female	16	Yes	Yes	238	20		

* Relative to Start of Study Medication

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PAROXETINE - PROTOCOL 329

Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.004.00019	Female	17	No	No	15	20	Lost to follow-up	
329.004.00212	Female	17	No	No	23	20	Protocol violation, including non-compliance	
329.004.00214	Female	15	Yes	No	88	20	Lack of Efficacy	
329.005.00002	Female	14	Yes	No	147	40	Other reason	PT.STOPPED TAKING MEDICATION BECAUSE SHE DIDN'T WANT TO TAKE PILLS ANYMORE
329.005.00004	Male	16	Yes	No	103	30	Other reason	PT. CHOSE TO WITHDRAW.
329.005.00008	Male	12	Yes	No	142	30	Protocol violation, including non-compliance	
329.005.00011	Female	16	Yes	No	156	30	Adverse event, including intercurrent illness	OVERDOSE WITH BAYER EXTRA STRENGTH {INTENTIONAL}
329.005.00109	Female	17	Yes	No	138	20	Protocol violation, including non-compliance	
329.005.00112	Male	13	Yes	No	93	20	Protocol violation, including non-compliance	
329.005.00116	Female	16	Yes	No	155	20	Adverse event, including intercurrent illness	SEVERE POISON IVY-TAKING PREDNISONE
329.005.00119	Female	14	Yes	No	141	30	Protocol violation, including non-compliance	
329.005.00151	Female	14	Yes	Yes	239	20		
329.005.00152	Female	15	No	No	5	20	Adverse event, including intercurrent illness	
329.005.00257	Female	12	Yes	Yes	239	20		
329.005.00258	Female	14	Yes	No	57	30		PT TO HAVE SURGERY UNDER GENERAL ANETHESIA 6/24/96

* Relative to Start of Study Medication

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.005.00299	Female	12	Yes	No	164	20	Lack of Efficacy	PT. REMOVED AT PARENTS REQUEST. PT HAD AN INC IN AFFECTIVE SYMPTOMS AFTER INITIAL IMPROVEMENT
329.005.00300	Male	12	Yes	No	57	20		
329.005.00333	Female	16	No	No	33	20	Lack of Efficacy	
329.005.00336	Female	14	Yes	No	58	20		MEETS CRITERIA FOR ENTRANCE INTO CONTINUATION PHASE BUT NO MEDS ARE AVAILABLE
329.006.00038	Female	15	No	No	57	20	Adverse event, including intercurrent illness	SEVERAL PERSONAL CRISIS LED PATIENT TO OVERDOSE ON SEVERAL MEDICATIONS INCLUDING STUDY MEDICATIONS ON 12APR95-MOVE TO WITHDRAW.
329.006.00039	Female	15	Yes	No	92	20	Lack of Efficacy	
329.006.00260	Female	17	Yes	No	154	20	Protocol violation, including non-compliance	
329.006.00261	Male	17	Yes	No	155	20	Protocol violation, including non-compliance	
329.007.00140	Male	11	Yes	No	69	20	Other reason	PATIENT WENT TO LIVE WITH HIS FATHER.HIS FATHER IS OPPOSED TO MEDICATION TREATMENT FOR DEPRESSION,FATHER WITHDREW CONSENT.
329.007.00142	Male	15	No	No	48	40	Lack of Efficacy	MOTHER WANTS PATIENT TO BE WITHDRAWN BECAUSE HIS DEPRESSION HAS NOT IMPROVED AT MAXIMUM DOSAGE.
329.007.00145	Male	16	Yes	Yes	226	20		

* Relative to Start of Study Medication

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.007.00265	Female	16	No	No	15	20	Lost to follow-up	NONCOMPLIANCE WITH MAKING STUDY APPOINTMENTS
329.007.00268	Female	13	Yes	Yes	262	20		
329.007.00294	Female	15	No	No	42	20	Lack of Efficacy	
329.007.00309	Female	18	Yes	Yes	255	20		DATE OF DOWN TITRATION VISIT
329.007.00310	Female	16	Yes	Yes	271	20		
329.007.00318	Male	13	No	No	1	20	Lost to follow-up	
329.008.00157	Male	15	Yes	No	174	20	Other reason	PATIENT DROPPED OUT. PT. FELT NO FURTHER NEED FOR MEDICATION BECAUSE HE IS DOING WELL.
329.008.00160	Female	14	Yes	Yes	281	20		
329.008.00188	Female	17	Yes	No	55	40	Protocol violation, including non-compliance	
329.008.00271	Female	13	Yes	Yes	255	20		
329.008.00275	Male	14	Yes	Yes	223	30		
329.009.00130	Male	15	Yes	No	182	20	Protocol violation, including non-compliance	
329.009.00131	Female	16	Yes	No	118	20	Protocol violation, including non-compliance	
329.009.00133	Female	16	No	No	45	40	Lost to follow-up	PT DECIDED TO STOP STUDY HERSELF NOT FOR LACK OF EFFICACY,PT WAS LOST TO FU
329.009.00138	Female	13	No	No	4	20	Other reason	PATIENT WITHDREW CONSENT
329.009.00170	Female	14	Yes	Yes	245	20		

* Relative to Start of Study Medication

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Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.009.00173	Female	12	Yes	No	100	20	Lack of Efficacy	
329.009.00193	Female	12	Yes	No	71	20	Lack of Efficacy	
329.009.00196	Female	17	Yes	No	70	20	Other reason	PATIENT WITHDREW CONSENT
329.009.00201	Male	14	Yes	No	59	20	Adverse event, including intercurrent illness	PHYSICIAN DISCRETIONS DUE TO IRREGULAR PARANOID BEHAVIOR
329.009.00204	Male	12	Yes	No	211	20	Lost to follow-up	
329.009.00235	Female	12	Yes	No	130	20	Lack of Efficacy	
329.009.00240	Male	14	No	No	51	30	Adverse event, including intercurrent illness	
329.009.00303	Male	17	Yes	Yes	265	20		
329.009.00304	Male	16	Yes	No	210	20	Other reason	PATIENT WITHDREW CONSENT
329.009.00324	Female	13	Yes	No	73	20	Adverse event, including intercurrent illness	RASH DEVELOPED BETWEEN WEEK 7 & 8
329.009.00328	Male	14	No	No	1	20	Other reason	WITHDREW CONSENT
329.009.00329	Male	14	Yes	No	70	30	Lack of Efficacy	
329.010.00182	Male	18	No	No	32	20	Lost to follow-up	
329.010.00278	Female	17	Yes	Yes	240	20		
329.010.00280	Female	13	Yes	No	74	40	Protocol violation, including non-compliance	PT. HAS SOME SYMPTOMS OF CONDUCT DISORDER AND OPPOSITIONAL DEFIANT DISORDER AND REFUSED TO PARTICIPATE FURTHER. PT.'S DEPRESSION DID RESPOND DURING TREATMENT, BUT HER OTHER PROBLEMS SEEMED TO WORSEN.

* Relative to Start of Study Medication

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PAROXETINE - PROTOCOL 329

Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.011.00283	Male	16	Yes	No	58	20	Protocol violation, including non-compliance	
329.011.00288	Male	15	No	No	43	20	Lack of Efficacy	PATIENT NO LONGER WANTS TO PARTICIPATE IN STUDY.
329.012.00025	Female	14	Yes	No	73	30	Lack of Efficacy	
329.012.00220	Male	15	Yes	No	159	30	Other reason	WITHDREW CONSENT
329.012.00222	Female	15	Yes	No	86	30	Other reason	NON-COMPLIANCE WITHDREW CONSENT
329.012.00226	Male	15	No	No	18	20	Adverse event, including intercurrent illness	
329.012.00228	Female	15	No	No	4	20	Protocol violation, including non-compliance	
329.012.00231	Female	16	Yes	No	165	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.001.00061	Female	16	No	No	48	200	Adverse event, including intercurrent illness	
329.001.00066	Female	17	No	No	22	100	Adverse event, including intercurrent illness	
329.001.00067	Male	14	No	No	22	100	Adverse event, including intercurrent illness	
329.001.00070	Male	12	No	No	31	150	Adverse event, including intercurrent illness	
329.001.00122	Male	15	Yes	No	182	200	Lack of Efficacy	
329.002.00050	Male	16	No	No	35	150	Adverse event, including intercurrent illness	MULTIPLE SIDE EFFECTS-INCREASED HEART RATE URINARY HESITANCY DIZZINESS
329.002.00056	Female	17	No	No	36	150	Adverse event, including intercurrent illness	INCREASED HEART RATE
329.002.00057	Female	15	Yes	No	129	50	Adverse event, including intercurrent illness	PT. BECAME PREGNANT
329.002.00098	Female	16	Yes	No	73	250	Lack of Efficacy	NOT RESPONDING TO TREATMENT AND DISCOMFORT DUE TO POSSIBLE SIDE EFFECTS.
329.002.00100	Male	15	Yes	No	85	250	Protocol violation, including non-compliance	
329.002.00103	Female	14	Yes	No	128	50	Lack of Efficacy	RELAPSE OF DEPRESSED SYMPTOMS AND SUICIDAL IDEATION.
329.002.00104	Male	13	Yes	Yes	259	50		
329.002.00243	Female	15	No	No	23	150	Adverse event, including intercurrent illness	HIT HEAD DURING A FALL
329.002.00244	Female	17	Yes	No	84	50	Lack of Efficacy	

* Relative to Start of Study Medication

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.002.00321	Male	14	No	No	12	50	Adverse event, including intercurrent illness	PT WAS HOSPITALIZED ON 6-2-96 AT BRADLEY HOSPITAL FOLLOWING ASSAULTIVE BEHAVIOR NO DOWN TITRATION SINCE PT WAS ONLY ON LEVEL 1.
329.002.00322	Male	14	No	No	46	200	Adverse event, including intercurrent illness	ORTHOSTATIC SIDE EFFECTS
329.003.00073	Female	16	No	No	45	250	Adverse event, including intercurrent illness	
329.003.00076	Female	16	Yes	Yes	240	200		
329.003.00079	Female	15	No	No	17	150	Other reason	PATIENT WITHDREW BY OWN VOLITION
329.003.00082	Female	17	No	No	38	250	Lost to follow-up	
329.003.00088	Female	15	No	No	41	200	Adverse event, including intercurrent illness	URINARY RETENTION
329.003.00090	Female	13	Yes	No	69	150	Lack of Efficacy	
329.003.00092	Female	12	Yes	Yes	261	50		
329.003.00093	Female	17	Yes	No	80	300	Protocol violation, including non-compliance	
329.003.00247	Male	16	Yes	No	111	200	Protocol violation, including non-compliance	CHOSE TO LEAVE STUDY EARLY
329.003.00249	Female	17	Yes	No	62	250	Lack of Efficacy	
329.003.00289	Female	16	Yes	Yes	238	50		
329.003.00290	Male	17	No	No	12	100	Adverse event, including intercurrent illness	HIGH BLOOD PRESSURE

* Relative to Start of Study Medication

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.003.00314	Female	15	Yes	No	77	250	Protocol violation, including non-compliance	
329.003.00317	Female	16	Yes	No	70	250	Lack of Efficacy	
329.004.00013	Male	17	Yes	Yes	248	50		
329.004.00014	Male	14	No	No	15	100	Adverse event, including intercurrent illness	
329.004.00211	Female	18	No	No	49	200	Adverse event, including intercurrent illness	DEHYDTRATION POST NAUSEA AND VOMITTING/DIARRHEA DUE TO BACTERIA GASTROENTERITIS RESULTED IN SEVERE DEHYDRATION AND MOUTH SORES/CUTS
UNABLE TO								TOLERATE SIDE EFFECTS OF DRY MOUTH.
329.004.00215	Female	14	No	No	40	200	Adverse event, including intercurrent illness	
329.005.00003	Female	13	No	No	15	100	Adverse event, including intercurrent illness	
329.005.00006	Male	17	Yes	No	175	50	Adverse event, including intercurrent illness	
329.005.00007	Female	15	Yes	No	192	250	Adverse event, including intercurrent illness	
329.005.00009	Female	16	Yes	No	73	250	Lack of Efficacy	
329.005.00110	Female	17	No	No	9	100	Adverse event, including intercurrent illness	POSITIVE PREGNANCY TEST
329.005.00113	Female	15	No	No	32	200	Adverse event, including intercurrent illness	
329.005.00117	Female	16	Yes	No	70	200	Lack of Efficacy	

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.005.00118	Male	15	No	No	50	250	Protocol violation, including non-compliance	POSITIVE DRUG SCREEN
329.005.00153	Female	18	Yes	Yes	236	50		
329.005.00255	Female	15	Yes	No	71	200	Lack of Efficacy	
329.005.00256	Female	16	Yes	No	135	50	Other reason	PT CHOSING TO WITHDRAW AS SHE WANTS TO BEGIN KNOWN MED THERAPY
329.005.00295	Female	13	Yes	No	69	250	Adverse event, including intercurrent illness	INVESTIGATOR'S DECISION TO DISCONTINUE STUDY BECAUSE PT. THREATENED TO KILL PARENTS.
329.005.00297	Male	18	No	No	26	200	Protocol violation, including non-compliance	
329.005.00332	Male	17	Yes	No	72	250	Lack of Efficacy	
329.005.00335	Female	15	Yes	No	68	150	Lack of Efficacy	
329.006.00040	Female	18	No	No	14	50	Adverse event, including intercurrent illness	FATIGUE,EYE DILATION,MEDICATION REACTION
329.006.00041	Male	18	Yes	Yes	245	50		
329.007.00139	Female	12	No	No	18	100	Adverse event, including intercurrent illness	CHEST PAIN-RESOLVED ON FOLLOW-UP ASSOCIATED WITH SHORTNESS OF BREATH
329.007.00143	Female	13	No	No	23	100	Adverse event, including intercurrent illness	ACNE
329.007.00146	Female	15	Yes	Yes	241	50		
329.007.00269	Male	15	No	No	15	100	Adverse event, including intercurrent illness	TACHYCARDIA,NEGATIVE/LOW T-WAVES

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.007.00270	Male	15	No	No	43	200	Adverse event, including intercurrent illness	CHEST PAIN, CHEST TIGHTNESS, SHORTNESS OF BREATH (PAGE 227, SECOND COL.)
329.007.00307	Female	15	No	No	36	200	Adverse event, including intercurrent illness	MORBILLIFORM
329.007.00308	Male	14	No	No	10	50	Protocol violation, including non-compliance	PATIENT RAN AWAY FROM HOME.
329.008.00159	Female	16	Yes	No	134	200	Protocol violation, including non-compliance	PATIENT DROPPED OUT, DUE TO NON COMPLIANCE.
329.008.00161	Male	17	Yes	No	56	200	Lost to follow-up	
329.008.00187	Female	16	Yes	No	73	200	Lack of Efficacy	PATIENT DEMONSTRATED NO SIGNIFICANT IMPROVEMENT.
329.008.00192	Male	13	No	No	38	200	Protocol violation, including non-compliance	
329.008.00272	Male	12	Yes	No	169	200	Protocol violation, including non-compliance	
329.008.00273	Female	12	Yes	No	116	300	Adverse event, including intercurrent illness	
329.009.00127	Female	12	No	No	47	200	Adverse event, including intercurrent illness	NONCOMPLIANT SECONDARY TO NAUSEA
329.009.00132	Male	12	Yes	No	167	50	Lack of Efficacy	
329.009.00134	Female	15	Yes	No	66	150	Adverse event, including intercurrent illness	PATIENT WITHDRAWN FOR TACHYCARDIA&INCREASED QT/QTC
329.009.00137	Male	14	Yes	No	68	150		TEAM FELT THAT DUE TO CONTINUING ADHD SYMPTOMS PATIENT NEEDED TREATMENT WITH STIMULANT

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Appendix B.1

Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.009.00171	Female	16	No	No	8	50	Adverse event, including intercurrent illness	MACULAR RASH
329.009.00172	Female	13	Yes	Yes	251	50		
329.009.00194	Male	12	Yes	No	184	200	Adverse event, including intercurrent illness	
329.009.00195	Female	14	No	No	36	150	Adverse event, including intercurrent illness	CARDIAC ARRHYTHYMIA(PVC'S)
329.009.00199	Female	14	Yes	No	71	200	Protocol violation, including non-compliance	
329.009.00203	Female	12	No	No	33	100	Adverse event, including intercurrent illness	BORDERLINE PROLONGED QT-QTC 1ST DEGREE AV BLOCK
329.009.00236	Female	13	No	No	41	200	Adverse event, including intercurrent illness	
329.009.00239	Female	16	Yes	No	147	200	Protocol violation, including non-compliance	PT. STOPPED MEDS ON OWN.
329.009.00262	Male	13	Yes	No	69	200	Lack of Efficacy	
329.009.00264	Female	14	Yes	No	65	200	Lack of Efficacy	
329.009.00301	Male	17	Yes	No	97	50	Other reason	WITHDREW CONSENT
329.009.00305	Male	14	Yes	Yes	261	50		
329.009.00325	Female	15	Yes	No	124	50	Lack of Efficacy	
329.009.00326	Male	13	Yes	No	115	50	Lack of Efficacy	THIS WAS PATIENTS ACTUD LAST VISIT TO CLINIC PATIENT WAS GIVEN DOWN TITRATION MEDS, FINISHED ON 28 DEC 96 BUT DID NOT RETURN TO CLINIC - MAILED MED PACKET TO US

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Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.010.00279	Female	13	Yes	Yes	246	50		
329.010.00281	Male	13	Yes	No	178	50	Adverse event, including intercurrent illness	
329.011.00163	Female	15	No	No	28	200	Adverse event, including intercurrent illness	WHEN PT.GOT SICK,THEY STOPPED GIVING MED.WITHOUT CONTACTING ANYONE.
329.011.00208	Male	13	Yes	No	79	50	Adverse event, including intercurrent illness	TOXIC IMIPRAMINE LEVEL (592)
329.011.00209	Male	12	Yes	No	100	250	Other reason	PATIENT WITHDREW CONSENT
329.011.00284	Male	17	Yes	No	138	250	Protocol violation, including non-compliance	STOPPED TAKING MEDS. WITHOUT NOTIFICATION OR DOWN TITRATION
329.011.00286	Female	15	Yes	No	209	300	Lost to follow-up	
329.012.00026	Male	14	No	No	8	100	Protocol violation, including non-compliance	
329.012.00219	Male	14	Yes	Yes	233	200		
329.012.00221	Male	17	Yes	No	132	200	Adverse event, including intercurrent illness	MINOR OVERDOSE OF LORAZEPAM AND WITHDREW CONSENT TO STUDY. REFUSED DOWN-TITRATION
329.012.00223	Female	13	No	No	44	150	Lack of Efficacy	PT WISHED TO WITHDRAW FROM THE STUDY TO BE TREATED OPENLY.
329.012.00227	Male	16	Yes	Yes	260	50		
329.012.00230	Male	15	Yes	No	88	50	Other reason	WITHDREW CONSENT.

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Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.001.00062	Female	15	No	No	27	0	Protocol violation, including non-compliance	PATIENT REFUSED FURTHER MEDICATION.
329.001.00064	Male	13	Yes	No	152	0	Lack of Efficacy	
329.001.00069	Male	16	Yes	No	62	0	Lack of Efficacy	NON RESPONDER
329.001.00071	Female	13	Yes	No	71	0	Lack of Efficacy	
329.001.00123	Female	16	No	No	49	0	Lack of Efficacy	
329.001.00207	Male	14	Yes	No	58	0	Lack of Efficacy	NON RESPONDER
329.002.00049	Male	15	Yes	No	74	0	Lack of Efficacy	
329.002.00059	Male	17	Yes	No	73	0	Lack of Efficacy	NON-RESPONSE TO TREATMENT
329.002.00060	Female	14	Yes	No	85	0	Lack of Efficacy	PT.FELT MEDICATION WASN'T WORKING
329.002.00097	Female	13	Yes	Yes	261	0		
329.002.00101	Male	16	Yes	No	106	0	Protocol violation, including non-compliance	MARIJUANA USE WITH POSITIVE URINE SCREEN, SEE LAB PG. ON WEEK 12 AND SEE A.E. PG. 408.
329.002.00107	Female	15	Yes	Yes	258	0		
329.002.00241	Male	15	Yes	No	108	0	Adverse event, including intercurrent illness	PT HOSPITALIZED DUE TO HOMICIDAL / SUICIDAL IDEATION
329.002.00246	Female	17	Yes	No	72	0	Lack of Efficacy	
329.002.00320	Female	13	Yes	No	146	0	Lack of Efficacy	ESCALATING DEPRESSIVE SYMPTOMS
329.002.00323	Female	17	Yes	Yes	227	0		
329.003.00074	Male	13	Yes	Yes	274	0		
329.003.00078	Female	17	Yes	No	64	0	Lack of Efficacy	

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Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.003.00080	Female	16	Yes	No	75	0	Lack of Efficacy	
329.003.00085	Female	17	Yes	No	71	0	Lack of Efficacy	
329.003.00086	Female	14	Yes	Yes	279	0		
329.003.00094	Female	13	Yes	No	73	0	Lack of Efficacy	
329.003.00251	Female	17	No	No	13	0	Lost to follow-up	
329.003.00252	Female	14	Yes	No	70	0	Lack of Efficacy	
329.003.00291	Female	16	Yes	No	120	0	Lost to follow-up	
329.003.00315	Female	16	Yes	No	60	0		PT. DID NOT WANT TO CONTINUE
329.003.00316	Female	16	Yes	No	64	0	Lack of Efficacy	
329.004.00016	Male	17	No	No	38	0	Lack of Efficacy	
329.004.00018	Female	17	Yes	No	73	0	Other reason	PATIENT WANTED TO TERMINATE,DID NOT WISH TO BE ON MEDICATION
329.004.00020	Female	14	No	No	16	0	Protocol violation, including non-compliance	
329.004.00213	Female	15	Yes	Yes	241	0		
329.005.00001	Female	16	Yes	No	70	0	Lack of Efficacy	-MINIMAL IMPROVEMENT OF DEPRESSION SYMPTOMS
329.005.00005	Female	13	No	No	9	0	Adverse event, including intercurrent illness	ELEVATED HEART RATE ON LEVEL ONE
329.005.00010	Female	16	Yes	Yes	255	0		
329.005.00012	Female	14	Yes	No	165	0	Adverse event, including intercurrent illness	RECURRENCE OF OCULAR TAXOPLASMOSIS

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Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.005.00111	Female	16	Yes	No	110	0	Adverse event, including intercurrent illness	
329.005.00114	Male	16	Yes	No	98	0	Lack of Efficacy	DEPRESSIVE SYMPTOMS RETURNED AFTER GIRLFRIEND BROKE UP WITH HIM.RETURN MAJOR DEPRESSIVE DISORDER SYMPTOMS.
329.005.00115	Female	18	Yes	No	75	0	Other reason	PT. REPORTS FEELING BETTER AND DOES NOT WANT TO TAKE MEDICATION ANY LONGER.
329.005.00120	Male	13	Yes	No	58	0	Lack of Efficacy	DIDN'T RETURN TAPER PACK ALTHOUGH MOM REPORTED THAT HE COMPLETED TAPER PACK DURING A PHONE CONVERSATION.THEY THEN MOVED OUT OF STATE.
329.005.00253	Female	16	Yes	No	56	0	Lack of Efficacy	
329.005.00254	Female	16	Yes	Yes	258	0		
329.005.00293	Female	16	Yes	No	57	0		STUDY MEDICATION FOR PHASE II UNAVAILABLE
329.005.00298	Female	13	Yes	Yes	248	0		
329.005.00331	Female	15	Yes	No	57	0		DRUG SUPPLIES NOT AVAILABLE FROM SKB
329.005.00334	Female	13	Yes	No	56	0		LACK OF STUDY MEDICATION AVAILABLE
329.006.00037	Female	17	No	No	25	0	Protocol violation, including non-compliance	LOST INTEREST,PATIENT HAS REFUSED FOLLOW-UP SAFETY EVALUATION AND ASSISTANCE WITH REFERRAL
329.006.00042	Male	18	Yes	Yes	238	0		

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Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.006.00259	Male	17	Yes	No	71	0	Lack of Efficacy	
329.007.00141	Male	13	No	No	22	0	Adverse event, including intercurrent illness	PHYSICIAN DISCRETION DUE TO COMPARATOR ARM,VIS-A-VIS AE OF CHEST PAIN.
329.007.00144	Female	12	Yes	No	57	0	Lost to follow-up	
329.007.00266	Female	12	Yes	No	71	0		PATIENT MOVING OUT OF STATE FOR SUMMER.
329.007.00267	Male	16	Yes	No	56	0	Protocol violation, including non-compliance	POSITIVE MULTIPLE DRUG SCREENS,MULTIPLES GIVEN PER JIM MCCAFERTY.
329.007.00311	Male	15	Yes	No	204	0	Lack of Efficacy	*DATE OF FOLLOW-UP VISIT AFTER TAPER FINISHED.
329.008.00158	Female	16	Yes	No	106	0	Protocol violation, including non-compliance	PATIENT DROPPED OUT. PT WAS DROPPED BECAUSE OF NON COMPLIANCE.
329.008.00162	Female	16	Yes	Yes	260	0		
329.008.00191	Female	17	Yes	No	134	0	Other reason	MOVED OUT OF STATE
329.009.00128	Male	13	No	No	22	0	Adverse event, including intercurrent illness	RIGHT BBB
329.009.00129	Male	16	No	No	36	0	Lack of Efficacy	PATIENT DOING SOME WHAT WORSE-MOTHER ANXIOUS ABOUT INCREASE DEATH WISHES
329.009.00135	Female	17	No	No	49	0	Lack of Efficacy	
329.009.00136	Female	14	Yes	No	70	0	Lack of Efficacy	
329.009.00169	Male	13	Yes	No	97	0	Adverse event, including intercurrent illness	

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Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.009.00174	Female	15	Yes	No	85	0	Lack of Efficacy	PT.HAD RELAPSE-NEEDED TX
329.009.00197	Male	12	Yes	Yes	248	0		
329.009.00198	Female	17	Yes	No	68	0	Lack of Efficacy	
329.009.00200	Female	17	No	No	57	0	Lack of Efficacy	
329.009.00202	Female	15	No	No	36	0	Protocol violation, including non-compliance	PATIENT WAS NON-COMPLIANT DUE TO POSITIVE DRUG SCREEN
329.009.00237	Male	17	No	No	9	0	Protocol violation, including non-compliance	
329.009.00238	Female	16	Yes	No	69	0	Lack of Efficacy	
329.009.00276	Male	13	Yes	No	71	0	Lack of Efficacy	ALTHOUGH IMPROVED REMAINS SYMPTOMATIC
329.009.00302	Male	17	No	No	15	0	Adverse event, including intercurrent illness	PATIENT WAS WITHDRAWN DUE TO MACULOPAPULAR RASH,SINUS BRADYCARDIA WITH ARRHYTHMIA AND JUNCTIONAL ESCAPE PATTERN
329.009.00306	Female	14	Yes	No	70	0	Lack of Efficacy	
329.009.00312	Female	17	Yes	No	78	0	Lack of Efficacy	
329.009.00327	Female	16	No	No	50	0	Lack of Efficacy	
329.009.00330	Male	12	No	No	15	0	Adverse event, including intercurrent illness	
329.010.00183	Male	14	No	No	18	0	Protocol violation, including non-compliance	
329.010.00263	Male	18	Yes	No	72	0		PT. DOES NOT FEEL HE CAN BE COMPLIANT FOR NEXT SIX MONTHS. ALSO DOES NOT WANT TO TAKE THAT MANY PILLS ANYMORE.

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Listing of Patient Terminations by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
329.010.00277	Female	14	Yes	No	113	0	Protocol violation, including non-compliance	
329.010.00282	Female	15	Yes	No	79	0		CONTINUATION PHASE MEDICATION IS NOT AVAILABLE.
329.011.00164	Male	15	No	No	36	0	Protocol violation, including non-compliance	
329.011.00210	Female	14	Yes	No	67	0	Lost to follow-up	
329.011.00285	Male	16	Yes	No	75	0	Lack of Efficacy	
329.011.00287	Female	14	Yes	No	70	0		DID NOT WANT TO CONTINUE
329.012.00027	Male	15	No	No	37	0	Other reason	EARLY WITHDRAWAL-WK 4VISIT PATIENT CHOSE TO WITHDRAW FROM STUDY BECAUSE HE WANTS TO BE TREATED BY PRIMARY THERAPIST AND WANTS TO BE ABLE TO TAKE OTHER MEDICATIONS LIKE LORAZEPAM.
329.012.00217	Female	14	No	No	25	0	Adverse event, including intercurrent illness	ABIVALENCE ABOUT MEDICATION,VIRAL ILLNESS,MEDICATION ON IP'S ADVICE,HOSPITALIZATION TO PSYCHIATRY,AND WANTING TO KNOW WHICH MED SHE WAS ON.
329.012.00218	Female	17	Yes	No	108	0	Other reason	WISHED TO DISCONTINUE STUDY MEDICATION, FEELS SHE CAN DO WELL WITHOUT "PILLS".
329.012.00224	Female	14	Yes	No	167	0	Protocol violation, including non-compliance	
329.012.00225	Male	14	Yes	Yes	258	0		

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Appendix B.2

Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Age (Years)	Sex	Race
329.001.00063	14	Female	Caucasian
329.001.00065	14	Male	Caucasian
329.001.00068	13	Female	Caucasian
329.001.00072	15	Male	Caucasian
329.001.00121	15	Male	Caucasian
329.001.00205	12	Male	Caucasian
329.001.00206	16	Male	Caucasian
329.002.00055	13	Male	Caucasian
329.002.00058	16	Female	Caucasian
329.002.00099	15	Male	Caucasian
329.002.00102	16	Female	Caucasian
329.002.00105	16	Male	WHITE/HISPANIC
329.002.00106	15	Female	Caucasian
329.002.00242	15	Female	Caucasian
329.002.00245	14	Female	Caucasian
329.002.00319	16	Female	Caucasian
329.003.00075	17	Female	HISPANIC
329.003.00077	16	Male	HISPANIC
329.003.00081	12	Female	HISPANIC
329.003.00087	14	Female	Caucasian
329.003.00089	14	Female	Caucasian

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Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Age (Years)	Sex	Race
329.003.00091	16	Female	Caucasian
329.003.00248	14	Female	Caucasian
329.003.00250	15	Female	Black
329.003.00292	16	Male	MONGOLOID (KOREAN)
329.003.00313	18	Male	HISPANIC
329.004.00015	16	Female	Caucasian
329.004.00017	16	Female	EAST INDIAN
329.004.00019	17	Female	Caucasian
329.004.00212	17	Female	Caucasian
329.004.00214	15	Female	Caucasian
329.005.00002	14	Female	Caucasian
329.005.00004	16	Male	Caucasian
329.005.00008	12	Male	Caucasian
329.005.00011	16	Female	Caucasian
329.005.00109	17	Female	Black
329.005.00112	13	Male	Caucasian
329.005.00116	16	Female	Caucasian
329.005.00119	14	Female	Caucasian
329.005.00151	14	Female	Caucasian
329.005.00152	15	Female	Caucasian
329.005.00257	12	Female	Caucasian

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Appendix B.2

Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Age (Years)	Sex	Race
329.005.00258	14	Female	Caucasian
329.005.00299	12	Female	Caucasian
329.005.00300	12	Male	Caucasian
329.005.00333	16	Female	Caucasian
329.005.00336	14	Female	Caucasian
329.006.00038	15	Female	Caucasian
329.006.00039	15	Female	Caucasian
329.006.00260	17	Female	Caucasian
329.006.00261	17	Male	LATINO - MEXICO
329.007.00140	11	Male	Caucasian
329.007.00142	15	Male	Caucasian
329.007.00145	16	Male	Black
329.007.00265	16	Female	HISPANIC
329.007.00268	13	Female	Caucasian
329.007.00294	15	Female	Caucasian
329.007.00309	18	Female	Caucasian
329.007.00310	16	Female	Caucasian
329.007.00318	13	Male	Caucasian
329.008.00157	15	Male	Caucasian
329.008.00160	14	Female	Caucasian
329.008.00188	17	Female	NATIVE AMERICAN

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Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Age (Years)	Sex	Race
329.008.00271	13	Female	Caucasian
329.008.00275	14	Male	Caucasian
329.009.00130	15	Male	Oriental
329.009.00131	16	Female	Caucasian
329.009.00133	16	Female	Caucasian
329.009.00138	13	Female	Caucasian
329.009.00170	14	Female	Caucasian
329.009.00173	12	Female	Black
329.009.00193	12	Female	Caucasian
329.009.00196	17	Female	Black
329.009.00201	14	Male	Caucasian
329.009.00204	12	Male	Caucasian
329.009.00235	12	Female	Caucasian
329.009.00240	14	Male	Caucasian
329.009.00303	17	Male	Caucasian
329.009.00304	16	Male	Caucasian
329.009.00324	13	Female	Caucasian
329.009.00328	14	Male	Caucasian
329.009.00329	14	Male	Caucasian
329.010.00182	18	Male	Caucasian
329.010.00278	17	Female	Caucasian

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PAROXETINE - PROTOCOL 329

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Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Age (Years)	Sex	Race
329.010.00280	13	Female	Caucasian
329.011.00283	16	Male	Caucasian
329.011.00288	15	Male	Caucasian
329.012.00025	14	Female	Caucasian
329.012.00220	15	Male	Caucasian
329.012.00222	15	Female	Caucasian
329.012.00226	15	Male	Caucasian
329.012.00228	15	Female	Caucasian
329.012.00231	16	Female	Caucasian

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Appendix B.2

Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Age (Years)	Sex	Race
329.001.00061	16	Female	Caucasian
329.001.00066	17	Female	Caucasian
329.001.00067	14	Male	Caucasian
329.001.00070	12	Male	Caucasian
329.001.00122	15	Male	Caucasian
329.002.00050	16	Male	Caucasian
329.002.00056	17	Female	Caucasian
329.002.00057	15	Female	Caucasian
329.002.00098	16	Female	Caucasian
329.002.00100	15	Male	Caucasian
329.002.00103	14	Female	Caucasian
329.002.00104	13	Male	Caucasian
329.002.00243	15	Female	Caucasian
329.002.00244	17	Female	Caucasian
329.002.00321	14	Male	Caucasian
329.002.00322	14	Male	Caucasian
329.003.00073	16	Female	Caucasian
329.003.00076	16	Female	HISPANIC
329.003.00079	15	Female	Caucasian
329.003.00082	17	Female	HISPANIC
329.003.00088	15	Female	Caucasian

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Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Age (Years)	Sex	Race
329.003.00090	13	Female	Caucasian
329.003.00092	12	Female	Caucasian
329.003.00093	17	Female	Caucasian
329.003.00247	16	Male	Caucasian
329.003.00249	17	Female	Black
329.003.00289	16	Female	HISPANIC
329.003.00290	17	Male	HISPANIC
329.003.00314	15	Female	Caucasian
329.003.00317	16	Female	Oriental
329.004.00013	17	Male	Caucasian
329.004.00014	14	Male	Caucasian
329.004.00211	18	Female	Caucasian
329.004.00215	14	Female	Oriental
329.005.00003	13	Female	Caucasian
329.005.00006	17	Male	Caucasian
329.005.00007	15	Female	Caucasian
329.005.00009	16	Female	1/2SPANISH 1/2WHITE
329.005.00110	17	Female	Black
329.005.00113	15	Female	Black
329.005.00117	16	Female	Caucasian
329.005.00118	15	Male	Caucasian

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Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Age (Years)	Sex	Race
329.005.00153	18	Female	Caucasian
329.005.00255	15	Female	Caucasian
329.005.00256	16	Female	Caucasian
329.005.00295	13	Female	Caucasian
329.005.00297	18	Male	Caucasian
329.005.00332	17	Male	Caucasian
329.005.00335	15	Female	Caucasian
329.006.00040	18	Female	Caucasian
329.006.00041	18	Male	EGYPTIAN
329.007.00139	12	Female	Caucasian
329.007.00143	13	Female	Caucasian
329.007.00146	15	Female	Caucasian
329.007.00269	15	Male	Caucasian
329.007.00270	15	Male	Caucasian
329.007.00307	15	Female	Caucasian
329.007.00308	14	Male	Caucasian
329.008.00159	16	Female	Caucasian
329.008.00161	17	Male	Caucasian
329.008.00187	16	Female	Caucasian
329.008.00192	13	Male	Caucasian
329.008.00272	12	Male	Caucasian

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Appendix B.2

Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Age (Years)	Sex	Race
329.008.00273	12	Female	Caucasian
329.009.00127	12	Female	HISPANIC
329.009.00132	12	Male	Caucasian
329.009.00134	15	Female	Caucasian
329.009.00137	14	Male	Caucasian
329.009.00171	16	Female	Caucasian
329.009.00172	13	Female	Caucasian
329.009.00194	12	Male	Caucasian
329.009.00195	14	Female	Caucasian
329.009.00199	14	Female	Caucasian
329.009.00203	12	Female	Caucasian
329.009.00236	13	Female	Caucasian
329.009.00239	16	Female	Caucasian
329.009.00262	13	Male	Caucasian
329.009.00264	14	Female	Caucasian
329.009.00301	17	Male	Caucasian
329.009.00305	14	Male	Caucasian
329.009.00325	15	Female	Caucasian
329.009.00326	13	Male	Caucasian
329.010.00279	13	Female	Caucasian
329.010.00281	13	Male	Caucasian

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Appendix B.2

Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Age (Years)	Sex	Race
329.011.00163	15	Female	Caucasian
329.011.00208	13	Male	Caucasian
329.011.00209	12	Male	Caucasian
329.011.00284	17	Male	Caucasian
329.011.00286	15	Female	Caucasian
329.012.00026	14	Male	Caucasian
329.012.00219	14	Male	Caucasian
329.012.00221	17	Male	Caucasian
329.012.00223	13	Female	Caucasian
329.012.00227	16	Male	Caucasian
329.012.00230	15	Male	Caucasian

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Appendix B.2

Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Age (Years)	Sex	Race
329.001.00062	15	Female	Caucasian
329.001.00064	13	Male	Caucasian
329.001.00069	16	Male	Caucasian
329.001.00071	13	Female	Caucasian
329.001.00123	16	Female	Black
329.001.00207	14	Male	Caucasian
329.002.00049	15	Male	Caucasian
329.002.00059	17	Male	Caucasian
329.002.00060	14	Female	Caucasian
329.002.00097	13	Female	Caucasian
329.002.00101	16	Male	Caucasian
329.002.00107	15	Female	Caucasian
329.002.00241	15	Male	PORTUGUESE
329.002.00246	17	Female	Caucasian
329.002.00320	13	Female	Caucasian
329.002.00323	17	Female	Caucasian
329.003.00074	13	Male	COLUMBIAN YUGOSLAVIC
329.003.00078	17	Female	Caucasian
329.003.00080	16	Female	HISPANIC
329.003.00085	17	Female	Caucasian
329.003.00086	14	Female	Caucasian

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Appendix B.2

Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Age (Years)	Sex	Race
329.003.00094	13	Female	Caucasian
329.003.00251	17	Female	Caucasian
329.003.00252	14	Female	Caucasian
329.003.00291	16	Female	HISPANIC
329.003.00315	16	Female	Caucasian
329.003.00316	16	Female	Caucasian
329.004.00016	17	Male	Caucasian
329.004.00018	17	Female	Caucasian
329.004.00020	14	Female	Caucasian
329.004.00213	15	Female	Caucasian
329.005.00001	16	Female	Caucasian
329.005.00005	13	Female	Caucasian
329.005.00010	16	Female	Caucasian
329.005.00012	14	Female	Caucasian
329.005.00111	16	Female	Caucasian
329.005.00114	16	Male	Caucasian
329.005.00115	18	Female	Caucasian
329.005.00120	13	Male	Caucasian
329.005.00253	16	Female	Caucasian
329.005.00254	16	Female	Caucasian
329.005.00293	16	Female	Caucasian

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Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Age (Years)	Sex	Race
329.005.00298	13	Female	Caucasian
329.005.00331	15	Female	Caucasian
329.005.00334	13	Female	Caucasian
329.006.00037	17	Female	HISPANIC
329.006.00042	18	Male	Caucasian
329.006.00259	17	Male	Caucasian
329.007.00141	13	Male	Caucasian
329.007.00144	12	Female	HISPANIC
329.007.00266	12	Female	Caucasian
329.007.00267	16	Male	Caucasian
329.007.00311	15	Male	Caucasian
329.008.00158	16	Female	Caucasian
329.008.00162	16	Female	Oriental
329.008.00191	17	Female	Caucasian
329.009.00128	13	Male	Caucasian
329.009.00129	16	Male	HISPANIC
329.009.00135	17	Female	Caucasian
329.009.00136	14	Female	Black
329.009.00169	13	Male	HISPANIC
329.009.00174	15	Female	Caucasian
329.009.00197	12	Male	Caucasian

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Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Age (Years)	Sex	Race
329.009.00198	17	Female	HISPANIC
329.009.00200	17	Female	Caucasian
329.009.00202	15	Female	Caucasian
329.009.00237	17	Male	Caucasian
329.009.00238	16	Female	Caucasian
329.009.00276	13	Male	Caucasian
329.009.00302	17	Male	Caucasian
329.009.00306	14	Female	Black
329.009.00312	17	Female	Black
329.009.00327	16	Female	Oriental
329.009.00330	12	Male	Caucasian
329.010.00183	14	Male	Black
329.010.00263	18	Male	Caucasian
329.010.00277	14	Female	Black
329.010.00282	15	Female	Caucasian
329.011.00164	15	Male	Caucasian
329.011.00210	14	Female	Caucasian
329.011.00285	16	Male	Caucasian
329.011.00287	14	Female	Caucasian
329.012.00027	15	Male	Caucasian
329.012.00217	14	Female	Caucasian

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Listing of Demographic Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Age (Years)	Sex	Race
329.012.00218	17	Female	Caucasian
329.012.00224	14	Female	Caucasian
329.012.00225	14	Male	Caucasian

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Paroxetine - Protocol 329
Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.001.00063	C																										
329.001.00065	C														C												
329.001.00068	C																										
329.001.00072	C																	C									
329.001.00121	C																	C					P				
329.001.00205	C																										
329.001.00206	C															P											
329.002.00055	B					P	P							P				P									
329.002.00058	C												C		B			C									
329.002.00099	C																										
329.002.00102	C												C														
329.002.00105	C					C									C	C			P	P	P						

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.002.00106	C																										
329.002.00242	C															C											
329.002.00245	C															C											
329.002.00319	C																										
329.003.00075	C										P																
329.003.00077	C																										
329.003.00087	C												C														
329.003.00089	C																										
329.003.00091																											
329.003.00248	C																										
329.003.00250	C																										
329.003.00292	C										C		C														

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.003.00313	C																										
329.004.00015	C																										
329.004.00017	B																										
329.004.00019	C																										
329.004.00212	B					C									P	P											
329.004.00214	C					C					C		C														
329.005.00002	C																										
329.005.00004	C																										
329.005.00008	C																										
329.005.00011	C																										
329.005.00109	C																										
329.005.00112	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.005.00116	C																										
329.005.00119	C							P										C									
329.005.00151	C																	C									
329.005.00152	C												C														
329.005.00257	C					C												C									
329.005.00258	C																										
329.005.00299	C					C																					
329.005.00300	B																										
329.005.00333	C																										
329.005.00336	B																										
329.006.00038	C																										
329.006.00039	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.006.00260	C																										
329.006.00261	C	C												P				C									
329.007.00140	C																										
329.007.00142	C																										
329.007.00145	C																										
329.007.00265	C															C											
329.007.00268	C																										
329.007.00294	C																										
329.007.00309	C							P																			
329.007.00310	C					C																					
329.007.00318	C					C																					
329.008.00157	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Disorders: Past or Continuing Episodes																									
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.008.00160	C																										
329.008.00188	C																										
329.008.00271	C					C																					
329.008.00275	C																										
329.009.00130	C												C														
329.009.00131	B												C														
329.009.00133	C																										
329.009.00138	B					P	P						C		P			C				P					
329.009.00170	B					C					C																
329.009.00173	B																										
329.009.00193	B																										
329.009.00196	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.009.00201	C																										
329.009.00204	C												C		C												
329.009.00235	C																	C									
329.009.00240	C																										
329.009.00303	C																										
329.009.00304	B																										
329.009.00324	B																										
329.009.00328	B												C														
329.009.00329	B																										
329.010.00182	C												C			C											
329.010.00278	C																										
329.010.00280	B																	P									

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.011.00283	C												C			C		C									
329.011.00288	C														C	C		C									
329.012.00025	C																										
329.012.00220	C														C								P				
329.012.00222	C																										
329.012.00226	C																										
329.012.00228	B																										
329.012.00231	B																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Paroxetine - Protocol 329
Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.001.00061	C					C																					
329.001.00066	C																										
329.001.00067	C														C												
329.001.00070	C														C												
329.001.00122	C												C		C			C									
329.002.00050	C																										
329.002.00056	C																										
329.002.00057	B														C	C		C									
329.002.00098	C																			P							
329.002.00100	B															C											
329.002.00103	C																										
329.002.00104	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.002.00243	C										C			P													
329.002.00244	C																										
329.002.00321	C										C				C	C		C									
329.002.00322	B																	P									
329.003.00073	C																										
329.003.00076	C																										
329.003.00079	C																										
329.003.00082	C																										
329.003.00088	C																										
329.003.00090	C																										
329.003.00092	C																										
329.003.00093	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = IMIPRAMINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.003.00247	C															P											
329.003.00249	C										C		C														
329.003.00289	C										C		C														
329.003.00290	C										C																
329.003.00317	C												B														
329.004.00013	C																										
329.004.00014	C						B	C																			
329.004.00211	C																										
329.004.00215	C																										
329.005.00003	C					C			C						P												
329.005.00006	C																										
329.005.00007	C							P					P														

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.005.00009	C																										
329.005.00110	C												C														
329.005.00113	C												C														
329.005.00117	C														C			C									
329.005.00118	C															C											
329.005.00153	C																										
329.005.00255	C														P												
329.005.00256	C					B					C																
329.005.00295	B																										
329.005.00297	C														C												
329.005.00332	C																										
329.005.00335	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = IMIPRAMINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.006.00040	C																										
329.006.00041	C																										
329.007.00139	C																										
329.007.00143	C										C												C				
329.007.00146	C																										
329.007.00269	C					P									C												
329.007.00270	C																										
329.007.00307	C																										
329.007.00308	C															C											
329.008.00159	C						P																				
329.008.00161	C																										
329.008.00187	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = IMIPRAMINE

Patient ID	Disorders: Past or Continuing Episodes																									
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.008.00192	C							P							C												
329.008.00272	C																	C									
329.008.00273	C												C														
329.009.00127	P						P																				
329.009.00132	C												C		C			C									
329.009.00134	C												C														
329.009.00137	B														C	C											
329.009.00171	B																										
329.009.00172	C																										
329.009.00194	B														C												
329.009.00195	B																										
329.009.00199	B					C																					

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = IMIPRAMINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.009.00203	C																										
329.009.00236	C																										
329.009.00239	B																										
329.009.00262	B												C														
329.009.00264	B																										
329.009.00301	C																										
329.009.00305	C														C												
329.009.00325	B																			P							
329.009.00326	C																										
329.010.00279	P																										
329.010.00281	P																										
329.011.00163	C					C		C			C		C		C								P				

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = IMIPRAMINE

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.011.00208	C												C														
329.011.00209	C						C											C									
329.011.00284	C																	C									
329.011.00286	C																					P					
329.012.00026	C																										
329.012.00219	C																										
329.012.00221	C																										
329.012.00223	B										P		C					P									
329.012.00227	C																										
329.012.00230	B																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.001.00062	C										C																
329.001.00064	C														C												
329.001.00069	C										C							C									
329.001.00071	C												C										P				
329.001.00123	C					C																					
329.001.00207	C														C			C									
329.002.00049	C																										
329.002.00059	C												C														
329.002.00060	C																										
329.002.00097	C																										
329.002.00101	C														P	C		C		P	P						
329.002.00107	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.002.00241	C																										
329.002.00246	C										C		C														
329.002.00320	C																										
329.002.00323	C												C														
329.003.00074	C																										
329.003.00078	C																										
329.003.00085	C																										
329.003.00086	B					P		P																			
329.003.00094	C										C		C														
329.003.00251	C						P				C		C									P					
329.003.00252	C																										
329.003.00291	C					C	C	C	C		C		C			P											

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = PLACEBO

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.003.00315	C																										
329.003.00316	C					C												C									
329.004.00016	C																										
329.004.00018	B												C			P											
329.004.00020	C						P									C											
329.004.00213	C					C																					
329.005.00001	B					P		C			C		C														
329.005.00005	C														P			P									
329.005.00010	C																										
329.005.00012	C																										
329.005.00111	B																										
329.005.00114	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = PLACEBO

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.005.00115	C																										
329.005.00120	C					C					C		C		P												
329.005.00253	C																										
329.005.00254	C										C		C														
329.005.00293	C										C																
329.005.00298	C																										
329.005.00331	B												C														
329.005.00334	C																										
329.006.00037	C																										
329.006.00042	C																										
329.006.00259	C																										
329.007.00141	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = PLACEBO

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.007.00144	C																										
329.007.00266	C																										
329.007.00267	C					P																					
329.007.00311	C																										
329.008.00158	C																										
329.008.00162	C																										
329.008.00191	C																										
329.009.00128	C																										
329.009.00129	C														P												
329.009.00135	B																										
329.009.00136	B						P																				
329.009.00169	B																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = PLACEBO

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.009.00174	C														C												
329.009.00197	C																										
329.009.00198	C																										
329.009.00200	B																										
329.009.00202	B																										
329.009.00237	B																	B									
329.009.00238	B																										
329.009.00276	C																										
329.009.00302	C																										
329.009.00306	B																										
329.009.00312	B												C														
329.009.00327	B												C														

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Treatment = PLACEBO

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.009.00330	B												C														
329.010.00183	C														P	C		C									
329.010.00263	P																										
329.010.00277	P																										
329.010.00282	P																										
329.011.00164	C												C														
329.011.00210	C																	C									
329.011.00285	C					C		C					C														
329.011.00287	C																	C									
329.012.00027	B																										
329.012.00217	C																	C									
329.012.00218	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Appendix B.3
Listing of K-SADS-L Diagnostic Criteria at Screening
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Disorders: Past or Continuing Episodes																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
329.012.00224	C						C																				
329.012.00225	C																										

P=Past, C=Continuing, B=Both

1=Major Depressive Episode, 2=Hypomanic Episode, 3=Manic Episode, 4=Anorexia Nervosa, 5=Bulimia Nervosa, 6=Specific Phobia, 7=Separation anxiety disorder, 8=Panic disorder (without agorophobia), 9=Panic disorder (with agorophobia), 10=Agorophobia (no panic), 11=Social Phobia, 12=Obsessive Compulsive Disorder, 13=Generalized anxiety disorder, 14=Post-traumatic stress disorder, 15=Attention-deficit/hyperactivity, 16=Conduct Disorder, 17=Antisocial personality disorder, 18=Oppositional Defiant disorder, 19=Alcohol Dependence, 20=Alcohol abuse, 21=Substance dependence, 22=Substance abuse, 23=Tic Disorders, 24=Schizophrenia, 25=Schizoaffective disorder, 26=Brief psychotic disorder, 27=Delusional disorder

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Paroxetine - Protocol 329
Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	-------- Q1 -------- Current Episode	-------- Q2 -------- Last 2 Weeks
329.001.00063	SC	02NOV94	-6 , .	31-40	31-40
329.001.00065	SC	07NOV94	-10 , .	31-40	31-40
329.001.00068	SC	01FEB95	-7 , .	31-40	31-40
329.001.00072	SC	07MAR95	-13 , .	31-40	31-40
329.001.00121	SC	22MAR95	-13 ,-69	31-40	31-40
329.001.00205	SC	29JAN96	-9 , .	31-40	31-40
329.001.00206	SC	12FEB96	-9 , .	31-40	31-40
329.002.00055	SC	09JUN94	-15 ,-70	41-50	41-50
	20	10NOV94	140 , 85	.	41-50
329.002.00058	SC	08SEP94	-12 ,-70	41-50	41-50
329.002.00099	SC	23FEB95	-7 ,-62	61-70	61-70
	32	26OCT95	239 ,184	31-40	41-50
329.002.00102	SC	03APR95	-10 ,-64	51-60	51-60
	32	05DEC96	603 ,549	81-90	.
329.002.00105	SC	20JUL95	-7 , .	51-60	51-60
329.002.00106	SC	20JUL95	-7 , .	51-60	51-60
329.002.00242	SC	26JAN96	-12 ,-70	51-60	51-60
	20	10JUL96	155 , 97	71-80	.

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.002.00245	SC	21MAR96	-7 , .	41-50	41-50
329.002.00319	SC	23APR96	-7 ,-63	51-60	51-60
	32	17DEC96	232 ,176	51-60	81-90
329.003.00075	SC	18JAN95	-7 ,-63	41-50	41-50
	32	13SEP95	232 ,176	41-50	71-80
329.003.00077	SC	01MAR95	-5 ,-64	41-50	41-50
329.003.00081	SC	04DEC95	-7 , .	41-50	41-50
329.003.00087	SC	23JAN95	-8 , .	41-50	41-50
329.003.00089	SC	24FEB95	-11 , .	41-50	41-50
329.003.00091	SC	14MAR95	-10 ,-64	51-60	51-60
	32	07NOV95	229 ,175	61-70	61-70
329.003.00248	SC	14FEB96	-16 , .	41-50	41-50
329.003.00250	SC	05MAR96	-9 ,-66	41-50	41-50
329.003.00292	SC	02AUG96	-5 ,-63	51-60	51-60
329.003.00313	SC	08MAY96	-9 , .	41-50	41-50
329.004.00015	SC	30NOV94	-8 ,-65	51-60	51-60
	28	14JUN95	189 ,132	41-50	71-80
329.004.00017	SC	15MAR95	-7 ,-63	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	-------- Q1 -------- Current Episode	-------- Q2 -------- Last 2 Weeks
329.004.00017	32	01NOV95	225 ,169	41-50	71-80
329.004.00019	SC	24MAY95	-7 , .	51-60	51-60
329.004.00212	SC	24MAY96	-10 , .	21-30	31-40
329.004.00214	SC	27SEP96	-7 ,-67	51-60	51-60
329.005.00002	SC	20MAY94	-5 ,-61	41-50	51-60
329.005.00004	SC	22SEP94	-18 ,-77	51-60	51-60
329.005.00008	SC	10NOV94	-6 ,-61	51-60	51-60
	24	10MAY95	176 ,121	51-60	71-80
329.005.00011	SC	06DEC94	-7 ,-63	51-60	51-60
329.005.00109	SC	22DEC94	-8 ,-61	61-70	41-50
329.005.00112	SC	17JAN95	-9 ,-64	81-90	51-60
329.005.00116	SC	30JAN95	-8 ,-66	71-80	51-60
	24	26JUL95	170 ,112	51-60	51-60
329.005.00119	SC	27JUN95	-14 ,-73	51-60	51-60
	24	02JAN96	176 ,117	51-60	51-60
329.005.00151	SC	29AUG95	-8 ,-65	51-60	51-60
	32	01MAY96	239 ,182	51-60	71-80
329.005.00152	SC	12OCT95	-14 , .	41-50	51-60

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	-------- Q1 -------- Current Episode	-------- Q2 -------- Last 2 Weeks
329.005.00257	SC	05MAR96	-6 ,-62	41-50	41-50
	32	21OCT96	225 ,169	91-100	.
329.005.00258	SC	06FEB96	-35 , .	51-60	51-60
329.005.00299	SC	28MAY96	-11 ,-71	51-60	51-60
	20	05NOV96	151 , 91	51-60	51-60
329.005.00300	SC	12SEP96	-7 , .	51-60	51-60
329.005.00333	SC	15JAN97	-8 , .	51-60	51-60
329.005.00336	SC	26FEB97	-6 , .	71-80	51-60
329.006.00038	SC	01FEB95	-14 , .	61-70	61-70
329.006.00039	SC	03FEB95	-5 ,-66	41-50	41-50
329.006.00260	SC	12JUL96	-6 ,-64	51-60	51-60
329.006.00261	SC	07NOV96	-19 ,-77	31-40	41-50
329.007.00140	SC	07SEP95	-8 ,-63	41-50	41-50
329.007.00142	SC	12OCT95	-6 , .	41-50	41-50
329.007.00145	SC	04JAN96	-7 ,-63	41-50	41-50
	32	23AUG96	226 ,170	.	81-90
329.007.00265	SC	25JAN96	-7 , .	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.007.00268	SC	21MAR96	-11 ,-70	41-50	41-50
	32	05DEC96	249 ,190	71-80	71-80
329.007.00294	SC	20FEB97	-8 , .	41-50	41-50
329.007.00309	SC	02JUL96	-13 ,-65	41-50	41-50
	32	13MAR97	242 ,190	.	71-80
329.007.00310	SC	19SEP96	-7 ,-67	41-50	41-50
	32	12JUN97	260 ,200	.	91-100
329.007.00318	SC	22NOV96	-10 , .	41-50	41-50
329.008.00157	SC	16AUG95	-14 ,-69	41-50	41-50
329.008.00160	SC	25OCT95	-7 ,-73	51-60	51-60
	32	23JUL96	266 ,200	81-90	81-90
329.008.00188	SC	14DEC95	-21 , .	41-50	41-50
329.008.00271	SC	25JAN96	-46 ,***	41-50	51-60
	32	05NOV96	240 ,176	.	71-80
329.008.00275	SC	30APR96	-8 ,-63	41-50	41-50
	32	16DEC96	223 ,168	.	81-90
329.009.00130	SC	12APR95	-6 ,-62	41-50	41-50
329.009.00131	SC	26APR95	-6 ,-62	31-40	41-50
329.009.00133	SC	07JUN95	-6 , .	31-40	31-40

* days relative to start of acute phase, days relative to start of continuation phase

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Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.009.00138	SC	02OCT95	-8 , .	41-50	41-50
329.009.00170	SC	26OCT95	-12 ,-69	41-50	41-50
	32	24JUN96	231 ,174	41-50	71-80
329.009.00173	SC	08NOV95	-12 ,-75	31-40	31-40
329.009.00193	SC	21NOV95	-7 , .	31-40	31-40
329.009.00196	SC	11DEC95	-7 , .	51-60	51-60
329.009.00201	SC	31JAN96	-6 , .	31-40	31-40
329.009.00204	SC	13MAR96	-6 ,-62	41-50	41-50
329.009.00235	SC	10DEC96	-8 ,-62	41-50	41-50
	16	14APR97	118 , 64	51-60	51-60
329.009.00240	SC	03JAN97	-11 , .	41-50	41-50
329.009.00303	SC	25MAR96	-8 ,-64	41-50	41-50
	32	10DEC96	253 ,197	81-90	81-90
329.009.00304	SC	03APR96	-6 ,-62	31-40	31-40
329.009.00324	SC	21OCT96	-7 , .	41-50	41-50
329.009.00328	SC	30SEP96	-7 , .	41-50	41-50
329.009.00329	SC	01OCT96	-8 , .	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.010.00182	SC	05DEC95	-14 , .	31-40	31-40
329.010.00278	SC	02FEB96	-7 ,-63	41-50	41-50
	32	19SEP96	224 ,168	41-50	81-90
329.010.00280	SC	10MAY96	-7 ,-62	41-50	41-50
	12	21AUG96	97 , 42	41-50	41-50
329.011.00283	SC	30JAN96	-9 ,-66	41-50	41-50
329.011.00288	SC	01JUL96	-24 , .	41-50	41-50
329.012.00025	SC	17OCT95	-7 , .	31-40	31-40
329.012.00220	SC	04JUN96	-13 ,-73	31-40	31-40
329.012.00222	SC	18JUN96	-10 ,-73	21-30	31-40
329.012.00226	SC	26NOV96	-7 , .	41-50	41-50
329.012.00228	SC	04MAR97	-15 , .	41-50	41-50
329.012.00231	SC	26FEB97	-9 ,-70	51-60	41-50
	24	19AUG97	166 ,105	.	61-70

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.001.00061	SC	19JUL94	-10 , .	31-40	31-40
329.001.00066	SC	14NOV94	-8 , .	41-50	41-50
329.001.00067	SC	15NOV94	-7 , .	31-40	31-40
329.001.00070	SC	14FEB95	-8 , .	31-40	31-40
329.001.00122	SC	13JUN95	-7 ,-64	31-40	31-40
329.002.00050	SC	10MAR95	-13 , .	31-40	31-40
329.002.00056	SC	24JUN94	-25 , .	51-60	51-60
329.002.00057	SC	11AUG94	-28 ,-85	31-40	31-40
329.002.00098	SC	03JAN95	1 , .	51-60	51-60
329.002.00100	SC	16FEB95	-19 ,-77	51-60	51-60
	16	06JUL95	122 , 64	.	41-50
329.002.00103	SC	11APR95	-9 ,-65	51-60	51-60
	16	10AUG95	113 , 57	71-80	61-70
329.002.00104	SC	28APR95	-6 ,-62	51-60	51-60
	32	02JAN96	244 ,188	61-70	81-90
329.002.00243	SC	27FEB96	-16 , .	51-60	51-60
329.002.00244	SC	14MAR96	-7 ,-64	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.002.00321	SC	15MAY96	-8 , .	51-60	51-60
329.002.00322	SC	06JAN97	-3 , .	51-60	51-60
329.003.00073	SC	11JAN95	-8 , .	31-40	31-40
329.003.00076	SC	24JAN95	-7 ,-62	41-50	41-50
	32	11OCT95	254 ,199	71-80	71-80
329.003.00079	SC	14APR95	-19 , .	41-50	41-50
329.003.00088	SC	06FEB95	-22 , .	41-50	41-50
329.003.00090	SC	08MAR95	-6 , .	41-50	41-50
329.003.00092	SC	13APR95	-20 ,-78	51-60	51-60
	32	02JAN96	245 ,187	71-80	71-80
329.003.00093	SC	08JUN95	-13 ,-76	41-50	41-50
	16	03OCT95	105 , 42	71-80	71-80
329.003.00247	SC	05JAN96	-27 ,-81	41-50	41-50
329.003.00249	SC	01MAR96	-6 , .	31-40	31-40
329.003.00289	SC	12FEB96	-16 ,-72	31-40	31-40
	32	11OCT96	227 ,171	.	71-80
329.003.00290	SC	06MAR96	-5 , .	41-50	41-50
329.003.00317	SC	12DEC96	-7 , .	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.4
Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.004.00013	SC	05JUL94	-14 ,-73	51-60	51-60
	32	10MAR95	235 ,176	.	91-100
329.004.00014	SC	22NOV94	-7 , .	41-50	41-50
329.004.00211	SC	24JAN96	-9 , .	31-40	31-40
329.004.00215	SC	12MAR97	-8 , .	31-40	41-50
329.005.00003	SC	12SEP94	-8 , .	41-50	31-40
329.005.00006	SC	27OCT94	-8 ,-68	71-80	51-60
329.005.00007	SC	02NOV94	-7 ,-70	51-60	41-50
329.005.00009	SC	07DEC94	-5 , .	51-60	51-60
329.005.00110	SC	04JAN95	-7 , .	51-60	41-50
329.005.00113	SC	20JAN95	-10 , .	51-60	31-40
329.005.00117	SC	06MAR95	-12 , .	51-60	51-60
329.005.00118	SC	09MAY95	-8 , .	51-60	41-50
329.005.00153	SC	11JAN96	-14 ,-70	41-50	41-50
	32	04SEP96	224 ,168	41-50	81-90
329.005.00255	SC	26FEB96	-7 , .	51-60	51-60
329.005.00256	SC	20FEB96	-14 ,-70	51-60	51-60

* days relative to start of acute phase, days relative to start of continuation phase

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Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.005.00256	16	02JUL96	120 , 64	51-60	61-70
329.005.00295	SC	21MAR96	-7 , .	51-60	41-50
329.005.00297	SC	28MAR96	-22 , .	51-60	41-50
329.005.00332	SC	05DEC96	-7 , .	41-50	41-50
329.005.00335	SC	20FEB97	-8 , .	61-70	51-60
329.006.00040	SC	10FEB95	-6 , .	51-60	51-60
329.006.00041	SC	22MAR95	-14 ,-78	61-70	61-70
	32	21NOV95	231 ,167	71-80	71-80
329.007.00139	SC	04MAY95	-4 , .	41-50	41-50
329.007.00143	SC	26OCT95	-14 , .	31-40	31-40
329.007.00146	SC	18JAN96	-7 ,-60	41-50	41-50
	32	09SEP96	229 ,176	71-80	71-80
329.007.00269	SC	04APR96	-7 , .	31-40	31-40
329.007.00270	SC	02MAY96	-7 , .	41-50	41-50
329.007.00307	SC	09MAY96	-7 , .	41-50	41-50
329.007.00308	SC	27JUN96	-5 , .	41-50	41-50
329.008.00159	SC	06SEP95	-7 ,-69	41-50	51-60

* days relative to start of acute phase, days relative to start of continuation phase

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Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.008.00161	SC	31OCT95	-16 ,-71	51-60	51-60
329.008.00187	SC	15NOV95	-14 , .	41-50	41-50
329.008.00192	SC	14FEB96	-20 , .	51-60	41-50
329.008.00272	SC	19MAR96	-15 ,-71	41-50	41-50
329.008.00273	SC	19APR96	-28 ,-91	61-70	61-70
329.009.00127	SC	03APR95	-7 , .	31-40	51-60
329.009.00132	SC	17MAY95	-6 ,-63	41-50	41-50
329.009.00134	SC	28JUN95	-8 , .	41-50	41-50
329.009.00137	SC	03OCT95	-7 , .	31-40	31-40
329.009.00171	SC	31OCT95	-7 , .	41-50	41-50
329.009.00172	SC	06NOV95	-7 ,-64	41-50	41-50
	32	08JUL96	239 ,182	41-50	71-80
329.009.00194	SC	28NOV95	-7 ,-63	41-50	41-50
329.009.00195	SC	06DEC95	-9 , .	41-50	41-50
329.009.00199	SC	10JAN96	-6 , .	31-40	41-50
329.009.00203	SC	28FEB96	-5 , .	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.009.00236	SC	17DEC96	-13 , .	41-50	41-50
329.009.00239	SC	11NOV96	-8 ,-65	41-50	41-50
329.009.00262	SC	07FEB97	-10 , .	41-50	41-50
329.009.00264	SC	25OCT96	-7 , .	41-50	41-50
329.009.00301	SC	06MAR96	-13 ,-69	31-40	41-50
329.009.00305	SC	01MAY96	-6 ,-63	41-50	41-50
	32	10JAN97	249 ,192	81-90	81-90
329.009.00325	SC	21AUG96	-6 ,-61	41-50	41-50
	16	16DEC96	112 , 57	41-50	41-50
329.009.00326	SC	26AUG96	-10 ,-63	41-50	41-50
	16	16DEC96	103 , 50	41-50	41-50
329.010.00279	SC	08MAR96	-14 ,-70	31-40	41-50
	32	06NOV96	230 ,174	31-40	61-70
329.010.00281	SC	19JUL96	-7 ,-68	41-50	41-50
	24	03JAN97	162 ,101	41-50	41-50
329.011.00163	SC	18NOV95	-7 , .	41-50	41-50
329.011.00208	SC	22AUG96	-15 ,-74	51-60	51-60
329.011.00209	SC	23AUG96	-19 ,-81	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Listing of C-GAS Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.011.00284	SC	13MAR96	-9 ,-65	41-50	41-50
329.011.00286	SC	15MAY96	-22 ,-90	51-60	51-60
329.012.00026	SC	09NOV95	-19 , .	41-50	41-50
329.012.00219	SC	24MAY96	-7 ,-67	31-40	41-50
	32	24JAN97	239 ,179	.	71-80
329.012.00221	SC	18JUN96	-7 ,-70	21-30	31-40
329.012.00223	SC	23AUG96	-7 , .	41-50	51-60
329.012.00227	SC	12DEC96	-6 ,-75	61-70	61-70
	32	19AUG97	245 ,176	.	71-80
329.012.00230	SC	20FEB97	-8 ,-77	41-50	51-60

* days relative to start of acute phase, days relative to start of continuation phase

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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.001.00062	SC	06OCT94	-14 , .	31-40	31-40
329.001.00064	SC	04NOV94	-6 ,-60	41-50	41-50
329.001.00069	SC	07FEB95	-9 , .	31-40	31-40
329.001.00071	SC	02FEB95	-21 , .	31-40	31-40
329.001.00123	SC	14DEC95	-21 , .	31-40	31-40
329.001.00207	SC	19FEB96	-9 , .	41-50	41-50
329.002.00049	SC	03MAR95	-6 , .	41-50	41-50
329.002.00059	SC	03NOV94	-7 , .	51-60	51-60
329.002.00060	SC	24JAN95	-7 ,-63	51-60	51-60
329.002.00097	SC	20DEC94	-14 ,-72	51-60	51-60
	32	05SEP95	246 ,188	61-70	61-70
329.002.00101	SC	20MAR95	-8 ,-66	51-60	51-60
329.002.00107	SC	18JAN96	-7 ,-63	41-50	41-50
	32	26SEP96	246 ,190	61-70	81-90
329.002.00241	SC	25JAN96	-12 ,-68	51-60	61-70
329.002.00246	SC	01APR96	-17 , .	51-60	51-60
329.002.00320	SC	09MAY96	-7 ,-68	51-60	51-60

* days relative to start of acute phase, days relative to start of continuation phase

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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.002.00323	SC	04NOV96	-8 ,-66	61-70	61-70
	32	12JUN97	213 ,155	61-70	71-80
329.003.00074	SC	18JAN95	-7 ,-63	41-50	41-50
	32	11OCT95	260 ,204	41-50	61-70
329.003.00078	SC	11APR95	-15 , .	51-60	51-60
329.003.00080	SC	27NOV95	1 , .	41-50	41-50
329.003.00085	SC	26OCT94	-13 , .	41-50	41-50
329.003.00086	SC	09NOV94	-19 ,-76	41-50	41-50
	32	17AUG95	263 ,206	.	71-80
329.003.00094	SC	20OCT95	-4 , .	41-50	41-50
329.003.00251	SC	19MAR96	-9 , .	31-40	31-40
329.003.00252	SC	19MAR96	-22 , .	41-50	41-50
329.003.00291	SC	01JUL96	-2 ,-67	41-50	41-50
329.003.00315	SC	29OCT96	-14 , .	41-50	41-50
329.003.00316	SC	05DEC96	-12 , .	41-50	41-50
329.004.00016	SC	01MAR95	-12 , .	51-60	51-60
329.004.00018	SC	19APR95	-14 , .	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.004.00020	SC	02NOV95	-7 , .	31-40	31-40
329.004.00213	SC	18JUL96	-15 ,-69	51-60	41-50
	32	19MAR97	230 ,176	41-50	71-80
329.005.00001	SC	11APR94	-9 , .	41-50	41-50
329.005.00005	SC	24OCT94	-8 , .	51-60	51-60
329.005.00010	SC	07DEC94	-6 ,-63	51-60	41-50
	32	09AUG95	240 ,183	61-70	91-100
329.005.00012	SC	12DEC94	-7 ,-66	61-70	51-60
329.005.00111	SC	05JAN95	-6 ,-62	51-60	41-50
329.005.00114	SC	23JAN95	-8 ,-65	51-60	41-50
329.005.00115	SC	27JAN95	-10 ,-81	51-60	51-60
329.005.00120	SC	22AUG95	-8 , .	51-60	51-60
329.005.00253	SC	31JAN96	-8 , .	51-60	51-60
329.005.00254	SC	08FEB96	-7 ,-62	51-60	41-50
	32	16OCT96	245 ,190	51-60	81-90
329.005.00293	SC	06MAR97	-6 , .	51-60	41-50
329.005.00298	SC	15MAY96	-7 ,-63	51-60	41-50
	32	13JAN97	237 ,181	51-60	81-90

* days relative to start of acute phase, days relative to start of continuation phase

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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.005.00331	SC	14NOV96	-7 , .	51-60	41-50
329.005.00334	SC	24JAN97	-7 , .	51-60	51-60
329.006.00037	SC	20JAN95	-8 , .	61-70	61-70
329.006.00042	SC	01DEC95	-6 ,-63	61-70	51-60
	32	16JUL96	223 ,166	61-70	71-80
329.006.00259	SC	22APR96	-32 , .	51-60	51-60
329.007.00141	SC	14SEP95	-7 , .	41-50	41-50
329.007.00144	SC	30NOV95	-7 ,-63	41-50	41-50
329.007.00266	SC	29FEB96	-7 , .	41-50	41-50
329.007.00267	SC	29FEB96	-7 , .	41-50	41-50
329.007.00311	SC	26SEP96	-7 ,-67	41-50	41-50
329.008.00158	SC	06SEP95	-7 ,-69	41-50	41-50
329.008.00162	SC	26OCT95	-6 ,-71	41-50	41-50
	32	02JUL96	245 ,180	71-80	71-80
329.008.00191	SC	12JAN96	-20 ,-81	41-50	41-50
329.009.00128	SC	05APR95	-6 , .	41-50	51-60
329.009.00129	SC	22MAR95	-20 , .	41-50	51-60

* days relative to start of acute phase, days relative to start of continuation phase

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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.009.00135	SC	25SEP95	-7 , .	21-30	21-30
329.009.00136	SC	26SEP95	-7 , .	41-50	41-50
329.009.00169	SC	25OCT95	-6 ,-71	41-50	41-50
329.009.00174	SC	14NOV95	-7 ,-64	31-40	31-40
329.009.00197	SC	20DEC95	-9 ,-63	41-50	41-50
	32	20AUG96	236 ,182	41-50	81-90
329.009.00198	SC	19DEC95	-14 , .	41-50	41-50
329.009.00200	SC	17JAN96	-6 , .	31-40	31-40
329.009.00202	SC	14FEB96	-6 , .	31-40	41-50
329.009.00237	SC	04NOV96	-7 , .	41-50	41-50
329.009.00238	SC	28OCT96	-15 , .	51-60	51-60
329.009.00276	SC	17JAN97	-4 , .	41-50	41-50
329.009.00302	SC	20MAR96	-7 , .	41-50	41-50
329.009.00306	SC	03JUN96	-8 , .	31-40	31-40
329.009.00312	SC	30OCT96	-5 , .	41-50	41-50
329.009.00327	SC	09SEP96	-7 , .	41-50	41-50

* days relative to start of acute phase, days relative to start of continuation phase

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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Q1 Current Episode	Q2 Last 2 Weeks
329.009.00330	SC	15OCT96	-6 , .	41-50	41-50
329.010.00183	SC	21NOV95	-12 , .	41-50	41-50
329.010.00263	SC	24JUL96	-16 , .	51-60	51-60
329.010.00277	SC	23FEB96	-7 ,-63	41-50	41-50
	24	07AUG96	160 ,104	81-90	81-90
329.010.00282	SC	19JUL96	-7 , .	51-60	51-60
329.011.00164	SC	15DEC95	-7 , .	31-40	31-40
329.011.00210	SC	13SEP96	-15 ,-81	51-60	51-60
329.011.00285	SC	08MAY96	-10 , .	41-50	41-50
329.011.00287	SC	25JUN96	-8 , .	51-60	51-60
329.012.00027	SC	23NOV95	-13 , .	41-50	31-40
329.012.00217	SC	14MAY96	-7 , .	21-30	31-40
329.012.00218	SC	04JUN96	-12 ,-70	31-40	31-40
329.012.00224	SC	30AUG96	-17 ,-83	21-30	31-40
329.012.00225	SC	19NOV96	-7 ,-71	41-50	41-50
	32	30JUL97	247 ,183	.	91-100

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.001.00063	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.001.00065	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.001.00068	Graduated Junior College (A.A.)	Graduated HS (do not count G.E.D.)	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.001.00072	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.001.00121	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Junior College (A.A.)	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.001.00205	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.001.00206	Graduated JHS	Dropped out of JHS	Skilled manual employees	Unskilled employees
329.002.00055	Dropped out of HS	Received G.E.D.	Unskilled employees	Unskilled employees
329.002.00058	Dropped out of HS	Graduated JHS	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.002.00099	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.002.00102	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Not relevant (e.g., was never employed)

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.002.00105	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Business managers in large concerns, proprietors of medium-sized businesses	Skilled manual employees
329.002.00106	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.002.00242	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.002.00245	Graduated HS (do not count G.E.D.)	Received G.E.D.	Skilled manual employees	Skilled manual employees
329.002.00319	Dropped out of College	Graduated HS (do not count G.E.D.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.003.00077	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Machine operators, semi-skilled employees	Not relevant (e.g., was never employed)
329.003.00081		Dropped out of JHS		Not relevant (e.g., was never employed)
329.003.00087	Dropped out of HS	Dropped out of College	Machine operators, semi-skilled employees	Business managers in large concerns, proprietors of medium-sized businesses
329.003.00089	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Business managers in large concerns, proprietors of medium-sized businesses	Higher executive, proprietors of large concerns, major professionals
329.003.00091	Dropped out of College	Graduated Senior College (B.A., B.S., B.F.A., etc)	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.003.00248	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Unskilled employees

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.003.00250	Graduated Junior College (A.A.)	Dropped out of College	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.003.00292	Graduated Senior College (B.A., B.S., B.F.A., etc)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Business managers in large concerns, proprietors of medium-sized businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.003.00313	Graduated JHS	Graduated JHS	Unskilled employees	Unskilled employees
329.004.00015	Graduated HS (do not count G.E.D.)	Dropped out of College	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.004.00017	Graduated Senior College (B.A., B.S., B.F.A., etc)	Completed Doctoral, Medical, Law or Comparable Degree	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.004.00019			Unskilled employees	Administrative personnel, owners of small independent businesses
329.004.00212		Dropped out of HS		Unskilled employees
329.004.00214	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.005.00002	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.005.00004	Graduated HS (do not count G.E.D.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.005.00008	Graduated Junior College (A.A.)	Graduated HS (do not count G.E.D.)	Unskilled employees	Machine operators, semi-skilled employees

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Listing of Personal History by Treatment Group and Patient: Part I
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Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.005.00011	Completed Doctoral, Medical, Law or Comparable Degree	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.005.00109	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Unskilled employees	Unskilled employees
329.005.00112	Graduated HS (do not count G.E.D.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Not relevant (e.g., was never employed)	Not relevant (e.g., was never employed)
329.005.00116	Dropped out of College	Graduated Senior College (B.A., B.S., B.F.A., etc)	Unskilled employees	Administrative personnel, owners of small independent businesses
329.005.00119	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Higher executive, proprietors of large concerns, major professionals	Higher executive, proprietors of large concerns, major professionals
329.005.00151	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Skilled manual employees	Machine operators, semi-skilled employees
329.005.00152	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Unskilled employees	Clerical and sales workers, technicians, owners of little businesses
329.005.00257	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.005.00258	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Business managers in large concerns, proprietors of medium-sized businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.005.00299	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.005.00300	Graduated HS (do not count G.E.D.)	Graduated JHS	Not relevant (e.g., was never employed)	Not relevant (e.g., was never employed)

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Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.005.00333	Completed Doctoral, Medical, Law or Comparable Degree	Graduated HS (do not count G.E.D.)	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.005.00336	Graduated HS (do not count G.E.D.)	Graduated JHS	Skilled manual employees	Not relevant (e.g., was never employed)
329.006.00038	Dropped out of JHS	Graduated HS (do not count G.E.D.)	Skilled manual employees	Skilled manual employees
329.006.00039	Completed Doctoral, Medical, Law or Comparable Degree	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Higher executive, proprietors of large concerns, major professionals	Higher executive, proprietors of large concerns, major professionals
329.006.00260	Graduated HS (do not count G.E.D.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Administrative personnel, owners of small independent businesses	Higher executive, proprietors of large concerns, major professionals
329.006.00261	Dropped out of JHS	Dropped out of JHS	Skilled manual employees	Unskilled employees
329.007.00140	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.007.00142	Dropped out of College	Dropped out of College	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.007.00145	Dropped out of HS	Dropped out of HS	Machine operators, semi-skilled employees	Machine operators, semi-skilled employees
329.007.00265	Dropped out of HS	Dropped out of HS	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.007.00268	Dropped out of College	Dropped out of College	Skilled manual employees	Administrative personnel, owners of small independent businesses

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Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.007.00294	Graduated HS (do not count G.E.D.)	Dropped out of College	Not relevant (e.g., was never employed)	Administrative personnel, owners of small independent businesses
329.007.00309	Graduated Junior College (A.A.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.007.00310	Graduated HS (do not count G.E.D.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.007.00318	Dropped out of College	Graduated Junior College (A.A.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.008.00157	Graduated Junior College (A.A.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.008.00160	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Unskilled employees	Clerical and sales workers, technicians, owners of little businesses
329.008.00188	Graduated JHS	Graduated JHS	Skilled manual employees	Skilled manual employees
329.008.00271	Graduated Junior College (A.A.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.008.00275	Completed Doctoral, Medical, Law or Comparable Degree	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Higher executive, proprietors of large concerns, major professionals	Higher executive, proprietors of large concerns, major professionals
329.009.00130	Dropped out of College	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.009.00131	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Junior College (A.A.)	Higher executive, proprietors of large concerns, major professionals	Administrative personnel, owners of small independent businesses

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Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.009.00133		Dropped out of College		Clerical and sales workers, technicians, owners of little businesses
329.009.00138	Received G.E.D.	Graduated HS (do not count G.E.D.)	Not relevant (e.g., was never employed)	Skilled manual employees
329.009.00170	Graduated HS (do not count G.E.D.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Not relevant (e.g., was never employed)	Business managers in large concerns, proprietors of medium-sized businesses
329.009.00173	Graduated Junior College (A.A.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Not relevant (e.g., was never employed)	Clerical and sales workers, technicians, owners of little businesses
329.009.00193	Graduated HS (do not count G.E.D.)	Dropped out of HS	Unskilled employees	Not relevant (e.g., was never employed)
329.009.00196	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.009.00201	Graduated HS (do not count G.E.D.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Clerical and sales workers, technicians, owners of little businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.009.00204	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Machine operators, semi-skilled employees
329.009.00235	Graduated JHS	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Machine operators, semi-skilled employees
329.009.00240	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.009.00303	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Higher executive, proprietors of large concerns, major professionals	Business managers in large concerns, proprietors of medium-sized businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.009.00304	Graduated HS (do not count G.E.D.)	Dropped out of HS	Clerical and sales workers, technicians, owners of little businesses	Not relevant (e.g., was never employed)
329.009.00324	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses
329.009.00328	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Business managers in large concerns, proprietors of medium-sized businesses	Machine operators, semi-skilled employees
329.009.00329	Received G.E.D.	Dropped out of College	Machine operators, semi-skilled employees	Not relevant (e.g., was never employed)
329.010.00182	Completed Doctoral, Medical, Law or Comparable Degree	Completed Doctoral, Medical, Law or Comparable Degree	Higher executive, proprietors of large concerns, major professionals	Higher executive, proprietors of large concerns, major professionals
329.010.00278	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.010.00280	Graduated JHS	Received G.E.D.	Not relevant (e.g., was never employed)	Not relevant (e.g., was never employed)
329.011.00283	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Skilled manual employees	Business managers in large concerns, proprietors of medium-sized businesses
329.011.00288	Graduated HS (do not count G.E.D.)	Dropped out of College	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses
329.012.00025	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.012.00220	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Business managers in large concerns, proprietors of medium-sized businesses	Business managers in large concerns, proprietors of medium-sized businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.012.00222	Graduated Junior College (A.A.)	Graduated HS (do not count G.E.D.)	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses
329.012.00226	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.012.00228	Dropped out of JHS	Dropped out of HS	Machine operators, semi-skilled employees	Unskilled employees
329.012.00231	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Higher executive, proprietors of large concerns, major professionals	Higher executive, proprietors of large concerns, major professionals

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.001.00061	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.001.00066	Completed Doctoral, Medical, Law or Comparable Degree	Graduated Senior College (B.A., B.S., B.F.A., etc)	Unskilled employees	Administrative personnel, owners of small independent businesses
329.001.00067	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Unskilled employees
329.001.00070	Graduated Junior College (A.A.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.001.00122	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.002.00050	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses
329.002.00056	Dropped out of College	Graduated HS (do not count G.E.D.)	Unskilled employees	Unskilled employees
329.002.00057	Graduated Senior College (B.A., B.S., B.F.A., etc)	Dropped out of College	Skilled manual employees	Skilled manual employees
329.002.00098	Dropped out of College	Dropped out of College	Administrative personnel, owners of small independent businesses	Not relevant (e.g., was never employed)
329.002.00100	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Unskilled employees
329.002.00103	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.002.00104	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Business managers in large concerns, proprietors of medium-sized businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.002.00243	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.002.00244	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Business managers in large concerns, proprietors of medium-sized businesses
329.002.00321	Dropped out of HS	Dropped out of College	Machine operators, semi-skilled employees	Unskilled employees
329.002.00322	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Not relevant (e.g., was never employed)
329.003.00073	Graduated HS (do not count G.E.D.)	Dropped out of College	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.003.00076	Graduated HS (do not count G.E.D.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.003.00079		Graduated Senior College (B.A., B.S., B.F.A., etc)	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.003.00088	Graduated Senior College (B.A., B.S., B.F.A., etc)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.003.00090	Completed Doctoral, Medical, Law or Comparable Degree	Graduated Senior College (B.A., B.S., B.F.A., etc)	Higher executive, proprietors of large concerns, major professionals	Business managers in large concerns, proprietors of medium-sized businesses
329.003.00092	Graduated JHS	Graduated Junior College (A.A.)	Skilled manual employees	Higher executive, proprietors of large concerns, major professionals

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.003.00093	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.003.00247	Dropped out of College	Dropped out of College	Higher executive, proprietors of large concerns, major professionals	Administrative personnel, owners of small independent businesses
329.003.00249	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.003.00289	Received G.E.D.	Dropped out of HS	Business managers in large concerns, proprietors of medium-sized businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.003.00290	Graduated JHS	Graduated JHS	Skilled manual employees	Not relevant (e.g., was never employed)
329.003.00314	Graduated HS (do not count G.E.D.)	Dropped out of College	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.003.00317	Graduated Junior College (A.A.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Clerical and sales workers, technicians, owners of little businesses	Skilled manual employees
329.004.00013	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.004.00014		Graduated Senior College (B.A., B.S., B.F.A., etc)		Administrative personnel, owners of small independent businesses
329.004.00211	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.004.00215	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Unskilled employees
329.005.00003	Graduated JHS	Graduated JHS	Not relevant (e.g., was never employed)	Not relevant (e.g., was never employed)
329.005.00006	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Business managers in large concerns, proprietors of medium-sized businesses	Not relevant (e.g., was never employed)
329.005.00007	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)		Clerical and sales workers, technicians, owners of little businesses
329.005.00009	Graduated Junior College (A.A.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Higher executive, proprietors of large concerns, major professionals	Higher executive, proprietors of large concerns, major professionals
329.005.00110	Graduated JHS	Graduated JHS	Unskilled employees	Not relevant (e.g., was never employed)
329.005.00113	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Not relevant (e.g., was never employed)	Unskilled employees
329.005.00117	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Unskilled employees
329.005.00118	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.005.00153	Graduated JHS	Graduated Senior College (B.A., B.S., B.F.A., etc)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.005.00255	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Completed Doctoral, Medical, Law or Comparable Degree	Business managers in large concerns, proprietors of medium-sized businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.005.00256	Graduated JHS	Graduated JHS	Unskilled employees	Unskilled employees

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Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.005.00295	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.005.00297	Completed Doctoral, Medical, Law or Comparable Degree	Graduated Senior College (B.A., B.S., B.F.A., etc)	Business managers in large concerns, proprietors of medium-sized businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.005.00332	Graduated Junior College (A.A.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Not relevant (e.g., was never employed)
329.005.00335	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Machine operators, semi-skilled employees	Not relevant (e.g., was never employed)
329.006.00040	Graduated JHS	Dropped out of College	Not relevant (e.g., was never employed)	Skilled manual employees
329.006.00041	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.007.00139	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)		Clerical and sales workers, technicians, owners of little businesses
329.007.00143		Graduated HS (do not count G.E.D.)		Clerical and sales workers, technicians, owners of little businesses
329.007.00146	Dropped out of College	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.007.00269	Dropped out of HS	Dropped out of College	Machine operators, semi-skilled employees	Machine operators, semi-skilled employees
329.007.00270	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.007.00307	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.007.00308	Dropped out of College	Graduated Junior College (A.A.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.008.00159	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.008.00161	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.008.00187		Graduated Junior College (A.A.)		Administrative personnel, owners of small independent businesses
329.008.00192	Graduated Junior College (A.A.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.008.00272	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Not relevant (e.g., was never employed)
329.008.00273	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.009.00127	Dropped out of JHS	Dropped out of HS	Unskilled employees	Unskilled employees
329.009.00132	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.009.00134	Dropped out of College	Graduated Senior College (B.A., B.S., B.F.A., etc)	Not relevant (e.g., was never employed)	Administrative personnel, owners of small independent businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.009.00137	Received G.E.D.	Graduated HS (do not count G.E.D.)	Unskilled employees	Clerical and sales workers, technicians, owners of little businesses
329.009.00171	Received G.E.D.	Graduated HS (do not count G.E.D.)	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses
329.009.00172	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated HS (do not count G.E.D.)	Higher executive, proprietors of large concerns, major professionals	Clerical and sales workers, technicians, owners of little businesses
329.009.00194	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.009.00195	Graduated HS (do not count G.E.D.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Clerical and sales workers, technicians, owners of little businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.009.00199	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Unskilled employees	Administrative personnel, owners of small independent businesses
329.009.00203	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.009.00236	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.009.00239	Dropped out of College	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.009.00262	Graduated HS (do not count G.E.D.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Clerical and sales workers, technicians, owners of little businesses	Business managers in large concerns, proprietors of medium-sized businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.009.00264	Dropped out of JHS	Graduated Senior College (B.A., B.S., B.F.A., etc)	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.009.00301	Dropped out of College	Dropped out of College	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.009.00305	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Higher executive, proprietors of large concerns, major professionals	Administrative personnel, owners of small independent businesses
329.009.00325	Dropped out of HS	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.009.00326	Graduated HS (do not count G.E.D.)	Dropped out of College	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.010.00279	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Clerical and sales workers, technicians, owners of little businesses	Not relevant (e.g., was never employed)
329.010.00281	Graduated HS (do not count G.E.D.)	Dropped out of College	Business managers in large concerns, proprietors of medium-sized businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.011.00163	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.011.00208	Graduated HS (do not count G.E.D.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Administrative personnel, owners of small independent businesses	Business managers in large concerns, proprietors of medium-sized businesses
329.011.00209	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Unskilled employees	Machine operators, semi-skilled employees

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.011.00284	Completed Doctoral, Medical, Law or Comparable Degree	Graduated Junior College (A.A.)	Higher executive, proprietors of large concerns, major professionals	Business managers in large concerns, proprietors of medium-sized businesses
329.011.00286	Graduated Junior College (A.A.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.012.00026	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.012.00219	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.012.00221	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.012.00223	Graduated JHS	Graduated JHS	Unskilled employees	Unskilled employees
329.012.00227	Received G.E.D.	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.012.00230	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.001.00062	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.001.00064	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.001.00069	Dropped out of College	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Clerical and sales workers, technicians, owners of little businesses	Administrative personnel, owners of small independent businesses
329.001.00071	Completed Doctoral, Medical, Law or Comparable Degree	Completed Doctoral, Medical, Law or Comparable Degree	Higher executive, proprietors of large concerns, major professionals	Business managers in large concerns, proprietors of medium-sized businesses
329.001.00123	Graduated HS (do not count G.E.D.)	Graduated JHS	Administrative personnel, owners of small independent businesses	Skilled manual employees
329.001.00207	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.002.00049	Completed Doctoral, Medical, Law or Comparable Degree	Graduated HS (do not count G.E.D.)	Business managers in large concerns, proprietors of medium-sized businesses	
329.002.00059	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.002.00060	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.002.00097	Dropped out of College	Dropped out of College	Administrative personnel, owners of small independent businesses	Not relevant (e.g., was never employed)

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.002.00101	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Not relevant (e.g., was never employed)
329.002.00107	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.002.00241	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.002.00246	Graduated HS (do not count G.E.D.)	Received G.E.D.	Machine operators, semi-skilled employees	Not relevant (e.g., was never employed)
329.002.00320	Graduated HS (do not count G.E.D.)	Dropped out of College	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.002.00323	Graduated Junior College (A.A.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Machine operators, semi-skilled employees
329.003.00074	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Machine operators, semi-skilled employees
329.003.00078	Graduated JHS	Graduated Senior College (B.A., B.S., B.F.A., etc)	Skilled manual employees	Business managers in large concerns, proprietors of medium-sized businesses
329.003.00080			Business managers in large concerns, proprietors of medium-sized businesses	Not relevant (e.g., was never employed)
329.003.00085	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.003.00086	Received G.E.D.	Graduated Junior College (A.A.)	Skilled manual employees	Administrative personnel, owners of small independent businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.003.00094	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.003.00252	Graduated HS (do not count G.E.D.)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Skilled manual employees	Business managers in large concerns, proprietors of medium-sized businesses
329.003.00291	Dropped out of JHS	Dropped out of JHS	Unskilled employees	Not relevant (e.g., was never employed)
329.003.00315	Dropped out of College	Graduated HS (do not count G.E.D.)	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.003.00316	Received G.E.D.	Received G.E.D.	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.004.00016	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.004.00018	Dropped out of College	Dropped out of JHS	Clerical and sales workers, technicians, owners of little businesses	Machine operators, semi-skilled employees
329.004.00020	Dropped out of HS	Dropped out of College	Unskilled employees	Clerical and sales workers, technicians, owners of little businesses
329.004.00213	Dropped out of JHS	Dropped out of College	Machine operators, semi-skilled employees	Administrative personnel, owners of small independent businesses
329.005.00001	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Machine operators, semi-skilled employees
329.005.00005	Graduated JHS	Graduated Junior College (A.A.)	Not relevant (e.g., was never employed)	Unskilled employees

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.005.00010	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Unskilled employees
329.005.00012	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Business managers in large concerns, proprietors of medium-sized businesses	Administrative personnel, owners of small independent businesses
329.005.00111	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Skilled manual employees
329.005.00114	Graduated Senior College (B.A., B.S., B.F.A., etc)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.005.00115	Graduated HS (do not count G.E.D.)	Dropped out of HS	Skilled manual employees	Not relevant (e.g., was never employed)
329.005.00120	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.005.00253	Completed Doctoral, Medical, Law or Comparable Degree	Graduated Senior College (B.A., B.S., B.F.A., etc)	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.005.00254	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Unskilled employees	Administrative personnel, owners of small independent businesses
329.005.00293	Graduated HS (do not count G.E.D.)	Graduated JHS	Skilled manual employees	Not relevant (e.g., was never employed)
329.005.00298	Graduated Junior College (A.A.)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.005.00331	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Not relevant (e.g., was never employed)	Clerical and sales workers, technicians, owners of little businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.005.00334	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.006.00037	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Skilled manual employees
329.006.00042	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.006.00259	Completed Doctoral, Medical, Law or Comparable Degree	Graduated Senior College (B.A., B.S., B.F.A., etc)	Higher executive, proprietors of large concerns, major professionals	Administrative personnel, owners of small independent businesses
329.007.00141	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Skilled manual employees	Administrative personnel, owners of small independent businesses
329.007.00144	Graduated JHS	Graduated JHS	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses
329.007.00266	Dropped out of College	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Machine operators, semi-skilled employees
329.007.00267	Graduated HS (do not count G.E.D.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.007.00311	Dropped out of College	Graduated Junior College (A.A.)	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.008.00158	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.008.00162	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.008.00191	Graduated Senior College (B.A., B.S., B.F.A., etc)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Higher executive, proprietors of large concerns, major professionals	Higher executive, proprietors of large concerns, major professionals
329.009.00128	Graduated HS (do not count G.E.D.)	Dropped out of College	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.009.00129	Graduated Junior College (A.A.)	Graduated Junior College (A.A.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.009.00135	Graduated Senior College (B.A., B.S., B.F.A., etc)	Dropped out of College	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.009.00136	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Not relevant (e.g., was never employed)	Skilled manual employees
329.009.00169	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Not relevant (e.g., was never employed)	Not relevant (e.g., was never employed)
329.009.00174	Dropped out of College	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Not relevant (e.g., was never employed)
329.009.00197	Received G.E.D.	Dropped out of HS	Skilled manual employees	Machine operators, semi-skilled employees
329.009.00198	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.009.00200	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses

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Listing of Personal History by Treatment Group and Patient: Part I
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Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.009.00202	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Junior College (A.A.)	Business managers in large concerns, proprietors of medium-sized businesses	Clerical and sales workers, technicians, owners of little businesses
329.009.00237	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Not relevant (e.g., was never employed)
329.009.00238	Received G.E.D.	Dropped out of College	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.009.00276	Graduated HS (do not count G.E.D.)	Graduated JHS	Clerical and sales workers, technicians, owners of little businesses	Clerical and sales workers, technicians, owners of little businesses
329.009.00302	Graduated Senior College (B.A., B.S., B.F.A., etc)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Higher executive, proprietors of large concerns, major professionals	Administrative personnel, owners of small independent businesses
329.009.00306		Dropped out of HS	Not relevant (e.g., was never employed)	Not relevant (e.g., was never employed)
329.009.00312	Graduated Senior College (B.A., B.S., B.F.A., etc)	Dropped out of College	Clerical and sales workers, technicians, owners of little businesses	Not relevant (e.g., was never employed)
329.009.00327	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated Junior College (A.A.)	Higher executive, proprietors of large concerns, major professionals	Administrative personnel, owners of small independent businesses
329.009.00330	Graduated JHS	Graduated JHS	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses
329.010.00183	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.010.00263	Graduated JHS	Graduated HS (do not count G.E.D.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.010.00277	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Skilled manual employees	Clerical and sales workers, technicians, owners of little businesses
329.010.00282	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Higher executive, proprietors of large concerns, major professionals	Clerical and sales workers, technicians, owners of little businesses
329.011.00164	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Skilled manual employees
329.011.00210	Dropped out of College	Received G.E.D.	Skilled manual employees	Not relevant (e.g., was never employed)
329.011.00285	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Machine operators, semi-skilled employees	Clerical and sales workers, technicians, owners of little businesses
329.011.00287	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Clerical and sales workers, technicians, owners of little businesses	Machine operators, semi-skilled employees
329.012.00027	Graduated HS (do not count G.E.D.)	Graduated Junior College (A.A.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.012.00217	Graduated HS (do not count G.E.D.)	Graduated HS (do not count G.E.D.)	Administrative personnel, owners of small independent businesses	Clerical and sales workers, technicians, owners of little businesses
329.012.00218	Graduated Senior College (B.A., B.S., B.F.A., etc)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Business managers in large concerns, proprietors of medium-sized businesses

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Listing of Personal History by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Highest Level of Education for Father	Highest Level of Education for Mother	Occupation for Father	Occupation for Mother
329.012.00224	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Graduated Senior College (B.A., B.S., B.F.A., etc)	Administrative personnel, owners of small independent businesses	Administrative personnel, owners of small independent businesses
329.012.00225	Graduated Senior College (B.A., B.S., B.F.A., etc)	Completed Masters Degree (M.A., M.S., M.S.W., etc.)	Administrative personnel, owners of small independent businesses	Business managers in large concerns, proprietors of medium-sized businesses

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.001.00063	2 parent home	6	Natural offspring	Regular education	
329.001.00065	1 parent & 1 step-parent	6	Natural offspring	Regular education	
329.001.00068	2 parent home	3	Natural offspring	Regular education	
329.001.00072	2 parent home	5	Natural offspring	Regular education	
329.001.00121	2 parent home	5	Natural offspring	Regular education	
329.001.00205	2 parent home	5	Natural offspring	Special education	LD CLASSES REMIDIAL SUPPORT
329.001.00206	2 parent home	4	Natural offspring	Regular education	
329.002.00055	Single parent alone	2	Natural offspring	Special education	FOR MILD TO MODERATE LEARNING DISABILITY
329.002.00058	Single parent alone	3	Natural offspring	Special education	ATTENTIONAL DIFFICULTIES
329.002.00099	Single parent alone	3	Natural offspring	Regular education	
329.002.00102	2 parent home	5	Natural offspring	Regular education	
329.002.00105	Single parent alone	3	Natural offspring	Regular education	
329.002.00106	2 parent home	4	Natural offspring	Regular education	
329.002.00242	2 parent home	4	Natural offspring	Regular education	
329.002.00245	Single parent alone	5	Natural offspring	Special education	BEHAVORIAL&ACADEMIC DIFFICULTIES
329.002.00319	Single parent alone	4	Natural offspring	Regular education	
329.003.00077	Single parent alone	4	Natural offspring	Regular education	
329.003.00081	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.003.00087	2 parent home	3	Natural offspring	Regular education	

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Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.003.00089	2 parent home	3	Natural offspring	Regular education	
329.003.00091	Single parent alone	4	Natural offspring	Regular education	
329.003.00248	2 parent home	5	Natural offspring	Regular education	
329.003.00250	Single parent alone	3	Natural offspring	Regular education	
329.003.00292	2 parent home	4	Natural offspring	Regular education	
329.003.00313	2 parent home	4	Natural offspring	Regular education	
329.004.00015	Single parent alone	2	Natural offspring	Regular education	
329.004.00017	2 parent home	4	Natural offspring	Regular education	
329.004.00019	Other relative(s) is (are) caregiver(s)	2	Natural offspring	Regular education	
329.004.00212		1	Natural offspring	Regular education	
329.004.00214	2 parent home	4	Natural offspring	Regular education	
329.005.00002	2 parent home	3	Natural offspring	Regular education	
329.005.00004	Single parent alone	2	Natural offspring	Regular education	
329.005.00008	Single parent alone	3	Natural offspring	Regular education	
329.005.00011	2 parent home	4	Adopted	Regular education	
329.005.00109	Other relative(s) is (are) caregiver(s)	5	Natural offspring	Regular education	
329.005.00112	2 parent home	7	Natural offspring	Regular education	
329.005.00116	Other relative(s) is (are) caregiver(s)	6	Natural offspring	Regular education	
329.005.00119	1 parent & 1 step-parent	5	Natural offspring	Regular education	

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Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.005.00151	Single parent alone	3	Natural offspring	Regular education	
329.005.00152	Single parent alone	2	Natural offspring	Regular education	HONORS CLASSES
329.005.00257	2 parent home	4	Natural offspring	Regular education	
329.005.00258	Single parent alone	3	Natural offspring	Regular education	
329.005.00299	Single parent alone	3	Natural offspring	Regular education	
329.005.00300	Single parent alone	4	Natural offspring	Regular education	
329.005.00333	Single parent alone	2	Natural offspring	Special education	ADVANCED PLACEMENT
329.005.00336	Single parent alone	7	Natural offspring	Regular education	
329.006.00038	1 parent & 1 step-parent	6	Natural offspring	Regular education	
329.006.00039	2 parent home	3	Natural offspring	Regular education	ART SPECIALTY
329.006.00260	Single parent alone	3	Natural offspring	Regular education	
329.006.00261	2 parent home	7	Natural offspring	Regular education	
329.007.00140	Single parent alone	4	Natural offspring	Regular education	
329.007.00142	2 parent home	3	Natural offspring	Regular education	
329.007.00145	2 parent home	4	Natural offspring	Regular education	
329.007.00265	1 parent & 1 step-parent	6	Natural offspring	Regular education	
329.007.00268	Single parent alone	2	Natural offspring	Regular education	
329.007.00294	Single parent alone	3	Natural offspring	Regular education	
329.007.00309	Other relative(s) is (are) caregiver(s)	3	Natural offspring	Regular education	
329.007.00310	2 parent home	4	Natural offspring	Regular education	

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Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.007.00318	2 parent home	4	Natural offspring	Regular education	
329.008.00157	Single parent alone	2	Natural offspring	Regular education	
329.008.00160	Parent & other relative(s) are caregiver(s)	2	Natural offspring	Regular education	
329.008.00188	Single parent alone	4	Natural offspring	Regular education	
329.008.00271	2 parent home	4	Natural offspring	Regular education	3MOS AGO HOME SCHOOL-NOW COMBO.PUBLIC SC
329.008.00275	2 parent home	4	Natural offspring	Regular education	HE IS DISLEXIC
329.009.00130	2 parent home	6	Adopted	Regular education	
329.009.00131	2 parent home	4	Natural offspring	Regular education	
329.009.00133	Single parent alone	3	Natural offspring	Regular education	
329.009.00138	Single parent alone	2	Natural offspring	Regular education	
329.009.00170	Single parent alone	2	Natural offspring	Regular education	
329.009.00173	Single parent alone	5	Natural offspring	Regular education	
329.009.00193	Single parent alone	3	Natural offspring	Regular education	
329.009.00196	2 parent home	4	Natural offspring	Regular education	
329.009.00201	Single parent alone	3	Natural offspring	Regular education	
329.009.00204	2 parent home	7	Natural offspring	Special education	HERMAN READING PROGRAM
329.009.00235	2 parent home	4	Natural offspring	Regular education	
329.009.00240	2 parent home	5	Natural offspring	Regular education	
329.009.00303	2 parent home	4	Natural offspring	Regular education	

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Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.009.00304	2 parent home	7	Natural offspring	Regular education	
329.009.00324	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.009.00328	2 parent home	5	Natural offspring	Regular education	
329.009.00329	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.010.00182	2 parent home	5	Natural offspring	Regular education	
329.010.00278	2 parent home	3	Natural offspring	Regular education	
329.010.00280	Other relative(s) is (are) caregiver(s)	2	Natural offspring	Regular education	
329.011.00283	1 parent & 1 common-law parent	5	Natural offspring	Regular education	
329.011.00288	Single parent alone	4	Natural offspring	Special education	12:1:1
329.012.00025	2 parent home	4	Natural offspring	Regular education	
329.012.00220	2 parent home	5	Natural offspring	Regular education	
329.012.00222	Single parent alone	2	Natural offspring	Regular education	
329.012.00226	2 parent home	4	Adopted	Regular education	
329.012.00228	Single parent alone	3	Natural offspring	Regular education	
329.012.00231	1 parent & 1 common-law parent	4	Adopted	Regular education	

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Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.001.00061	Parent & other relative(s) are caregiver(s)	3	Natural offspring	Regular education	
329.001.00066	2 parent home	4	Natural offspring	Regular education	
329.001.00067	1 parent & 1 step-parent	4	Natural offspring	Regular education	
329.001.00070	2 parent home	3	Natural offspring	Regular education	
329.001.00122	2 parent home	7	Natural offspring	Regular education	
329.002.00050	Single parent alone	2	Natural offspring	Regular education	
329.002.00056	2 parent home	4	Natural offspring	Regular education	
329.002.00057	2 parent home	5	Natural offspring	Special education	MAINSTREAMED
329.002.00098	2 parent home	5	Natural offspring	Regular education	
329.002.00100	1 parent & 1 step-parent	4	Natural offspring	Special education	HAS INDIVIDUALIZED EDUCATION PLAN/MAINST
329.002.00103	2 parent home	4	Natural offspring	Regular education	
329.002.00104	2 parent home	5	Natural offspring	Regular education	
329.002.00243	Single parent alone	4	Natural offspring	Regular education	
329.002.00244	2 parent home	4	Natural offspring	Regular education	
329.002.00321	1 parent & 1 step-parent	4	Natural offspring	Regular education	
329.002.00322	1 parent & 1 step-parent	6	Natural offspring	Regular education	
329.003.00073	2 parent home	5	Natural offspring	Regular education	
329.003.00076	Single parent alone	2	Natural offspring	Regular education	
329.003.00079	Single parent alone	2	Natural offspring	Regular education	

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Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.003.00088	Single parent alone	2	Natural offspring	Regular education	
329.003.00090	2 parent home	5	Natural offspring	Regular education	
329.003.00092	Single parent alone	4	Natural offspring	Regular education	
329.003.00093	Single parent alone	3	Natural offspring	Regular education	
329.003.00247	1 parent & 1 step-parent	5	Natural offspring	Special education	EAC PORT WASHINGTON
329.003.00249	1 parent & 1 common-law parent	3	Natural offspring	Regular education	
329.003.00289	Single parent alone	3	Natural offspring	Regular education	
329.003.00290	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.003.00314	Parent & other relative(s) are caregiver(s)	5	Natural offspring	Regular education	
329.003.00317	2 parent home	4	Natural offspring	Regular education	
329.004.00013	2 parent home	5	Natural offspring	Regular education	
329.004.00014	Single parent alone	2	Natural offspring	Regular education	
329.004.00211	2 parent home	3	Natural offspring	Regular education	
329.004.00215	2 parent home	4	Natural offspring	Regular education	
329.005.00003	Other relative(s) is (are) caregiver(s)	3	Adopted	Regular education	
329.005.00006	2 parent home	3	Natural offspring	Regular education	NOTE:ALL ADVANCED PLACEMENT CLASSES
329.005.00007	Single parent alone	3	Natural offspring	Regular education	
329.005.00009	2 parent home	6	Natural offspring	Regular education	+1HONORS CLASS

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.005.00110	Other relative(s) is (are) caregiver(s)	3	Natural offspring	Regular education	
329.005.00113	Single parent alone	3	Natural offspring	Regular education	
329.005.00117	2 parent home	4	Natural offspring	Regular education	
329.005.00118	2 parent home	5	Natural offspring	Regular education	
329.005.00153	Single parent alone	2	Adopted	Special education	MOST CLASSES
329.005.00255	2 parent home	4	Natural offspring	Regular education	
329.005.00256	Single parent alone	4	Natural offspring	Regular education	
329.005.00295	2 parent home	3	Natural offspring	Regular education	
329.005.00297	2 parent home	4	Natural offspring	Special education	ENGLISH AND HISTORY - LEARNING DISABLED
329.005.00332	2 parent home	5	Natural offspring	Regular education	
329.005.00335	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.006.00040	2 parent home	3	Natural offspring	Special education	WILLOWPARK H.S.
329.006.00041	2 parent home	4	Natural offspring	Regular education	
329.007.00139	Single parent alone	3	Natural offspring	Regular education	
329.007.00143	Other relative(s) is (are) caregiver(s)	2	Natural offspring	Special education	EMOTIONALLY DISABLED
329.007.00146	2 parent home	3	Adopted	Regular education	
329.007.00269	Single parent alone	3	Natural offspring	Regular education	
329.007.00270	Single parent alone	4	Natural offspring	Regular education	
329.007.00307	2 parent home	5	Natural offspring	Regular education	

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.007.00308	2 parent home	5	Natural offspring	Regular education	
329.008.00159	Single parent alone	6	Natural offspring	Regular education	
329.008.00161	Single parent alone	3	Natural offspring	Regular education	
329.008.00187	Single parent alone	3	Natural offspring	Regular education	
329.008.00192	2 parent home	4	Natural offspring	Regular education	
329.008.00272	1 parent & 1 step-parent	6	Natural offspring	Regular education	
329.008.00273	1 parent & 1 common-law parent	3	Natural offspring	Regular education	
329.009.00127	Single parent alone	4	Natural offspring	Regular education	
329.009.00132	2 parent home	5	Adopted	Regular education	
329.009.00134	Single parent alone	2	Natural offspring	Regular education	
329.009.00137	Single parent alone	3	Natural offspring	Regular education	
329.009.00171	1 parent & 1 step-parent	6	Natural offspring		
329.009.00172	Single parent alone	2	Natural offspring	Regular education	
329.009.00194	Single parent alone	3	Natural offspring	Regular education	
329.009.00195	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.009.00199	Single parent alone	5	Natural offspring	Special education	CONTENT MASTERY
329.009.00203	1 parent & 1 step-parent	6	Natural offspring	Regular education	
329.009.00236	Single parent alone	2	Natural offspring	Regular education	
329.009.00239	2 parent home	3	Adopted	Regular education	
329.009.00262	1 parent & 1 step-parent	5	Natural offspring	Regular education	

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.009.00264	1 parent & 1 step-parent	3	Natural offspring	Special education	RESOURCE FOR EVERY CLASS EXCEPT BAND
329.009.00301	Single parent alone	3	Natural offspring	Regular education	
329.009.00305	2 parent home	5	Natural offspring	Regular education	
329.009.00325	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.009.00326	Single parent alone	3	Natural offspring	Regular education	
329.010.00279	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.010.00281	Single parent alone	5	Natural offspring	Special education	LD (READING & LANG. ARTS)
329.011.00163	2 parent home	7	Natural offspring	Special education	REGULAR CLASS WITH RESOURCE ROOM
329.011.00208	Single parent alone	2	Natural offspring	Regular education	
329.011.00209	2 parent home	4	Natural offspring	Regular education	
329.011.00284	2 parent home	5	Natural offspring	Regular education	
329.011.00286	2 parent home	5	Natural offspring	Regular education	
329.012.00026	Single parent alone	3	Natural offspring	Regular education	
329.012.00219	2 parent home	4	Natural offspring	Regular education	
329.012.00221	Single parent alone	5	Natural offspring	Regular education	
329.012.00223	Parent & other relative(s) are caregiver(s)	4	Natural offspring	Regular education	
329.012.00227	2 parent home	3	Natural offspring	Regular education	
329.012.00230	Single parent alone	4	Natural offspring	Regular education	

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.001.00062	1 parent & 1 common-law parent	3	Natural offspring	Regular education	
329.001.00064	2 parent home	4	Natural offspring	Regular education	
329.001.00069	1 parent & 1 step-parent	3	Natural offspring	Regular education	
329.001.00071	2 parent home	4	Natural offspring	Regular education	
329.001.00123	2 parent home	5	Natural offspring	Regular education	
329.001.00207	Single parent alone	4	Natural offspring	Regular education	
329.002.00049	2 parent home	3	Natural offspring	Regular education	
329.002.00059	Single parent alone	3	Natural offspring	Regular education	
329.002.00060	2 parent home	5	Natural offspring	Regular education	
329.002.00097	2 parent home	5	Natural offspring	Regular education	
329.002.00101	2 parent home	3	Natural offspring	Regular education	
329.002.00107	Single parent alone	3	Natural offspring	Regular education	
329.002.00241	2 parent home	4	Natural offspring	Regular education	
329.002.00246	Parent & other relative(s) are caregiver(s)	3	Natural offspring	Regular education	
329.002.00320	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.002.00323	2 parent home	4	Natural offspring	Regular education	
329.003.00074	Single parent alone	4	Natural offspring	Regular education	
329.003.00078	2 parent home	5	Natural offspring	Regular education	
329.003.00080	1 parent & 1 step-parent	3	Natural offspring	Regular education	

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.003.00085	2 parent home	5	Natural offspring	Regular education	
329.003.00086	2 parent home	5	Natural offspring	Regular education	
329.003.00094	2 parent home	3	Natural offspring	Regular education	
329.003.00252	Single parent alone	2	Natural offspring	Regular education	
329.003.00291	2 parent home	6	Natural offspring	Regular education	
329.003.00315	Single parent alone	4	Natural offspring	Regular education	
329.003.00316	2 parent home	6	Natural offspring	Regular education	
329.004.00016	1 parent & 1 step-parent	4	Natural offspring	Regular education	
329.004.00018	Single parent alone	3	Natural offspring	Regular education	
329.004.00020	2 parent home	4	Natural offspring	Regular education	
329.004.00213	2 parent home	4	Natural offspring	Regular education	
329.005.00001	Single parent alone	2	Natural offspring	Regular education	
329.005.00005	Single parent alone	4	Natural offspring	Regular education	
329.005.00010	2 parent home	8	Natural offspring	Regular education	
329.005.00012	2 parent home	4	Natural offspring	Regular education	
329.005.00111	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.005.00114	1 parent & 1 step-parent	4	Natural offspring	Regular education	
329.005.00115	2 parent home	4	Natural offspring	Regular education	
329.005.00120	Single parent alone	3	Natural offspring	Regular education	
329.005.00253	Single parent alone	4	Natural offspring	Regular education	

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.005.00254	1 parent & 1 step-parent	4	Natural offspring	Regular education	
329.005.00293	Single parent alone	7	Natural offspring	Regular education	
329.005.00298	Single parent alone	5	Natural offspring	Special education	"QUEST" - ACCELERATED CLASSES
329.005.00331	1 parent & 1 step-parent	4	Natural offspring	Special education	ADVANCED CLASSES
329.005.00334	2 parent home	4	Natural offspring	Regular education	
329.006.00037	2 parent home	4	Natural offspring	Regular education	
329.006.00042	1 parent & 1 step-parent	4	Natural offspring	Regular education	
329.006.00259	2 parent home	5	Natural offspring	Regular education	
329.007.00141	2 parent home	4	Natural offspring	Regular education	
329.007.00144	1 parent & 1 step-parent	3	Natural offspring	Regular education	
329.007.00266	2 parent home	4	Natural offspring	Regular education	
329.007.00267	2 parent home	3	Natural offspring	Regular education	
329.007.00311	2 parent home	4	Natural offspring	Regular education	
329.008.00158	Single parent alone	6	Natural offspring	Regular education	
329.008.00162	Single parent alone	2	Natural offspring	Regular education	
329.008.00191	Other relative(s) is (are) caregiver(s)	5	Natural offspring	Regular education	
329.009.00128	2 parent home	4	Natural offspring	Special education	EMOTIONALLY DISTURBED MAINSTREAM FROM CL
329.009.00129	2 parent home	4	Natural offspring	Regular education	
329.009.00135	Single parent alone	2	Natural offspring	Regular education	

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.009.00136	Single parent alone	2	Natural offspring	Regular education	
329.009.00169	Other relative(s) is (are) caregiver(s)	3	Natural offspring	Regular education	
329.009.00174	2 parent home	4	Natural offspring	Regular education	
329.009.00197	2 parent home	5	Natural offspring	Special education	CONTENT MASTERY-SPELLING READING
329.009.00198	Single parent alone	3	Natural offspring	Regular education	
329.009.00200	2 parent home	2	Natural offspring		
329.009.00202	Single parent alone	2	Natural offspring	Regular education	
329.009.00237	2 parent home	8	Natural offspring	Regular education	
329.009.00238	2 parent home	4	Natural offspring	Regular education	
329.009.00276	Other relative(s) is (are) caregiver(s)	2	Natural offspring	Regular education	
329.009.00302	2 parent home	5	Natural offspring	Regular education	
329.009.00306	Other relative(s) is (are) caregiver(s)	3	Adopted	Special education	LEARNING DISABILITIES
329.009.00312	Single parent alone	7	Natural offspring	Regular education	
329.009.00327	1 parent & 1 step-parent	4	Natural offspring	Regular education	
329.009.00330	1 parent & 1 common-law parent	3	Natural offspring	Regular education	
329.010.00183	1 parent & 1 step-parent	5	Natural offspring	Regular education	
329.010.00263	1 parent & 1 step-parent	8	Natural offspring	Special education	HISTORY, SCIENCE, ENGLISH, & MATH

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Appendix B.5

Listing of Personal History by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Composition	Number of People in Household	Adopted/Natural Offspring	School Placement	Specify
329.010.00277	Single parent alone	2	Natural offspring	Regular education	
329.010.00282	Single parent alone	4	Natural offspring	Regular education	
329.011.00164	Single parent alone	3	Natural offspring	Regular education	
329.011.00210	2 parent home	5	Natural offspring	Regular education	
329.011.00285	2 parent home	4	Natural offspring	Regular education	
329.011.00287	2 parent home	6	Natural offspring	Regular education	
329.012.00027	Single parent alone	2	Natural offspring	Regular education	
329.012.00217	2 parent home	4	Natural offspring	Regular education	
329.012.00218	2 parent home	5	Natural offspring	Regular education	
329.012.00224	2 parent home	4	Natural offspring	Regular education	
329.012.00225	2 parent home	4	Natural offspring	Regular education	

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.001.00063	Biologic Mother	40	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Biologic Father	43	Male	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	14	Female	No	1	1	0	0	.	.	.	1	1	1	1	.	.	0	0
	Sibling #2	13	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #3	10	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #4	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.001.00068	Biologic Mother	41	Female	No	.	.	0	0	0	.	.	1	1	.	.	.	.	0	0
	Biologic Father	43	Male	No	.	.	0	0	0	.	.	.	.	.	.	.	.	0	0
	Sibling #1	19	Female	No	.	.	0	0	0	.	.	.	.	.	.	.	.	0	0
	Sibling #2	13	Female	No	1	1	0	0	0	1	1	1	1	1	1	1	1	0	0
329.001.00072	Biologic Mother	45	Female	No	1	1	0	0	.	1	1	1	1	1	1	1	.	0	0
	Biologic Father	45	Male	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	15	Male	No	1	1	0	0	.	.	.	1	1	1	1	1	1	0	0
	Sibling #2	12	Female	No	.	1	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #3	10	Male	No	.	1	0	0	.	.	.	.	.	.	.	.	.	0	0
329.001.00121	Biologic Mother	43	Female	No	1	1	0	0	1	0	0	1	1	1	1	.	.	.	0
	Biologic Father	46	Male	No	.	.	0	0	.	0	0	.	.	.	.	.	.	.	0
	Sibling #1	15	Male	No	1	1	0	0	.	0	0	1	1	1	1	.	.	.	0
	Sibling #2	12	Male	No	1	1	0	0	.	0	0	.	.	1	1	1	1	.	0
	Sibling #3	10	Female	No	.	.	0	0	.	0	0	.	.	.	.	.	.	1	0
329.001.00205	Biologic Mother	37	Female	No	.	.	0	0	0	.	.	1	1	.	.	.	.	.	0
	Biologic Father	38	Male	No	.	.	0	0	0	.	.	.	.	.	.	1	1	.	0
	Sibling #1	12	Male	No	1	1	0	0	0	1	1	1	1	1	1	.	1	.	0
	Sibling #2	10	Female	No	.	.	0	0	0	.	.	.	.	.	.	.	1	1	0
	Sibling #3	5	Female	No	.	.	0	0	0	.	.	.	.	.	.	.	1	.	0
329.001.00206	Biologic Mother	52	Female	No	1	1	0	0	0	.	.	1	.	.	.	.	.	0	0
	Biologic Father	54	Male	No	1	.	0	0	0	.	.	1	.	.	.	1	.	0	0
	Sibling #1	17	Male	No	1	1	0	0	0	1	1	1	1	1	1	1	1	0	0
	Sibling #2	14	Female	No	.	.	0	0	0	.	.	1	.	.	.	.	.	0	0
329.002.00055	Biologic Mother	48	Female	No	.	1	.	9	.	.	.	1	.	1	1	1	1	9	9
	Biologic Father	43	Male	No	1	.	.	9	.	.	.	.	.	.	.	.	.	9	9
	Sibling #1	29	Female	No	1	1	.	9	.	.	1	1	.	.	.	.	.	9	9
	Sibling #2	23	Male	Yes	1	1	1	9	1	1	1	1	1	1	1	1	1	9	9
	Sibling #3	26	Male	No	.	.	.	9	.	.	.	.	.	.	.	.	.	9	9

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.002.00055	Sibling #4	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00058	Biologic Mother	42	Female	No	1	1	0	0	1	1	.	1	1	1	1	1	1	0	0
	Biologic Father	36	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	24	Male	No	.	.	0	0	.	1	.	1	.	.	.	.	.	0	0
	Sibling #2	22	Male	No	1	1	0	0	.	1	.	.	.	.	.	.	.	0	0
	Sibling #3	16	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #4	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00099	Biologic Mother	37	Female	Yes	0	.	0	0	0	0	.	1	0	.	0	.	.	1	0
	Biologic Father	47	Male	No	0	1	0	0	0	0	.	1	0	.	0	1	1	1	0
	Sibling #1	15	Male	No	0	.	0	0	0	0	.	1	0	1	0	.	.	1	0
	Sibling #2	9	Female	No	0	.	0	0	0	0	.	1	0	.	0	.	.	1	0
329.002.00102	Biologic Mother	35	Female	No	0	1	0	0	1	1	1	1	1	1	1	1	1	1	.
	Biologic Father	39	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	0	.	0	0	.	.	.	1	.	.	.	1	1	1	1
	Sibling #2	13	Female	No	0	.	0	0	.	1	1	.	.	.	.	1	1	.	.
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00105	Biologic Mother	43	Female	No	0	0	0	0	.	0	0	.	.	.	.	.	.	0	0
	Biologic Father	52	Male	Yes	0	0	0	0	.	0	0	.	.	.	.	.	.	0	0
	Sibling #1	17	Male	No	0	0	0	0	1	0	0	1	.	.	.	.	.	0	0
	Sibling #2	16	Male	Yes	0	0	0	0	.	0	0	1	1	1	1	1	1	0	0
329.002.00106	Biologic Mother	32	Female	No	.	.	0	0	0	.	.	.	.	.	0	.	.	0	.
	Biologic Father	36	Male	No	1	.	0	0	0	1	.	.	.	.	0	.	.	0	.
	Sibling #1	15	Female	No	.	1	0	0	0	1	1	1	1	1	0	1	1	0	.
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00242	Biologic Mother	36	Female	No	.	1	.	0	.	.	.	1	1	1	1	.	.	0	0
	Biologic Father	39	Male	No	.	1	.	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	15	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	.	0	0
	Sibling #2	12	Male	No	1	1	1	0	.	1	1	1	.	.	.	1	1	0	0
329.002.00245	Biologic Mother	36	Female	No	0	.	.	0	.	.	.	1	0	1	0	.	.	0	0
	Biologic Father	44	Male	No	0	.	.	0	.	.	.	.	0	.	0	.	.	0	0
	Sibling #1	14	Female	No	0	1	1	0	1	1	1	1	0	1	0	1	.	0	0
	Sibling #2	18	Male	No	0	1	.	0	.	.	.	.	0	.	0	.	.	0	0
	Sibling #3	16	Female	No	0	.	.	0	.	.	.	1	0	.	0	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.002.00245	Sibling #4	11	Female	No	0	.	.	0	.	.	.	.	0	.	0	.	.	0	0
	Sibling #5	9	Male	No	0	1	.	0	.	.	.	.	0	.	0	.	.	0	0
329.002.00319	Biologic Mother	42	Female	No	.	.	0	0	0	0	.	.	.	0	.	.	.	0	.
	Biologic Father	55	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	24	Male	No	.	.	0	0	0	0	.	.	.	0	.	1	1	0	.
	Sibling #2	17	Male	No	.	.	0	0	0	0	.	.	.	0	.	.	.	0	.
	Sibling #3	16	Female	No	1	1	0	0	0	0	.	1	1	0	.	1	1	0	.
329.003.00077		.			.	.	.	0	.	.	.	.	0	.	.	.	.	0	0
	Biologic Mother	45	Female	No	1	1	1	0	1	1	.	1	0	1	1	1	1	0	0
	Biologic Father	55	Male	No	.	.	.	0	.	.	1	.	0	.	.	.	.	0	0
	Sibling #1	29	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00087	Biologic Mother	49	Female	No	.	.	0	0	.	.	.	.	.	1	.	.	.	0	0
	Biologic Father	50	Male	No	1	1	0	0	1	.	.	1	1	1	1	1	1	0	0
	Sibling #1	14	Female	Yes	1	1	0	0	.	1	1	1	1	1	1	.	.	0	0
329.003.00089	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	60	Male	No	1	1	1	0	1	0	0	1	0	.	0	0	0	0	0
	Sibling #1	14	Female	No	1	1	.	0	1	0	0	1	0	1	0	0	0	0	0
329.003.00091	Biologic Mother	.	Female	No	.	1	.	0	.	.	.	1	.	1	.	.	.	0	0
	Biologic Father	.	Male	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	.	Male	No	.	1	.	0	.	1	1	1	1	1	.	1	.	0	0
	Sibling #3	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00248	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	22	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	12	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	8	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00250		.			0	0	0	0	0	0	9	9	9	.	9	.	9	.	0
	Biologic Mother	43	Female	No	0	0	0	0	0	0	9	9	9	1	9	1	9	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.003.00250	Biologic Father	42	Male	No	0	0	0	0	0	0	9	9	9	.	9	1	9	.	0
	Sibling #1	18	Female	No	0	0	0	0	0	0	9	9	9	1	9	1	9	1	0
	Sibling #2	15	Female	No	0	0	0	0	0	0	9	9	9	1	9	1	9	1	0
	Sibling #3	8	Female	No	0	0	0	0	0	0	9	9	9	.	9	.	9	.	0
	Sibling #4	2	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00292	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	.	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	0	0	0	.	0	0	0	0	0
	Sibling #1	16	Male	No	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	0	0	0	.	0	0	0	0	0
329.003.00313	Biologic Mother	36	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	37	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #2	18	Male	No	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
329.004.00015	Biologic Mother	42	Female	No	1	1	0	0	1	9	9	1	1	1	1	1	1	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	.	.	0	0	.	9	9	1	.	1	1	1	1	0	0
329.004.00017	Biologic Mother	50	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	52	Male	No	0	0	0	0	0	0	.	0	.	0	.	1	1	0	.
	Sibling #1	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00019	Biologic Mother	.	Female	No	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0
	Biologic Father	.	Male	No	1	.	.	0	0	1	1	.	.	.	.	.	.	0	0
	Sibling #1	.	Female	No	1	1	.	0	0	1	1	1	1	1	1	1	1	0	0
329.004.00212	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00214	Biologic Mother	41	Female	No	1	1	0	0	1	0	1	1	1	1	1	1	1	0	0
	Biologic Father	43	Male	No	1	1	0	0	1	0	1	1	1	1	1	1	1	0	0
	Sibling #1	21	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	1	.	0	0	1	0	.	1	1	1	1	1	1	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.005.00002	Biologic Mother	35	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	0	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00004	Biologic Mother	41	Female	No	0	1	0	0	0	0	0	.	.	.	.	.	.	0	0
	Biologic Father	44	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Male	Yes	0	.	0	0	0	0	0	1	1	1	0	1	1	0	0
329.005.00008	Biologic Mother	34	Female	No	0	1	0	0	0	.	0	1	1	1	1	1	1	0	0
	Biologic Father	33	Male	No	0	1	0	0	0	1	0	.	.	.	.	.	.	0	0
	Sibling #1	12	Male	No	0	1	0	0	0	.	0	1	1	1	.	1	1	0	0
	Sibling #2	9	Male	No	0	1	0	0	0	.	0	1	.	.	.	.	.	0	0
329.005.00109	Biologic Mother	31	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	28	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	15	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #1	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00112	Biologic Mother	61	Male	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	54	Female	No	.	1	.	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	21	Female	No	.	1	.	0	.	.	.	1	.	.	.	1	.	0	0
	Sibling #2	18	Male	No	1	1	1	0	1	1	1	1	1	.	.	1	1	0	0
	Sibling #3	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Female	No	1	1	.	0	.	1	1	1	1	1	.	1	.	0	0
	Sibling #5	13	Male	No	1	1	.	0	.	1	1	1	1	.	.	1	.	0	0
329.005.00116	Biologic Mother	39	Female	No	.	.	.	0	.	1	1	1	1	1	9	.	.	0	0
	Biologic Father	51	Male	No	1	1	1	0	.	1	1	.	.	1	9	.	.	0	0
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	25	Female	No	1	1	.	0	1	.	.	1	1	.	9	.	.	0	0
	Sibling #3	24	Female	No	.	1	.	0	.	.	.	1	.	.	9	.	.	0	0
	Sibling #4	22	Male	No	.	.	.	0	.	.	.	.	.	.	9	.	.	0	0
	Sibling #5	16	Female	No	1	1	1	0	1	.	.	1	1	1	9	1	1	0	0
	Child #1	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00119	Biologic Mother	44	Female	No	.	1	0	0	.	.	0	.	.	.	.	.	.	0	0
	Biologic Father	46	Male	No	1	1	0	0	1	.	0	1	1	1	1	1	1	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.005.00119	Sibling #1	19	Female	No	1	1	0	0	1	1	0	1	1	1	1	1	1	0	0
	Sibling #2	14	Female	No	1	1	0	0	1	.	0	1	1	1	1	1	1	0	0
	Sibling #3	7	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00151	Biologic Mother	40	Female	No	1	1	.	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	40	Male	No	1	1	.	0	.	1	1	1	1	1	1	.	1	0	0
	Sibling #1	17	Male	No	1	1	.	0	1	.	.	1	1	1	1	1	1	0	0
	Sibling #2	15	Male	No	1	1	1	0	1	1	1	1	1	.	.	1	1	0	0
	Sibling #3	14	Female	No	1	1	.	0	.	1	1	1	1	1	1	1	1	0	0
	Sibling #4	13	Female	No	1	1	.	0	.	.	.	1	1	.	.	.	.	0	0
329.005.00152	Biologic Mother	37	Female	No	1	1	1	0	1	0	0	1	1	1	0	.	0	0	0
	Biologic Father	39	Male	No	.	.	.	0	.	0	0	.	.	.	0	.	0	0	0
	Sibling #1	15	Female	No	.	1	.	0	.	0	0	1	1	1	0	1	0	0	0
329.005.00257	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	1	.	.	.	0	0	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	.	.	.	.	0	0	0	0
	Sibling #2	12	Female	No	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0
329.005.00258	Biologic Mother	45	Male	No	1	1	1	.	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	44	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	1	.	.
	Sibling #1	14	Female	No	1	.	.	.	.	.	.	1	1	1	1	1	1	.	.
	Sibling #2	9	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00299	Biologic Mother	34	Female	No	1	1	0	0	.	0	0	1	.	1	.	0	0	0	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	1	1	0	0	.	0	0	1	1	1	1	0	0	0	0
	Sibling #2	9	Male	No	.	.	0	0	1	0	0	.	.	.	.	0	0	0	0
329.005.00300	Biologic Mother	45	Female	No	0	1	0	0	1	0	0	1	1	1	1	1	1	0	0
	Biologic Father	50	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	1	0	0	1	0	0	.	.	.	.	.	.	0	0
	Sibling #2	12	Male	No	0	1	0	0	1	0	0	1	.	.	.	1	1	0	0
	Sibling #3	9	Male	No	0	1	0	0	.	0	0	.	.	.	.	.	.	0	0
329.005.00333	Biologic Mother	46	Female	No	1	1	0	0	1	1	1	1	1	.	.	1	1	0	0
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	19	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #2	16	Female	No	.	.	0	0	.	1	1	1	1	1	1	1	1	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.005.00336	Biologic Mother	42	Female	No	1	1	1	.	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	41	Male	No	.	.	.	1	1	1	1	.	.	1	1	1	1	.	.
	Sibling #1	16	Female	No	.	1	.	.	.	1	1	1	1	1	1	1	1	.	.
	Sibling #2	14	Female	No	.	1	.	.	.	1	1	1	1	1	1	1	1	.	.
	Sibling #3	7	Male	No	.	1	.	.	1	1	1	.	.	.	.	.	.	.	.
	Sibling #4	12	Male	No	.	1	.	.	1	1	1	.	.	.	.	1	.	.	.
329.006.00038	Biologic Mother	35	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	1	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	1	1	1	.	1	1	.	1	.	1	.	1	1	.	.
	Sibling #3	12	Female	No	1	1	.	.	.	1	.	.	.	.	.	.	.	.	1
	Sibling #4	11	Female	No	.	1	.	.	.	.	.	.	.	.	.	.	.	1	.
	Sibling #5	5	Male	No	1	1	.	.	.	.	.	.	.	.	.	.	.	.	1
329.006.00039		.			.	.	0	0	.	.	0	.	.	.	.	.	.	0	.
	Biologic Mother	47	Female	No	.	1	0	0	1	.	0	1	.	1	.	1	1	0	.
	Biologic Father	48	Male	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	.
	Sibling #1	24	Male	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	.
	Sibling #2	21	Male	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	.
	Sibling #3	15	Female	No	1	1	0	0	.	1	0	1	1	1	1	1	1	0	.
329.006.00260	Biologic Mother	56	Female	No	.	1	0	0	1	0	.	1	1	1	.	1	1	0	.
	Biologic Father	56	Male	Yes	1	.	0	0	.	0	.	1	.	.	.	.	.	0	.
	Sibling #1	17	Female	No	.	1	0	0	.	0	.	1	1	1	1	.	.	0	.
	Sibling #2	10	Male	No	.	1	0	0	.	0	.	.	.	.	.	.	.	0	.
329.006.00261	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	38	Male	No	0	.	0	0	0	.	.	.	.	0	0	.	.	.	.
	Sibling #1	19	Female	No	0	.	0	0	0	.	.	.	.	0	0	.	.	1	1
	Sibling #2	17	Male	No	0	1	0	0	0	1	1	1	1	0	0	1	1	.	.
	Sibling #3	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	7	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00140	Biologic Mother	32	Female	No	0	.	0	0	0	.	0	.	.	.	0	1	.	1	0
	Biologic Father	37	Male	No	0	.	0	0	0	1	0	.	.	.	0	.	.	.	0
	Sibling #1	11	Male	No	0	1	0	0	0	.	0	1	1	1	0	1	1	1	0
	Sibling #2	9	Male	No	0	.	0	0	0	.	0	.	.	.	0	.	.	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.007.00142	Biologic Mother	44	Female	No	1	1	0	0	1	1	0	1	1	1	1	1	1	0	.
	Biologic Father	46	Male	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	.
	Sibling #1	15	Male	No	.	1	0	0	.	.	0	1	1	1	1	1	1	0	.
329.007.00145	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	41	Male	No	0	0	0	0	0	0	.	.	0	.	0	0	.	9	.
	Sibling #1	23	Female	No	0	0	0	0	0	0	.	.	0	.	0	0	.	9	.
	Sibling #2	16	Male	No	0	0	0	0	0	0	.	1	0	1	0	0	.	9	.
	Sibling #3	14	Female	No	0	0	0	0	0	0	.	.	0	.	0	0	.	9	.
329.007.00265	Biologic Mother	34	Female	No	1	1	0	0	9	.	.	1	.	1	.	0	.	0	.
	Biologic Father	29	Male	Yes	1	.	0	0	9	1	1	1	1	1	1	0	.	0	.
	Sibling #1	16	Female	No	.	1	0	0	9	1	1	1	1	1	1	0	.	0	.
	Sibling #2	13	Male	No	.	1	0	0	9	.	.	.	.	.	.	0	.	0	.
	Sibling #3	12	Male	No	.	1	0	0	9	.	.	.	.	.	.	0	.	0	.
	Sibling #4	6	Female	No	.	1	0	0	9	.	.	.	.	.	.	0	.	0	.
329.007.00268	Biologic Mother	37	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	.
	Biologic Father	33	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #1	13	Female	No	.	.	0	0	.	.	.	1	1	1	1	1	.	0	.
329.007.00294	Biologic Mother	37	Female	No	.	.	.	0	.	1	0	1	1	1	.	1	.	0	0
	Biologic Father	40	Male	No	.	.	.	0	.	.	0	.	.	.	.	.	.	0	0
	Sibling #1	15	Female	No	1	1	.	0	.	1	0	1	1	1	1	1	1	0	0
	Sibling #2	14	Male	No	1	1	1	0	1	1	0	1	1	1	.	1	1	0	0
329.007.00309	Biologic Mother	39	Female	No	0	.	0	0	.	.	.	1	1	1	.	0	.	0	.
	Biologic Father	44	Male	No	0	.	0	0	.	.	.	.	.	.	.	0	.	0	.
	Sibling #1	18	Female	No	0	1	0	0	1	1	1	1	1	1	1	0	.	0	.
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00310		.			.	.	0	0	.	0	.	.	.	.	0	.	0	0	.
	Biologic Mother	41	Female	No	.	1	0	0	.	0	.	1	1	.	0	.	0	0	.
	Biologic Father	41	Male	No	1	1	0	0	1	0	.	1	.	1	0	1	0	0	.
	Sibling #1	16	Female	No	.	1	0	0	.	0	.	1	.	1	0	1	0	0	.
	Sibling #2	15	Male	No	.	1	0	0	.	0	.	.	.	.	0	.	0	0	.
329.007.00318	Biologic Mother	44	Female	No	0	1	.	.	1	.	0	1	0	.	0	1	1	.	0
	Biologic Father	62	Male	No	0	.	.	1	.	.	0	1	0	.	0	1	1	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.007.00318	Sibling #1	15	Male	No	0	1	.	1	1	.	0	1	0	.	0	1	1	.	0
	Sibling #2	13	Male	No	0	1	.	.	.	.	0	.	0	.	0	1	1	.	0
	Sibling #3	18	Female	No	0	1	1	.	1	1	0	1	0	1	0	1	1	1	0
329.008.00157	Biologic Mother	47	Female	No	.	1	0	0	0	1	1	1	0	1	1	1	1	0	0
	Biologic Father	39	Male	No	1	1	0	0	0	.	.	1	0	1	1	.	.	0	0
329.008.00160	Biologic Mother	38	Female	No	1	1	0	.	1	1	.	1	1	1	1	1	1	0	0
	Biologic Father	43	Male	No	1	1	0	1	.	1	1	1	1	1	1	1	1	0	0
329.008.00188	Biologic Mother	37	Female	No	.	.	0	0	1	0	0	1	1	1	1	1	1	0	0
	Biologic Father	42	Male	No	1	1	0	0	1	0	0	1	1	1	1	.	.	0	0
	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	.	.	0	0	.	0	0	.	.	.	.	.	.	0	0
	Child #1	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00271	Biologic Mother	41	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	41	Male	No	.	.	.	0	1	.	.	1	1	1	1	.	.	0	0
	Sibling #1	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	10	Male	No	.	.	.	0	.	.	.	.	.	.	.	.	.	0	0
329.008.00275	Biologic Mother	44	Female	No	1	1	0	0	1	0	0	1	1	1	1	1	.	0	0
	Biologic Father	46	Male	No	.	.	0	0	.	0	0	.	1	.	.	1	1	0	0
	Sibling #1	19	Male	No	.	.	0	0	.	0	0	.	.	.	.	.	.	0	0
	Sibling #2	17	Female	No	.	.	0	0	.	0	0	.	.	.	.	.	.	0	0
329.009.00130	Biologic Mother	49	Female	No	.	1	0	0	.	.	.	.	.	1	.	.	.	.	0
	Biologic Father	52	Male	No	1	1	0	0	1	1	1	1	1	1	1	1	1	.	0
	Sibling #1	16	Male	No	1	1	0	0	1	1	1	1	1	1	1	1	1	1	0
	Sibling #2	15	Male	No	1	1	0	0	.	.	.	1	1	1	1	1	1	.	0
	Sibling #3	10	Female	No	1	1	0	0	1	.	.	1	1	1	1	1	1	.	0
	Sibling #4	7	Female	No	.	1	0	0	.	.	.	.	.	.	.	1	.	.	0
329.009.00131	Biologic Mother	.	Female	No	1	1	.	0	.	1	1	1	1	1	1	1	1	1	1
	Biologic Father	41	Male	No	.	.	.	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	1	1	.	0	1	1	1	1	1	1	1	1	1	.	.
	Sibling #2	13	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
329.009.00133	Biologic Mother	37	Female	No	.	0	0	0	1	.	.	.	.	.	.	.	.	0	.
	Biologic Father	37	Male	No	.	0	0	0	.	1	.	.	.	.	.	.	.	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.009.00133	Sibling #1	16	Female	No	1	0	0	0	.	1	1	1	1	1	1	1	1	0	.
	Sibling #2	14	Male	No	.	0	0	0	.	.	.	1	1	.	.	.	.	0	.
329.009.00138		.			.	.	.	.	.	.	.	.	.	.	.	.	.	0	0
	Biologic Mother	34	Female	No	1	.	.	.	.	.	.	1	.	.	.	.	.	0	0
	Biologic Father	33	Male	No	.	1	1	1	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	13	Female	No	1	1	.	.	1	1	1	1	1	1	1	1	1	0	0
	Sibling #2	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	0	0
329.009.00170	Biologic Mother	41	Female	No	.	1	0	0	1	1	0	1	1	1	1	1	1	.	9
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	1	.	0	0	.	.	0	1	1	1	1	1	.	.	9
	Sibling #2	22	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00173	Biologic Mother	43	Female	No	.	1	.	0	1	1	1	1	1	1	1	1	1	.	.
	Biologic Father	45	Male	Yes	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
	Sibling #1	12	Female	No	.	1	.	0	.	1	1	1	1	1	1	1	1	.	.
329.009.00193	Biologic Mother	36	Female	No	0	1	0	9	1	1	0	1	1	1	1	1	1	.	0
	Biologic Father	38	Male	No	0	.	0	9	.	1	0	1	.	.	.	.	.	.	0
	Sibling #1	12	Female	No	0	.	0	9	.	1	0	1	1	1	1	1	1	1	0
	Sibling #2	3	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00196	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	0	.	0	0	0	.	.	.	.	.	.	1	.	0	.
	Sibling #1	17	Female	No	0	1	0	0	0	1	1	1	1	1	1	.	.	0	.
	Sibling #2	9	Female	No	0	.	0	0	0	.	.	.	.	.	.	.	.	0	.
329.009.00201	Biologic Mother	43	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Biologic Father	47	Male	No	.	.	0	0	.	1	1	1	.	.	.	.	.	0	0
	Sibling #1	17	Male	No	1	1	0	0	1	.	.	.	.	.	.	.	.	0	0
	Sibling #2	14	Male	No	1	1	0	0	.	1	1	1	1	1	1	1	1	0	0
329.009.00204	Biologic Mother	39	Female	No	.	1	0	0	.	.	0	1	1	1	.	.	.	0	.
	Sibling #6	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	47	Male	No	1	1	0	0	1	1	0	1	1	1	1	1	1	0	.
	Sibling #1	13	Male	No	.	.	0	0	.	1	0	1	.	1	.	1	1	0	.
	Sibling #2	12	Male	No	1	1	0	0	1	1	0	1	1	.	.	1	1	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.009.00204	Sibling #3	10	Female	No	.	.	0	0	.	.	0	1	.	.	.	.	.	0	.
	Sibling #4	9	Male	No	1	1	0	0	.	.	0	1	.	.	.	.	.	0	.
	Sibling #5	21	Female	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	.
	Child #1	.			.	.	0	0	.	.	0	.	.	.	.	.	.	0	.
329.009.00235	Biologic Mother	32	Female	No	0	.	0	0	0	0	0	.	0	.	0	0	0	0	0
	Biologic Father	30	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	0	1	0	0	0	0	0	1	0	1	0	0	0	0	0
	Sibling #2	8	Male	No	0	.	0	0	0	0	0	.	0	.	0	0	0	0	0
329.009.00240	Biologic Mother	48	Female	No	.	.	0	0	.	0	0	1	.	.	.	.	.	0	0
	Biologic Father	52	Male	No	.	.	0	0	.	0	0	1	.	.	.	1	1	0	0
	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	1	1	0	0	1	0	0	1	1	1	1	1	1	0	0
	Sibling #4	13	Female	No	.	.	0	0	.	0	0	.	.	.	.	.	.	0	0
329.009.00303	Biologic Mother	43	Female	No	0	1	0	0	1	0	.	.	.	1	.	.	.	0	.
	Biologic Father	49	Male	No	0	1	0	0	.	0	.	.	.	1	.	.	.	0	.
	Sibling #1	17	Male	No	0	1	0	0	.	0	.	1	1	1	1	1	1	0	.
	Sibling #2	14	Female	No	0	1	0	0	.	0	.	.	.	.	.	.	.	0	.
329.009.00304	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	23	Male	No	.	.	0	0	0	.	.	1	.	.	.	.	.	0	.
	Sibling #2	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Male	No	1	1	0	0	0	1	.	1	1	1	1	1	1	0	.
329.009.00324	Biologic Mother	33	Female	No	0	0	0	0	1	0	0	0	0	0	0	.	.	.	0
	Biologic Father	35	Female	No	0	0	0	0	.	0	0	0	0	0	0	1	1	.	0
	Sibling #1	13	Female	No	0	0	0	0	.	0	0	0	0	0	0	.	.	1	0
	Sibling #2	8	Female	No	0	0	0	0	.	0	0	0	0	0	0	.	.	.	0
	Sibling #3	5	Female	No	0	0	0	0	.	0	0	0	0	0	0	.	.	.	0
329.009.00328	Biologic Mother	45	Female	No	0	1	0	0	1	1	0	1	1	1	0	1	1	0	0
	Biologic Father	46	Male	No	0	.	0	0	.	.	0	1	1	1	0	.	.	0	0
	Sibling #1	23	Male	No	0	.	0	0	1	.	0	1	.	.	0	.	.	0	0
	Sibling #2	21	Male	No	0	.	0	0	1	.	0	1	1	1	0	1	1	0	0
	Sibling #3	14	Male	No	0	.	0	0	.	.	0	1	.	.	0	.	.	0	0
	Sibling #4	12	Male	No	0	1	0	0	.	.	0	1	.	.	0	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.009.00329	Biologic Mother	32	Female	No	0	.	.	0	.	0	0	.	.	.	.	1	1	0	0
	Biologic Father	34	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Male	No	0	1	1	0	1	0	0	1	1	1	1	.	.	0	0
	Sibling #2	10	Male	No	0	.	.	0	.	0	0	.	.	.	.	.	.	0	0
	Sibling #3	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.010.00182	Biologic Mother	42	Female	No	0	0	0	0	0	.	.	1	1	1	1	0	.	0	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	0	0	0	0	1	1	1	1	1	1	0	.	0	.
	Sibling #2	17	Female	No	0	0	0	0	0	.	.	1	1	1	1	0	.	0	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.010.00278	Biologic Mother	49	Female	No	.	.	0	0	0	0	.	.	.	.	.	.	.	0	.
	Biologic Father	49	Male	No	1	1	0	0	0	0	.	.	.	.	.	.	.	0	.
	Sibling #1	20	Female	No	.	.	0	0	0	0	.	.	.	.	.	.	.	0	.
	Sibling #2	17	Female	No	.	.	0	0	0	0	.	1	1	1	1	1	1	0	.
329.010.00280	Biologic Mother	33	Female	No	.	.	0	0	0	1	1	.	.	0	.	0	.	0	.
	Biologic Father	32	Male	No	.	.	0	0	0	1	1	.	.	0	.	0	.	0	.
	Sibling #1	13	Female	No	1	1	0	0	0	.	.	1	1	0	.	0	.	0	.
	Sibling #2	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.011.00283	Biologic Mother	36	Female	No	0	1	0	0	.	.	.	1	1	1	.	.	.	0	0
	Biologic Father	42	Male	No	0	1	0	0	1	1	.	1	1	1	.	1	1	0	0
	Sibling #1	16	Male	No	0	1	0	0	.	1	1	1	1	1	1	1	1	0	0
329.011.00288	Biologic Mother	41	Female	No	0	.	.	.	0	.	0	1	.	1	1	1	1	0	0
	Biologic Father	45	Male	No	0	.	1	1	0	1	0	.	.	.	.	.	.	0	0
	Sibling #1	15	Male	No	0	1	.	.	0	.	0	1	1	1	1	1	1	0	0
329.012.00025	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	0	.	.	0	0	.	0	.	.	.	.	.	.	0	0
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Female	No	0	1	1	0	0	1	0	1	1	1	1	1	1	0	0
329.012.00220	Biologic Mother	40	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	.
	Biologic Father	41	Male	No	.	.	0	0	.	.	.	.	.	1	1	.	.	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.012.00220	Sibling #1	17	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #2	15	Male	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	.
	Sibling #3	13	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	.
329.012.00222	Biologic Mother	37	Female	No	.	1	.	0	1	.	.	.	.	.	.	1	1	.	0
	Biologic Father	38	Male	No	.	.	.	0	.	.	.	.	.	.	.	.	.	.	0
	Sibling #1	15	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	0
329.012.00226	Biologic Mother	50	Female	No	.	.	0	0	.	0	0	1	.	.	.	.	.	0	0
	Biologic Father	50	Male	No	.	.	0	0	.	0	0	1	.	.	.	.	.	0	0
	Sibling #1	23	Female	No	.	.	0	0	1	0	0	1	.	.	.	.	.	0	0
	Sibling #2	18	Male	No	.	.	0	0	.	0	0	1	.	1	1	.	.	0	0
	Sibling #3	16	Male	No	1	1	0	0	1	0	0	1	1	1	1	1	1	0	0
329.012.00228	Biologic Mother	40	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #2	12	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.001.00061	Biologic Mother	39	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	.	0	0
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	16	Female	No	1	1	.	.	.	.	.	1	1	1	1	1	1	0	0
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	0	0
329.001.00066	Biologic Mother	48	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	52	Male	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	17	Female	No	1	1	.	0	.	.	.	1	1	1	1	1	.	0	0
	Sibling #2	13	Male	No	.	.	.	0	.	.	.	1	1	1	1	.	.	0	0
329.001.00067	Biologic Mother	42	Female	No	.	.	.	0	.	.	.	.	.	.	.	.	.	0	.
	Biologic Father	44	Male	No	1	1	.	0	.	.	.	1	.	1	.	1	1	0	.
	Sibling #1	21	Female	No	.	.	.	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #2	16	Female	No	1	1	1	0	1	1	1	1	1	.	.	.	.	0	.
	Sibling #3	14	Male	No	1	1	.	0	.	1	1	1	1	1	1	1	1	0	.
329.001.00070	Biologic Mother	47	Female	No	1	1	0	0	1	0	0	1	.	1	.	1	.	0	0
	Biologic Father	46	Male	No	.	.	0	0	.	0	0	.	.	.	.	1	1	0	0
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	12	Male	No	1	.	0	0	.	0	0	1	1	1	1	1	.	0	0
329.001.00122	Biologic Mother	53	Female	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	0
	Sibling #6	16	Male	No	.	1	0	0	.	.	0	.	.	.	.	.	.	0	0
	Sibling #7	15	Male	No	.	1	0	0	.	1	0	1	1	1	.	.	.	0	0
	Biologic Father	58	Male	No	.	.	0	0	.	.	0	1	1	1	.	1	1	0	0
	Sibling #1	26	Female	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	0
	Sibling #2	23	Female	No	1	1	0	0	1	1	0	1	1	1	.	1	1	0	0
	Sibling #3	22	Female	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	0
	Sibling #4	20	Male	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	0
	Sibling #5	20	Female	No	.	.	0	0	.	.	0	.	.	.	.	.	.	0	0
329.002.00050	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	49	Male	No	.	.	0	0	0	0	0	.	.	.	.	.	.	0	0
	Sibling #1	19	Male	No	.	.	0	0	0	0	0	.	.	.	.	.	.	0	0
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Male	No	1	1	0	0	0	0	0	1	1	1	1	1	1	0	0
329.002.00056	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	41	Male	No	0	.	0	0	0	0	0	.	.	.	.	.	.	0	.
	Sibling #1	18	Female	No	0	1	0	0	0	0	0	1	1	1	1	1	1	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.002.00056	Sibling #2	10	Male	No	0	1	0	0	0	0	0	.	.	.	.	1	.	0	.
329.002.00057	Biologic Mother	33	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	36	Male	No	.	1	.	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	1	1	1	0	.	1	1	1	1	1	1	1	1	1	1
	Sibling #2	14	Female	No	.	1	.	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	12	Male	No	.	1	.	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	.			.	.	.	0	.	.	.	.	.	.	.	.	.	.	.
329.002.00098	Biologic Mother	43	Female	No	0	1	0	0	1	1	1	1	1	.	0	1	0	0	0
	Biologic Father	45	Male	No	0	1	0	0	.	1	1	1	1	.	0	.	0	0	0
	Sibling #1	16	Female	No	0	1	0	0	.	1	1	1	1	1	0	1	0	0	0
	Sibling #2	13	Female	No	0	1	0	0	.	1	1	1	1	1	0	1	0	0	0
	Sibling #3	9	Male	No	0	1	0	0	.	.	.	.	.	.	0	.	0	0	0
329.002.00100		.			.	.	0	0	.	0	0	.	.	.	.	.	.	1	.
	Biologic Mother	36	Female	No	1	1	0	0	1	0	0	1	1	1	1	1	1	.	.
	Biologic Father	35	Male	No	.	.	0	0	.	0	0	.	.	.	.	.	.	.	.
	Sibling #1	15	Male	No	1	1	0	0	.	0	0	1	1	.	.	.	.	.	1
	Sibling #2	9	Female	No	.	.	0	0	1	0	0	.	.	.	.	.	.	.	.
329.002.00103	Biologic Mother	39	Female	No	0	1	0	0	0	0	.	0	.	0	.	.	.	0	.
	Biologic Father	38	Male	No	0	.	0	0	0	0	.	0	.	0	.	.	.	0	.
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Female	No	0	.	0	0	0	0	.	0	.	0	.	1	1	0	.
329.002.00104	Biologic Mother	41	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	46	Male	No	1	1	.	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	18	Female	No	.	.	.	0	.	.	1	.	.	.	.	.	.	0	0
	Sibling #2	15	Female	No	1	1	.	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #3	13	Male	No	1	1	.	0	1	1	1	1	1	1	1	1	1	0	0
329.002.00243	Biologic Mother	39	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	0
	Biologic Father	44	Male	No	.	.	.	0	.	.	.	.	.	.	.	.	.	.	0
	Sibling #1	20	Female	No	1	1	.	0	.	1	1	1	1	1	1	.	.	.	0
	Sibling #2	17	Male	No	.	.	.	0	.	.	.	.	.	.	.	.	.	.	0
	Sibling #3	15	Female	No	1	1	.	0	1	1	1	1	1	1	1	1	1	.	0
329.002.00244	Biologic Mother	40	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.002.00244	Sibling #1	17	Female	No	.	.	0	0	.	.	.	1	1	1	1	1	.	0	0
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00321	Biologic Mother	39	Female	No	.	1	.	9	.	.	.	.	.	.	.	.	.	0	.
	Biologic Father	37	Male	No	.	.	.	9	.	.	.	.	.	.	.	.	.	0	.
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	.	1	.	9	.	.	.	.	.	.	.	.	.	0	.
	Sibling #3	14	Male	No	1	1	1	9	1	1	1	1	1	1	1	1	1	0	.
329.002.00322	Biologic Mother	34	Female	No	.	1	.	9	1	0	0	1	1	1	1	1	1	0	0
	Biologic Father	56	Male	No	.	.	.	9	.	0	0	.	.	.	.	.	.	0	0
	Sibling #1	14	Don't	No	.	.	.	9	.	0	0	.	.	.	.	.	.	0	0
	Sibling #2	14	Don't	No	1	1	1	9	1	0	0	1	1	.	.	1	1	0	0
	Sibling #3	10	Don't	No	.	.	.	9	.	0	0	1	.	.	.	.	.	0	0
	Sibling #4	8	Don't	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	6	Don't	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00073	Biologic Mother	39	Female	No	.	1	0	0	0	1	1	1	.	1	1	1	.	.	0
	Biologic Father	41	Male	No	.	1	0	0	0	1	1	1	.	.	.	1	1	1	0
	Sibling #1	19	Female	No	1	1	0	0	0	1	1	1	1	.	.	1	1	.	0
	Sibling #2	17	Female	No	.	1	0	0	0	1	1	1	1	.	.	1	1	1	0
	Sibling #3	16	Female	No	.	1	0	0	0	1	1	1	1	.	.	1	1	.	0
	Sibling #4	11	Male	No	.	1	0	0	0	1	1	1	.	.	.	.	.	.	0
329.003.00076	Biologic Mother	35	Female	No	0	.	0	0	0	0	0	1	.	.	.	1	0	.	0
	Biologic Father	45	Male	No	0	.	0	0	0	0	0	.	.	.	.	.	0	.	0
	Sibling #1	16	Female	No	0	1	0	0	0	0	0	1	1	1	1	1	0	1	0
329.003.00079		.			.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Mother	.	Female	No	1	1	.	.	1	1	.	1	.	.	.	.	.	.	.
	Biologic Father	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	.	Female	No	1	1	.	.	1	1	.	1	.	.	.	.	.	.	.
	Sibling #2	.	Female	No	1	1	.	.	1	1	.	1	.	.	.	.	.	.	.
329.003.00088	Biologic Mother	46	Female	No	0	1	0	0	0	0	0	1	0	1	0	0	0	0	0
	Biologic Father	50	Male	No	0	.	0	0	0	0	0	.	0	.	0	0	0	0	0
	Sibling #1	24	Female	No	0	.	0	0	0	0	0	.	0	.	0	0	0	0	0
	Sibling #2	21	Female	No	0	.	0	0	0	0	0	.	0	.	0	0	0	0	0
	Sibling #3	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.003.00090	Biologic Mother	44	Female	No	0	.	0	0	0	0	0	.	.	0	0	1	1	0	0
	Biologic Father	51	Male	No	0	.	0	0	0	0	0	.	.	0	0	.	.	0	0
	Sibling #1	18	Male	No	0	1	0	0	0	0	0	.	.	0	0	.	.	0	0
	Sibling #2	16	Male	No	0	1	0	0	0	0	0	.	.	0	0	.	.	0	0
	Sibling #3	14	Female	No	0	.	0	0	0	0	0	1	1	0	0	.	.	0	0
329.003.00092	Biologic Mother	42	Female	No	1	1	0	.	1	1	0	1	1	1	1	1	1	1	.
	Biologic Father	43	Male	No	.	.	0	1	.	.	0	.	.	.	.	1	.	1	.
	Sibling #1	16	Female	No	1	1	0	.	.	.	0	.	.	.	.	1	.	1	1
	Sibling #2	12	Female	No	1	1	0	.	.	.	0	1	1	1	.	1	1	1	.
329.003.00093	Biologic Mother	50	Female	No	0	1	0	0	0	1	0	1	.	1	0	1	0	.	0
	Biologic Father	53	Male	Yes	0	1	0	0	0	.	0	.	.	.	0	.	0	.	0
	Sibling #1	21	Male	No	0	1	0	0	0	.	0	.	.	.	0	.	0	.	0
	Sibling #2	17	Female	No	0	1	0	0	0	.	0	1	1	1	0	1	0	1	0
329.003.00247	Biologic Mother	41	Female	No	0	.	0	0	.	0	0	.	0	.	0	9	9	9	9
	Biologic Father	44	Male	No	0	1	0	0	1	0	0	1	0	.	0	9	9	9	9
	Sibling #1	16	Male	No	0	.	0	0	.	0	0	1	0	1	0	9	9	9	9
	Sibling #2	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00249	Biologic Mother	46	Female	No	9	9	9	0	9	0	0	9	0	0	0	9	9	9	9
	Biologic Father	52	Male	No	9	9	9	0	9	0	0	9	0	0	0	9	9	9	9
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00289		.			0	0	0	0	0	.	9	.	0	.	0	.	0	0	0
	Biologic Mother	41	Female	No	0	0	0	0	0	1	9	.	0	.	0	1	0	0	0
	Biologic Father	45	Male	No	0	0	0	0	0	.	9	.	0	.	0	.	0	0	0
	Sibling #1	16	Female	No	0	0	0	0	0	1	9	.	0	1	0	1	0	0	0
	Sibling #2	13	Male	No	0	0	0	0	0	.	9	1	0	.	0	.	0	0	0
329.003.00290	Biologic Mother	37	Female	No	.	0	0	0	0	0	0	.	.	.	.	1	.	1	1
	Biologic Father	48	Male	No	.	0	0	0	0	0	0	.	.	.	.	.	.	1	1
	Sibling #1	3	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Male	No	1	0	0	0	0	0	0	1	1	1	1	1	1	.	.
	Sibling #3	10	Male	No	.	0	0	0	0	0	0	.	.	.	.	.	.	1	1
	Sibling #4	17	Male	No	.	0	0	0	0	0	0	.	.	.	.	.	.	1	1

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.003.00314	Biologic Mother	39	Female	No	0	1	0	0	0	.	.	1	.	.	.	0	0	0	0
	Biologic Father	36	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	1	0	0	0	1	1	1	1	1	1	0	0	0	0
	Sibling #2	12	Female	No	0	1	0	0	0	.	.	.	.	.	.	0	0	0	0
329.003.00317		.			0	1	1	0	0	0	0	.	0	.	.	.	.	0	0
	Biologic Mother	50	Female	No	0	.	.	0	0	0	0	1	0	1	1	1	1	0	0
	Biologic Father	50	Male	No	0	.	.	0	0	0	0	.	0	.	.	.	.	0	0
	Sibling #1	17	Don't	No	0	.	.	0	0	0	0	.	0	1	.	.	.	0	0
	Sibling #2	16	Female	No	0	.	.	0	0	0	0	1	0	.	1	1	1	0	0
329.004.00013	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00014	Biologic Mother	52	Female	No	1	1	0	0	1	0	0	1	1	1	1	9	9	0	0
	Biologic Father	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00211	Biologic Mother	49	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	1	1	0	0	1	0	.	1	1	1	1	1	1	0	.
	Sibling #2	18	Female	No	1	1	0	0	.	0	.	1	1	1	1	.	.	0	.
329.004.00215	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	.	0	0	0	.	.	.	1	.	1	1	1	1	0	0
	Sibling #1	14	Female	No	1	0	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00003	Biologic Mother	30	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Female	No	1	1	0	0	0	1	.	1	1	1	1	1	1	0	0
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	7	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	5	Male	No	1	1	0	0	0	.	.	.	.	.	.	.	.	0	0
	Sibling #5	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00006	Biologic Mother	47	Female	No	1	1	0	0	1	0	0	1	1	1	0	1	1	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.005.00006	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00007	Biologic Mother	41	Female	No	.	.	0	0	.	.	.	1	.	.	.	1	1	.	.
	Biologic Father	44	Male	No	1	.	0	0	.	1	1	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	1	1	0	0	1	1	1	1	.	1	1	1	1	1	1
	Sibling #2	15	Female	No	1	.	0	0	.	.	.	1	1	1	1	1	1	.	.
329.005.00009	Biologic Mother	47	Female	No	0	1	0	0	0	0	0	1	.	.	.	.	.	0	0
	Biologic Father	46	Male	No	0	1	0	0	0	0	0	.	.	.	.	.	.	0	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	.	0	0	0	0	0	1	1	1	1	1	1	0	0
	Sibling #3	5	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00117	Biologic Mother	47	Female	No	0	0	0	0	0	.	0	.	.	.	.	.	.	1	0
	Biologic Father	49	Male	No	0	0	0	0	0	.	0	1	1	1	.	1	1	.	0
	Sibling #1	22	Female	No	0	0	0	0	0	.	0	.	.	.	.	.	.	.	0
	Sibling #2	16	Female	No	0	0	0	0	0	1	0	1	1	1	.	1	1	.	0
	Sibling #3	12	Male	No	0	0	0	0	0	.	0	.	.	.	.	.	.	1	0
329.005.00118	Biologic Mother	46	Female	No	.	1	0	0	0	.	.	1	1	1	1	.	.	0	0
	Biologic Father	47	Male	No	.	1	0	0	0	.	.	.	.	.	.	.	.	0	0
	Sibling #1	17	Female	No	.	.	0	0	0	.	.	1	1	1	1	.	.	0	0
	Sibling #2	15	Male	No	1	1	0	0	0	1	1	1	1	1	1	1	1	0	0
	Sibling #3	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00153	Biologic Mother	44	Female	No	.	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Biologic Father	51	Male	No	.	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #1	18	Female	No	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0
329.005.00255	Biologic Mother	47	Female	No	0	1	0	0	0	.	.	1	1	1	1	1	.	0	0
	Biologic Father	48	Male	No	0	1	0	0	0	1	1	1	1	1	1	1	.	0	0
	Sibling #1	17	Male	No	0	1	0	0	0	.	.	.	.	1	.	1	.	0	0
	Sibling #2	15	Female	No	0	1	0	0	0	.	.	1	1	1	1	1	1	0	0
329.005.00256	Biologic Mother	55	Female	No	1	1	0	0	1	0	0	1	1	.	0	0	0	0	0
	Biologic Father	52	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	24	Female	No	.	.	0	0	.	0	0	.	.	1	0	0	0	0	0
	Sibling #2	23	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.005.00256	Sibling #4	16	Female	No	1	.	0	0	.	0	0	1	1	1	0	0	0	0	0
329.005.00295	Biologic Mother	31	Female	No	0	0	0	0	0	0	0	.	.	.	.	0	0	0	0
	Biologic Father	36	Male	No	0	0	0	0	0	0	0	.	.	.	.	0	0	0	0
	Sibling #1	13	Female	No	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0
329.005.00297	Biologic Mother	46	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Male	No	.	.	0	0	.	.	.	1	1	1	1	1	1	0	0
329.005.00332	Biologic Mother	50	Female	No	.	1	0	0	.	0	0	1	.	1	.	.	.	1	0
	Biologic Father	54	Male	No	1	1	0	0	1	0	0	1	1	1	1	1	1	.	0
	Sibling #1	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	21	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	.	.	0	0	.	0	0	1	1	1	1	1	.	.	0
329.005.00335	Biologic Mother	37	Female	No	1	1	.	.	1	0	0	1	1	1	0	1	1	0	0
	Biologic Father	39	Male	No	.	.	1	1	.	0	0	.	.	.	0	.	.	0	0
	Sibling #1	15	Female	No	.	.	.	.	.	0	0	1	1	1	0	1	1	0	0
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	6	Female	No	1	1	.	.	1	0	0	.	.	.	0	.	.	0	0
329.006.00040	Biologic Mother	46	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	.
	Biologic Father	66	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #1	28	Male	No	.	1	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #2	18	Female	No	1	.	0	0	1	1	.	1	1	1	.	1	1	0	.
329.006.00041	Biologic Mother	44	Female	No	0	.	0	0	0	0	.	.	.	.	0	.	.	0	.
	Biologic Father	50	Male	No	0	1	0	0	0	0	.	1	1	1	0	1	1	0	.
	Sibling #1	21	Male	No	0	.	0	0	0	0	.	.	.	.	0	.	.	0	.
	Sibling #2	18	Male	No	0	1	0	0	0	0	.	1	.	1	0	.	.	0	.
329.007.00139	Biologic Mother	38	Female	No	1	1	.	0	1	0	.	1	1	1	1	1	1	0	0
	Biologic Father	36	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	1	1	1	0	1	0	.	1	1	1	1	1	1	0	0
329.007.00143	Biologic Mother	28	Female	No	1	1	1	9	1	0	.	1	1	1	1	1	0	1	1
	Biologic Father	.	Male	Unknown	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Female	No	.	1	1	9	1	0	.	.	.	.	.	1	0	.	.

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.007.00143	Sibling #2	.			.	.	.	9	.	0	.	.	.	.	.	.	0	.	.
329.007.00146	Biologic Mother	39	Female	No	0	.	0	0	0	0	.	.	.	.	.	.	.	0	.
	Biologic Father	39	Male	No	0	.	0	0	0	0	.	.	.	.	.	.	.	0	.
	Sibling #1	15	Female	No	0	1	0	0	0	0	.	1	1	1	1	1	1	0	.
329.007.00269	Biologic Mother	45	Female	No	1	1	0	0	1	.	.	1	1	1	1	1	1	0	.
	Biologic Father	60	Male	Yes	.	.	0	0	.	.	.	.	.	.	.	1	.	0	.
	Sibling #1	15	Male	No	1	1	0	0	.	1	1	1	1	1	1	1	1	0	.
	Sibling #2	12	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	.
329.007.00270	Biologic Mother	34	Female	No	0	1	0	0	1	.	.	1	1	1	1	1	1	0	.
	Biologic Father	35	Male	No	0	.	0	0	.	1	1	.	.	.	.	.	.	0	.
	Sibling #1	15	Male	No	0	1	0	0	.	1	.	1	.	1	1	1	1	0	.
	Sibling #2	10	Male	No	0	1	0	0	.	.	.	1	.	1	.	.	.	0	.
	Sibling #3	8	Male	No	0	1	0	0	.	1	.	1	.	.	.	.	.	0	.
	Sibling #4	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00307	Biologic Mother	42	Female	No	9	1	0	0	1	1	1	1	1	1	1	1	1	0	.
	Biologic Father	43	Male	No	9	.	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #1	15	Female	No	9	.	0	0	.	.	.	1	.	1	1	1	1	0	.
	Sibling #2	14	Female	No	9	.	0	0	.	.	.	.	.	.	.	.	.	0	.
329.007.00308	Biologic Mother	45	Female	No	0	.	.	.	1	.	.	.	.	.	.	.	.	0	.
	Biologic Father	43	Male	No	0	.	.	.	.	.	.	.	.	.	.	.	.	0	.
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	0	1	1	1	1	1	1	1	1	1	1	1	1	0	.
329.008.00159	Biologic Mother	47	Female	No	.	1	.	0	1	.	.	1	1	1	.	1	.	0	0
	Biologic Father	49	Male	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	.	1	.	0	1	.	.	1	1	.	.	.	.	0	0
	Sibling #3	16	Female	No	.	1	.	0	1	.	.	1	1	1	.	1	1	0	0
329.008.00161	Biologic Mother	44	Female	No	0	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	45	Male	No	0	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	4	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	4	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.008.00187	Biologic Mother	47	Female	No	0	1	0	0	1	0	.	0	.	0	.	1	.	0	.
	Sibling #1	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00192	Biologic Mother	35	Female	No	1	1	0	.	1	0	0	1	1	1	1	1	1	0	0
	Biologic Father	40	Male	No	.	.	0	1	.	0	0	.	.	.	.	.	.	0	0
	Sibling #1	5	Female	No	.	.	0	.	1	0	0	.	.	.	.	.	.	0	0
329.008.00272	Biologic Mother	42	Female	No	0	1	0	0	1	0	0	1	1	1	1	0	0	0	0
	Biologic Father	62	Male	No	0	.	0	0	.	0	0	.	.	.	.	0	0	0	0
	Sibling #1	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00273	Biologic Mother	42	Female	No	1	1	0	0	0	0	0	1	1	1	1	1	1	0	0
	Biologic Father	43	Male	No	.	1	0	0	0	0	0	.	.	.	.	.	.	0	0
	Sibling #1	15	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00127	Biologic Mother	31	Female	No	1	.	0	0	.	.	.	.	.	.	.	1	1	0	.
	Biologic Father	41	Male	No	1	.	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #1	12	Female	No	1	1	0	0	1	1	1	.	.	.	.	1	1	0	.
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00132	Biologic Mother	30	Female	No	1	.	0	.	.	1	1	1	1	1	.	.	.	0	.
	Biologic Father	31	Male	No	1	1	0	1	.	1	1	1	1	1	.	1	1	0	.
	Sibling #1	13	Male	No	.	1	0	.	1	1	1	1	1	1	1	1	1	0	.
	Sibling #2	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00134	Biologic Mother	38	Female	No	.	1	0	0	0	1	0	1	1	1	1	1	1	0	.
	Biologic Father	31	Male	Yes	.	1	0	0	0	.	0	1	1	.	.	.	.	0	.
	Sibling #1	15	Female	No	1	1	0	0	0	.	0	1	1	1	1	.	1	0	.
	Sibling #2	.			.	.	0	0	0	.	0	.	.	.	.	1	.	0	.
329.009.00137	Biologic Mother	34	Female	No	.	1	.	0	.	0	.	1	.	1	0	1	1	0	.
	Biologic Father	41	Male	No	.	1	1	0	1	0	.	.	.	.	0	.	.	0	.
	Sibling #1	20	Female	No	.	1	.	0	.	0	.	.	.	.	0	.	.	0	.
	Sibling #2	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	1	1	.	0	.	0	.	1	1	.	0	1	1	0	.
	Sibling #4	12	Female	No	.	.	.	0	.	0	.	.	.	.	0	.	.	0	.

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.009.00171	Biologic Mother	38	Female	No	.	.	9	.	9	.	9	.	.	.	.	.	9	9	9
	Biologic Father	41	Male	No	.	.	9	1	9	1	9	.	.	.	.	.	9	9	9
	Sibling #1	23	Male	No	.	.	9	.	9	.	9	.	.	.	.	.	9	9	9
	Sibling #2	16	Female	No	1	1	9	.	9	.	9	1	1	1	1	1	9	9	9
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	12	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	4	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00172	Biologic Mother	43	Female	No	.	1	0	0	1	0	.	1	1	1	.	1	1	0	.
	Biologic Father	45	Male	No	.	.	0	0	.	0	.	.	.	.	.	.	.	0	.
	Sibling #1	23	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	19	Female	No	.	.	0	0	.	0	.	1	1	1	.	.	.	0	.
	Sibling #3	13	Female	No	1	1	0	0	.	0	.	1	1	1	.	1	.	0	.
329.009.00194	Biologic Mother	36	Female	No	0	1	0	9	1	9	.	1	1	1	1	1	1	9	9
	Biologic Father	33	Male	No	0	.	0	9	.	9	.	.	.	.	.	.	.	9	9
	Sibling #1	12	Male	No	0	1	0	9	.	9	.	1	1	1	1	1	1	9	9
	Sibling #2	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	3	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00195	Biologic Mother	39	Female	No	.	1	.	0	.	.	.	1	.	.	.	1	.	.	.
	Biologic Father	40	Male	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
	Sibling #1	16	Female	No	.	1	.	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Female	No	.	1	.	0	.	.	.	1	1	1	.	1	.	.	.
	Sibling #3	12	Male	No	.	1	.	0	.	.	.	.	.	.	.	.	.	.	.
329.009.00199	Biologic Mother	49	Female	No	.	1	.	0	.	.	.	1	.	.	.	.	.	.	.
	Biologic Father	56	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
	Sibling #2	14	Female	No	1	1	.	0	.	.	.	1	1	1	1	1	1	.	.
	Sibling #3	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00203	Biologic Mother	36	Female	No	1	1	0	0	1	.	.	1	1	1	.	1	1	0	0
	Biologic Father	38	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	12	Female	Yes	.	.	0	0	.	1	1	1	1	1	1	1	1	0	0
	Sibling #2	5	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00236	Biologic Mother	45	Female	No	1	1	.	.	1	1	.	1	1	1	1	1	1	.	.
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.009.00236	Sibling #2	16	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Sibling #3	13	Female	No	.	.	.	.	.	.	.	1	1	1	1	.	.	.	.
329.009.00262	Biologic Mother	38	Female	No	.	1	.	.	1	.	.	1	.	.	.	.	.	0	0
	Biologic Father	43	Male	No	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	13	Male	No	.	1	.	.	.	.	.	1	1	1	1	.	.	0	0
	Sibling #2	11	Male	No	.	1	.	.	.	.	.	.	.	.	.	.	.	0	0
329.009.00264	Biologic Mother	37	Female	No	.	.	0	0	0	.	.	1	.	1	.	.	.	1	0
	Biologic Father	40	Male	No	1	1	0	0	0	1	.	1	1	1	1	1	1	1	0
	Sibling #1	14	Female	No	.	1	0	0	0	1	1	1	1	1	1	1	.	1	0
329.009.00301	Biologic Mother	39	Female	No	0	1	0	0	0	0	.	1	.	1	.	.	.	0	.
	Biologic Father	39	Male	No	0	1	0	0	0	0	.	1	.	1	.	.	.	0	.
	Sibling #1	17	Male	No	0	1	0	0	0	0	.	1	1	1	1	1	1	0	.
	Sibling #2	10	Male	No	0	.	0	0	0	0	.	1	.	1	.	.	.	0	.
	Sibling #3	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00305	Biologic Mother	44	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	.
	Biologic Father	45	Male	No	.	1	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #1	17	Female	No	.	1	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #2	14	Male	No	.	1	0	0	.	.	.	1	1	1	1	1	1	0	.
	Sibling #3	12	Female	No	.	1	0	0	.	.	.	1	.	.	.	.	.	0	.
329.009.00325	Biologic Mother	33	Female	No	9	.	.	9	9	9	0	.	.	.	.	.	.	.	.
	Biologic Father	38	Male	No	9	1	1	9	9	9	0	1	.	.	.	1	1	.	.
	Sibling #1	15	Female	No	9	1	.	9	9	9	0	1	1	1	1	1	1	1	1
329.009.00326	Biologic Mother	31	Female	No	0	0	0	0	0	.	0	.	.	.	.	1	.	1	0
	Biologic Father	34	Male	No	0	0	0	0	0	1	0	1	1	1	.	.	.	.	0
	Sibling #1	13	Male	No	0	0	0	0	0	1	0	1	1	1	1	1	1	.	0
	Sibling #2	9	Male	No	0	0	0	0	0	.	0	.	.	.	.	.	.	1	0
329.010.00279	Biologic Mother	37	Female	No	.	0	0	0	0	0	.	1	.	.	.	.	.	0	.
	Biologic Father	48	Male	No	1	0	0	0	0	0	.	1	1	1	1	.	.	0	.
	Sibling #1	13	Female	No	1	0	0	0	0	0	.	1	1	1	1	1	1	0	.
	Sibling #2	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	1	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.010.00281	Biologic Mother	43	Female	No	.	.	.	0	.	0	.	.	.	.	.	.	.	0	.
	Biologic Father	48	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	.	.	.	0	.	0	.	.	.	1	1	1	1	0	.
	Sibling #2	16	Male	No	.	.	.	0	.	0	.	.	.	.	.	.	.	0	.
	Sibling #3	14	Female	No	.	.	.	0	.	0	.	.	.	.	.	.	.	0	.
	Sibling #4	13	Male	No	1	1	1	0	1	0	.	1	1	1	1	1	1	0	.
329.011.00163	Biologic Mother	42	Female	No	0	.	0	0	.	0	0	.	.	.	.	0	0	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	1	0	0	1	0	0	1	1	1	1	0	0	0	0
	Sibling #2	9	Male	No	0	1	0	0	1	0	0	.	.	.	.	0	0	0	0
329.011.00208	Biologic Mother	51	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	44	Male	No	.	.	.	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	.	1	.	0	.	.	.	1	1	1	.	1	.	.	.
329.011.00209	Biologic Mother	41	Female	No	1	1	0	0	1	0	0	1	1	1	1	.	.	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Male	No	.	.	0	0	.	0	0	1	1	1	1	1	1	0	0
	Sibling #2	10	Female	No	.	.	0	0	.	0	0	.	.	.	.	.	.	0	0
329.011.00284	Biologic Mother	46	Female	No	0	1	0	0	.	.	.	1	.	.	.	.	.	0	0
	Biologic Father	47	Male	No	0	1	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	0	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #3	10	Male	No	0	.	0	0	.	.	.	.	.	.	.	.	.	0	0
329.011.00286	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	1	.	.	.	1	1	.	0
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	.	.	.	.	.	.	.	0
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	.	.	.	.	.	.	.	0
	Sibling #2	15	Female	No	0	0	0	0	0	0	0	1	1	1	9	1	1	1	0
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00026	Biologic Mother	37	Female	No	.	.	0	0	.	0	.	0	.	.	0	.	.	0	.
	Biologic Father	36	Male	No	.	.	0	0	.	0	.	0	.	.	0	.	.	0	.
	Sibling #1	15	Female	No	1	1	0	0	1	0	.	0	.	.	0	.	.	0	.
	Sibling #2	14	Male	No	.	1	0	0	.	0	.	0	.	1	0	1	1	0	.
329.012.00219	Biologic Mother	42	Female	No	.	.	.	0	.	.	.	.	.	.	.	.	.	0	0
	Biologic Father	42	Male	No	1	1	1	0	1	1	1	1	1	.	.	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.012.00219	Sibling #1	16	Female	No	.	.	.	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #2	14	Male	No	1	1	.	0	1	1	1	1	1	1	1	1	1	0	0
329.012.00221	Biologic Mother	44	Female	No	.	.	0	0	.	0	0	.	.	0	0	0	0	0	0
	Biologic Father	44	Male	No	.	.	0	0	.	0	0	.	.	0	0	0	0	0	0
	Sibling #1	17	Male	No	1	1	0	0	1	0	0	1	1	0	0	0	0	0	0
	Sibling #2	15	Male	No	.	1	0	0	.	0	0	.	.	0	0	0	0	0	0
	Sibling #3	14	Female	No	.	1	0	0	.	0	0	1	.	0	0	0	0	0	0
329.012.00223	Biologic Mother	32	Female	No	.	1	0	0	1	0	.	1	1	.	.	.	.	.	0
	Biologic Father	34	Male	No	.	.	0	0	.	0	.	.	.	.	.	.	.	.	0
	Sibling #1	13	Female	No	1	1	0	0	.	0	.	1	1	1	1	1	1	1	0
	Sibling #2	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00227	Biologic Mother	49	Female	No	.	.	.	0	0	0	0	.	.	1	1	.	0	.	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Male	No	.	.	.	0	0	0	0	.	.	.	.	.	0	.	0
	Sibling #2	22	Male	No	.	.	.	0	0	0	0	.	.	.	.	1	0	.	0
	Sibling #3	16	Male	No	1	1	1	0	0	0	0	1	1	1	1	.	0	1	0
329.012.00230	Biologic Mother	36	Female	No	1	1	.	.	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	53	Male	Yes	1	.	1	1	.	1	1	1	1	1	1	1	.	0	0
	Sibling #1	15	Male	No	1	1	.	.	1	1	1	1	1	1	1	1	1	0	0
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.001.00062	Biologic Mother	38	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	37	Male	No	1	.	.	0	.	1	.	.	.	.	.	.	.	0	0
	Sibling #1	18	Female	No	.	.	.	0	.	.	.	1	.	1	.	1	.	0	0
	Sibling #2	16	Female	No	1	.	.	0	.	1	.	1	1	1	1	1	1	0	0
	Sibling #3	15	Female	No	1	1	.	0	.	.	.	1	1	1	1	1	1	0	0
329.001.00064	Biologic Mother	32	Female	No	0	.	0	0	.	0	0	1	.	1	.	.	.	0	0
	Biologic Father	42	Male	No	0	.	0	0	.	0	0	.	.	.	.	.	.	0	0
	Sibling #1	13	Male	No	0	1	0	0	1	0	0	1	1	1	1	1	1	0	0
	Sibling #2	8	Male	No	0	.	0	0	.	0	0	.	.	.	.	1	1	0	0
329.001.00069	Biologic Mother	49	Female	No	.	.	.	0	.	.	.	.	.	.	.	1	1	.	.
	Biologic Father	55	Male	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
	Sibling #1	26	Female	No	1	.	.	0	.	.	.	1	1	1	1	.	.	.	.
	Sibling #2	24	Male	No	1	1	.	0	1	.	.	1	1	1	1	.	.	.	.
	Sibling #3	22	Female	No	.	.	.	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Male	No	1	1	.	0	1	.	.	1	.	1	1	.	.	.	.
329.001.00071	Biologic Mother	48	Female	No	1	1	0	0	.	0	0	1	1	1	1	1	1	0	0
	Biologic Father	46	Male	No	1	1	0	0	1	0	0	1	1	1	.	1	.	0	0
	Sibling #1	18	Male		1	1	0	0	1	0	0	1	1	.	.	.	.	0	0
	Sibling #2	13	Female		1	1	0	0	.	0	0	1	1	1	1	1	1	0	0
329.001.00123	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	47	Male	No	1	1	0	0	0	.	.	1	1	1	1	.	.	0	0
	Sibling #1	22	Male	No	.	.	0	0	0	1	1	.	.	.	.	.	.	0	0
	Sibling #2	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Female	No	1	1	0	0	0	1	1	1	1	1	1	1	1	0	0
329.001.00207	Biologic Mother	48	Female	No	.	.	0	0	0	.	.	1	.	.	.	.	.	0	.
	Biologic Father	49	Male	No	.	.	0	0	0	.	.	1	.	.	.	.	.	0	.
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	1	1	0	0	0	1	1	1	1	1	1	1	1	0	.
329.002.00049	Biologic Mother	52	Female	No	0	.	0	0	.	.	9	1	1	.	9	1	1	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	23	Male	No	0	1	0	0	.	.	9	.	.	.	9	1	1	0	0
	Sibling #3	20	Male	No	0	.	0	0	.	1	9	.	.	.	9	.	.	0	0
	Sibling #4	16	Male	No	0	1	0	0	1	.	9	1	.	1	9	1	1	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.002.00059	Biologic Mother	46	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	50	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	.	.	0	0	1	1	1	1	1	1	1	1	1	0	0
329.002.00060	Biologic Mother	47	Female	No	.	1	.	0	.	0	.	1	1	1	1	0	.	0	.
	Biologic Father	45	Male	No	1	1	1	0	1	0	.	1	1	1	1	0	.	0	.
	Sibling #1	16	Female	No	.	.	.	0	.	0	.	1	.	.	.	0	.	0	.
	Sibling #2	14	Female	No	.	1	.	0	.	0	.	1	1	1	1	0	.	0	.
	Sibling #3	11	Male	No	.	.	.	0	.	0	.	.	.	.	.	0	.	0	.
329.002.00097	Biologic Mother	43	Female	No	0	1	0	0	1	1	1	1	1	.	0	1	0	0	0
	Biologic Father	45	Male	No	0	1	0	0	.	1	1	1	1	.	0	.	0	0	0
	Sibling #1	16	Female	No	0	1	0	0	.	1	1	1	1	1	0	1	0	0	0
	Sibling #2	13	Female	No	0	1	0	0	.	1	1	1	1	1	0	1	0	0	0
	Sibling #3	9	Male	No	0	1	0	0	.	.	.	.	.	.	0	.	0	0	0
329.002.00101	Biologic Mother	48	Female	No	.	1	.	.	.	.	.	1	1	.	.	.	.	1	0
	Biologic Father	52	Male	No	1	1	1	.	1	1	1	1	1	1	1	1	1	1	0
	Sibling #1	26	Male	No	.	1	.	.	.	.	.	1	.	1	.	.	.	1	0
	Sibling #2	28	Female	No	.	1	.	.	.	.	.	1	.	.	.	.	.	1	0
	Sibling #3	22	Female	No	.	1	.	.	.	.	.	1	.	.	.	.	.	1	0
	Sibling #4	16	Male	No	1	1	.	1	1	1	1	1	1	1	1	1	1	1	0
329.002.00107	Biologic Mother	47	Female	No	1	1	0	0	1	.	1	1	1	1	1	1	1	.	0
	Biologic Father	53	Male	Yes	.	.	0	0	.	.	.	.	.	.	.	.	.	.	0
	Sibling #1	27	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	.	0
	Sibling #2	20	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	.	0
	Sibling #3	18	Male	No	1	1	0	0	1	1	1	1	1	1	1	1	1	1	0
	Sibling #4	15	Female	No	.	1	0	0	.	1	1	1	1	1	1	1	1	.	0
329.002.00241	Biologic Mother	38	Female	No	0	.	0	0	0	.	.	.	.	1	.	.	.	0	0
	Biologic Father	42	Male	No	0	.	0	0	0	.	.	.	.	1	.	.	.	0	0
	Sibling #1	15	Male	No	0	1	0	0	0	1	1	1	1	1	1	1	1	0	0
	Sibling #2	17	Male	No	0	.	0	0	0	.	.	.	.	1	.	.	.	0	0
329.002.00246	Biologic Mother	34	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	1	1	.	.	1	1	.	.
	Sibling #1	17	Female	No	1	1	.	.	.	.	.	1	1	1	1	1	1	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.002.00246	Sibling #2	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	2	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00320	Biologic Mother	40	Female	No	0	.	0	.	.	.	.	1	.	1	.	1	.	0	0
	Biologic Father	44	Male	No	0	.	0	1	.	1	1	.	.	.	.	.	.	0	0
	Sibling #1	16	Male	No	0	.	0	.	.	.	.	.	.	.	.	.	.	0	0
	Sibling #2	13	Female	No	0	1	0	.	.	.	.	1	1	1	1	1	1	0	0
	Sibling #3	9	Female	No	0	1	0	.	1	.	.	.	.	.	.	.	.	0	0
329.002.00323	Biologic Mother	44	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	1	1	0	0	1	0	0	.	.	9	0	1	1	0	0
	Sibling #2	17	Female	No	1	1	0	0	.	0	0	1	1	9	0	1	1	0	0
329.003.00074	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
	Sibling #2	5	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00078		.			.	.	0	0	.	.	.	.	.	.	.	.	.	9	9
	Biologic Mother	40	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	9	9
	Biologic Father	47	Male	No	.	1	0	0	.	.	.	1	.	.	.	.	.	9	9
	Sibling #1	17	Female	No	.	1	0	0	.	.	.	.	.	.	.	1	.	9	9
	Sibling #2	15	Female	No	1	1	0	0	.	1	1	1	1	1	1	1	1	9	9
	Sibling #3	12	Female	No	.	1	0	0	.	.	.	.	.	.	.	.	.	9	9
329.003.00080	Biologic Mother	43	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	48	Male	No	1	.	0	0	0	.	0	1	0	.	.	.	.	0	0
	Sibling #1	16	Female	No	1	1	0	0	0	1	0	1	0	1	1	1	1	0	0
	Sibling #2	14	Male	No	.	.	0	0	0	1	0	.	0	.	.	.	.	0	0
329.003.00085	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	0	1	0	0	0	1	1	1	1	1	1	1	1	1	1
	Sibling #2	14	Female	No	0	.	0	0	0	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00086	Biologic Mother	38	Female	No	0	.	0	0	0	.	.	.	.	.	.	0	0	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	1	0	0	0	1	1	1	1	1	1	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.003.00086	Sibling #2	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00094	Biologic Mother	55	Female	No	0	0	0	0	1	0	0	.	.	9	0	0	0	0	0
	Biologic Father	55	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Female	No	0	0	0	0	.	0	0	1	1	9	0	0	0	0	0
329.003.00252	Biologic Mother	42	Female	No	0	1	0	0	1	0	0	1	1	1	9	1	1	1	0
	Biologic Father	45	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	.	0	0	.	0	0	1	.	1	9	1	.	.	0
329.003.00291	Biologic Mother	38	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	35	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	13	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	.			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00315	Biologic Mother	52	Female	No	.	.	.	.	.	1	1	.	.	.	.	.	.	.	0
	Biologic Father	52	Male	No	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
	Sibling #1	16	Female	No	.	.	.	.	.	.	.	1	1	1	1	1	1	.	0
	Sibling #2	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00316	Biologic Mother	40	Female	No	1	.	.	.	.	1	1	1	1	.	.	1	1	1	.
	Biologic Father	38	Male	No	.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	1	1	1	1	1	1	.	.	.	1	.	1	1	1	1
	Sibling #2	16	Female	No	1	.	.	.	.	1	.	1	1	1	1	1	1	.	.
	Sibling #3	10	Female	No	1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	6	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00016	Biologic Mother	46	Female	No	1	1	0	0	1	1	.	1	1	1	1	1	1	0	0
	Biologic Father	46	Male	No	.	1	0	0	.	1	1	.	.	.	.	.	.	0	0
	Sibling #1	22	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	.	1	0	0	.	.	.	1	1	1	1	1	1	0	0
329.004.00018	Biologic Mother	42	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	1	0	.
	Biologic Father	49	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.004.00018	Sibling #1	17	Female	No	1	1	.	.	.	1	1	1	1	1	1	1	1	0	.
	Sibling #2	14	Male	No	1	1	1	.	1	1	1	1	1	1	1	1	1	0	.
329.004.00020	Biologic Mother	38	Female	No	1	1	0	0	1	1	1	1	1	.	.	.	.	0	.
	Biologic Father	45	Male	No	.	1	0	0	1	.	.	1	.	.	.	.	.	0	.
	Sibling #1	18	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	.
	Sibling #2	14	Female	No	1	1	0	0	.	1	1	1	1	1	1	1	1	0	.
329.004.00213	Biologic Mother	45	Female	No	.	.	0	0	.	0	.	.	.	.	.	.	.	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	1	1	0	0	.	0	.	1	1	1	1	1	1	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00001	Biologic Mother	41	Female	No	1	.	.	0	.	.	.	1	1	.	.	1	1	.	.
	Biologic Father	45	Male	No	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	1	.	.	0	.	.	.	1	1	.	.	.	.	.	.
	Sibling #3	16	Female	No	1	1	.	0	.	1	1	1	1	1	.	1	.	.	.
329.005.00005	Biologic Mother	40	Female	No	.	.	0	1	.	0	0	1	.	.	.	0	0	0	0
	Biologic Father	46	Male	No	.	.	0	.	.	0	0	.	.	.	.	0	0	0	0
	Sibling #1	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	1	1	0	.	1	0	0	1	1	1	1	0	0	0	0
329.005.00010	Biologic Mother	45	Female	No	0	.	.	0	0	0	0	.	.	.	0	.	.	0	0
	Biologic Father	47	Male	No	0	.	.	0	0	0	0	1	1	1	0	1	1	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Female	No	0	.	.	0	0	0	0	1	1	1	0	1	1	0	0
	Sibling #5	15	Female	No	0	.	.	0	0	0	0	.	.	.	0	.	.	0	0
	Child #1	12	Male	No	0	1	1	0	0	0	0	.	.	.	0	.	.	0	0
329.005.00012	Biologic Mother	41	Female	No	0	1	0	0	1	0	0	1	1	1	1	1	1	0	0
	Biologic Father	44	Male	No	0	.	0	0	.	0	0	.	.	.	.	.	.	0	0
	Sibling #1	18	Male	No	0	.	0	0	.	0	0	.	.	.	.	.	.	0	0
	Sibling #2	14	Female	No	0	.	0	0	.	0	0	1	1	1	.	.	.	0	0
329.005.00111	Biologic Mother	36	Female	No	0	.	0	0	.	.	.	.	.	.	.	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.005.00111	Biologic Father	40	Male	No	0	1	0	0	1	1	1	1	1	1	1	.	.	0	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	.	0	0	.	.	.	1	1	1	.	1	1	0	0
	Sibling #3	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00114	Biologic Mother	47	Female		1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	55	Male		.	.	.	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	22	Male	No	.	1	.	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #2	16	Male	No	.	.	.	0	.	.	.	1	1	1	1	1	1	0	0
	Sibling #3	25	Female	No	1	1	.	0	1	.	.	1	1	1	1	1	1	0	0
329.005.00115	Biologic Mother	41	Female	Yes	0	0	0	.	0	1	0	.	.	.	.	.	.	.	0
	Biologic Father	0	Male	Yes	0	0	0	1	0	.	0	.	.	.	.	.	.	.	0
	Sibling #1	25	Male	No	0	0	0	.	0	1	0	.	.	.	.	.	.	.	0
	Sibling #2	18	Female	No	0	0	0	.	0	.	0	1	1	1	1	1	1	1	0
	Sibling #3	17	Male	No	0	0	0	.	0	1	0	.	.	.	.	.	.	.	0
329.005.00120	Biologic Mother	36	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	1	1	0	0	.	.	.	1	1	1	1	1	1	0	0
	Sibling #2	9	Male	No	1	1	0	0	1	1	1	.	.	.	.	.	.	0	0
329.005.00253	Biologic Mother	44	Female	No	1	1	1	.	1	1	1	1	1	1	0	1	.	0	0
	Biologic Father	44	Male	No	.	1	1	1	.	.	.	.	.	.	0	1	1	0	0
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	.	1	.	.	.	.	.	1	1	1	0	1	1	0	0
	Sibling #3	10	Male	No	.	1	.	.	.	.	.	.	.	.	0	.	.	0	0
329.005.00254	Biologic Mother	41	Female	No	.	1	1	1	1	1	1	.	.	1	1	1	1	1	1
	Biologic Father	45	Male	No	.	1	1	1	1	1	1	1	1	1	.	.	.	.	.
	Sibling #1	16	Female	No	.	.	.	.	.	1	.	1	1	1	1	1	1	.	.
	Sibling #2	12	Female	No	1	1	.	.	.	1	.	1	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00293	Biologic Mother	42	Female	No	1	1	1	.	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	41	Male	No	.	.	.	1	1	1	1	.	.	1	1	1	1	.	.
	Sibling #1	16	Female	No	.	1	.	.	.	1	1	1	1	1	1	1	1	.	.
	Sibling #2	14	Female	No	.	1	.	.	.	1	1	1	1	1	1	1	1	.	.
	Sibling #3	7	Male	No	.	1	.	.	1	1	1	.	.	.	.	.	.	.	.
	Sibling #4	12	Male	No	.	1	.	.	1	1	1	.	.	.	.	1	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.005.00293	Child #1	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00298	Biologic Mother	42	Female	No	0	1	0	0	1	1	0	1	1	1	1	1	1	0	0
	Biologic Father	44	Male	No	0	.	0	0	.	.	0	.	.	.	.	.	.	0	0
	Sibling #1	14	Female	No	0	1	0	0	.	.	0	1	.	.	.	.	.	0	0
	Sibling #2	13	Female	No	0	1	0	0	.	.	0	1	1	1	1	1	1	0	0
	Sibling #3	8	Male	No	0	1	0	0	.	.	0	1	.	.	.	.	.	0	0
	Sibling #4	6	Male	No	0	1	0	0	.	.	0	1	.	.	.	.	.	0	0
329.005.00331	Biologic Mother	38	Female	No	1	1	0	1	.	.	0	1	.	1	1	1	1	0	0
	Biologic Father	48	Male	Unknown	1	1	0	.	1	1	0	1	1	.	.	.	.	0	0
	Sibling #1	15	Female	No	.	1	0	.	.	.	0	1	1	1	1	1	1	0	0
	Sibling #2	11	Female	No	.	.	0	.	.	.	0	1	.	.	.	1	1	0	0
329.005.00334	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	Sibling #2	13	Female	No	0	0	0	0	0	0	0	0	0	.	0	0	0	0	0
329.006.00037	Biologic Mother	59	Female	No	1	1	0	0	1	.	.	1	.	1	1	1	1	1	0
	Biologic Father	55	Male	No	1	1	0	0	1	.	.	.	.	.	.	1	1	1	0
	Sibling #1	39	Male	No	.	.	0	0	.	.	.	.	.	.	.	1	1	1	0
	Sibling #2	36	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	1	0
	Sibling #3	17	Female	No	.	1	0	0	1	.	.	1	1	1	1	1	1	1	0
329.006.00042	Biologic Mother	40	Female	No	0	9	0	0	0	.	.	.	.	.	0	.	.	0	.
	Biologic Father	43	Male	No	0	9	0	0	0	1	1	1	.	.	0	.	.	0	.
	Sibling #1	18	Male	No	0	9	0	0	0	.	.	1	1	1	0	1	1	0	.
	Sibling #2	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	0	9	0	0	0	.	.	.	.	.	0	.	.	0	.
	Sibling #4	7	Female	No	0	9	0	0	0	.	.	.	.	.	0	.	.	0	.
329.006.00259	Biologic Mother	49	Female	No	0	1	0	0	.	0	.	.	.	.	.	.	9	0	.
	Biologic Father	53	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	0	1	0	0	1	0	.	1	1	1	1	1	9	0	.
	Sibling #2	15	Male	No	0	.	0	0	.	0	.	.	.	.	.	.	9	0	.
	Sibling #3	10	Female	No	0	.	0	0	.	0	.	.	.	.	.	.	9	0	.
329.007.00141	Biologic Mother	32	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.007.00141	Biologic Father	32	Male	No	.	.	.	.	.	.	.	.	.	1	.	.	.	.	0
	Sibling #1	13	Male	No	.	1	.	.	.	.	.	1	.	1	.	1	.	.	0
	Sibling #2	9	Female	Yes	.	1	.	.	.	.	.	1	.	.	.	1	.	.	0
329.007.00144	Biologic Mother	28	Female	No	0	0	0	0	0	0	.	.	.	1	1	1	1	0	.
	Biologic Father	39	Male	No	0	0	0	0	0	0	.	.	.	.	.	.	.	0	.
	Sibling #1	12	Female	No	0	0	0	0	0	0	.	1	1	1	1	1	1	0	.
329.007.00266	Biologic Mother	33	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	.	1	1
	Biologic Father	34	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	.	.	.	.	.	1	.	1	1	1	.	1	1	1	.
	Sibling #2	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00267	Biologic Mother	46	Female	No	0	1	0	9	0	0	.	.	0	.	0	.	0	0	.
	Biologic Father	46	Male	No	0	.	0	9	0	0	.	.	0	.	0	.	0	0	.
	Sibling #1	16	Male	No	0	1	0	9	0	0	.	1	0	1	0	1	0	0	.
329.007.00311	Biologic Mother	44	Female	No	0	1	.	.	1	.	0	1	0	1	0	.	.	1	0
	Biologic Father	62	Male	No	0	1	.	.	1	.	0	.	0	1	0	.	.	.	0
	Sibling #1	18	Female	No	0	1	1	1	1	1	0	1	0	1	0	1	1	1	0
	Sibling #2	15	Male	No	0	1	.	.	1	1	0	1	0	1	0	.	.	1	0
	Sibling #3	13	Male	No	0	1	.	.	1	.	0	1	0	1	0	1	.	1	0
329.008.00158		.			.	.	.	0	.	.	.	.	1	.	.	.	.	0	0
	Biologic Mother	47	Female	No	.	1	.	0	1	.	.	1	.	1	.	1	.	0	0
	Biologic Father	49	Male	No	1	1	1	0	1	1	1	1	.	1	1	1	1	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	.	1	.	0	1	.	.	1	.	.	.	.	.	0	0
	Sibling #3	16	Female	No	.	1	.	0	1	.	.	1	.	1	.	1	1	0	0
	Child #2	.			.	.	.	0	.	.	.	.	.	.	1	.	.	0	0
329.008.00162	Biologic Mother	46	Female	No	0	0	0	.	1	1	0	1	1	1	1	1	1	0	0
	Biologic Father	41	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Male	No	0	0	0	1	.	.	0	.	.	.	.	.	.	0	0
329.008.00191	Biologic Mother	43	Female	No	.	1	0	0	1	0	0	1	1	1	1	1	1	0	0
	Biologic Father	45	Male	No	.	.	0	0	.	0	0	1	.	.	.	.	.	0	0
	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.008.00191	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	.			.	.	0	0	.	0	0	.	.	.	.	.	.	0	0
329.009.00128	Biologic Mother	50	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	49	Male	No	1	1	0	0	1	1	1	1	1	1	1	.	.	0	0
	Sibling #1	23	Male	No	1	1	0	0	.	1	1	1	1	.	.	.	.	0	0
	Sibling #2	13	Male	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #3	10	Female	No	.	1	0	0	.	.	.	.	.	.	.	.	.	0	0
329.009.00129	Biologic Mother	42	Female	No	1	1	0	0	1	1	.	1	1	1	1	1	1	1	.
	Biologic Father	47	Male	No	.	.	0	0	.	1	.	1	1	1	1	1	1	.	.
	Sibling #1	16	Male	No	1	1	0	0	1	1	.	1	1	1	1	1	1	.	.
	Sibling #2	12	Female	No	.	.	0	0	.	.	.	1	1	1	1	1	.	.	.
329.009.00135	Biologic Mother	48	Female	No	1	1	0	0	0	.	.	1	.	1	1	.	.	0	.
	Biologic Father	48	Male	No	.	1	0	0	0	.	.	1	.	.	.	.	.	0	.
	Sibling #1	17	Female	No	1	.	0	0	0	1	1	1	1	1	1	1	1	0	.
329.009.00136	Biologic Mother	39	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #6	15	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #7	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #8	14	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #9	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	48	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	23	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	18	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	16	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
329.009.00169	Biologic Mother	27	Female	No	9	9	0	.	0	1	1	.	.	0	.	.	.	0	.
	Biologic Father	32	Male	No	9	9	0	1	0	1	1	.	.	0	.	.	.	0	.
	Sibling #1	13	Male	No	9	9	0	.	0	1	1	1	1	0	.	1	1	0	.
	Sibling #2	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	5	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00174	Biologic Mother	44	Female	No	0	1	0	0	1	0	.	1	1	1	1	1	1	0	.
	Biologic Father	48	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.009.00174	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Male	No	0	.	0	0	.	0	.	.	.	.	.	1	1	0	.
	Sibling #3	15	Female	No	0	.	0	0	.	0	.	1	1	1	1	1	1	0	.
329.009.00197	Biologic Mother	29	Female	No	0	0	0	0	1	0	.	1	1	0	.	1	0	0	.
	Biologic Father	31	Male	No	0	0	0	0	.	0	.	.	.	0	.	.	0	0	.
	Sibling #1	12	Male	No	0	0	0	0	.	0	.	.	.	0	.	.	0	0	.
	Sibling #2	4	Female	No	0	0	0	0	.	0	.	.	.	0	.	.	0	0	.
	Sibling #3	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00198	Biologic Mother	34	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	.	0
	Biologic Father	35	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	.	0
	Sibling #1	17	Female	No	1	1	0	0	.	1	1	1	1	1	1	1	1	.	0
	Sibling #2	15	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	.	0
	Sibling #3	13	Female	No	.	.	0	0	.	.	.	.	.	.	.	.	.	1	0
329.009.00200	Biologic Mother	49	Female	No	.	.	.	0	.	.	.	1	.	.	.	1	1	0	.
	Biologic Father	53	Male	No	1	.	.	0	.	1	1	1	1	1	1	.	.	0	.
	Sibling #1	17	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	.
	Sibling #2	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00202	Biologic Mother	40	Female	No	1	1	.	.	1	1	1	1	1	1	.	1	1	.	0
	Biologic Father	41	Male	No	1	.	.	1	.	1	1	1	.	.	.	.	.	.	0
	Sibling #1	19	Male	No	1	1	1	.	.	.	1	1	.	.	.	.	.	.	0
	Sibling #2	15	Female	No	1	1	.	.	.	1	1	1	1	1	1	1	1	1	0
	Sibling #3	14	Male	No	1	1	.	.	1	1	1	1	.	.	.	.	.	.	0
329.009.00237	Biologic Mother	43	Female	No	0	.	0	0	0	0	0	1	.	1	1	.	0	1	0
	Sibling #6	9	Female	No	0	.	0	0	0	0	0	.	.	.	.	.	0	1	0
	Biologic Father	44	Male	No	0	.	0	0	0	0	0	.	.	.	.	1	0	1	0
	Sibling #1	21	Male	No	0	.	0	0	0	0	0	.	.	.	.	.	0	1	0
	Sibling #2	19	Female	No	0	.	0	0	0	0	0	.	.	.	.	.	0	1	0
	Sibling #3	17	Male	No	0	1	0	0	0	0	0	1	1	1	1	1	0	1	0
	Sibling #4	12	Male	No	0	.	0	0	0	0	0	.	.	.	.	.	0	1	0
	Sibling #5	10	Male	No	0	.	0	0	0	0	0	.	.	.	.	.	0	1	0
329.009.00238	Biologic Mother	42	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	42	Male	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Sibling #1	21	Male	Yes	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #2	16	Female	Yes	.	1	0	0	.	.	.	1	1	1	1	1	1	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.009.00238	Sibling #3	9	Female	Yes	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
329.009.00276	Biologic Mother	30	Female	No	1	1	0	1	0	1	1	.	.	.	.	.	.	1	0
	Biologic Father	32	Male	No	1	.	0	.	0	1	.	.	.	.	.	.	.	.	0
	Sibling #1	13	Male	No	1	.	0	.	0	1	1	1	1	1	1	1	1	1	0
329.009.00302	Biologic Mother	40	Female	No	0	.	0	0	.	.	.	.	.	.	.	.	.	0	.
	Biologic Father	41	Male	No	0	1	0	0	.	.	.	.	.	1	.	.	.	0	.
	Sibling #1	17	Male	No	0	1	0	0	1	1	1	1	1	1	1	1	1	0	.
	Sibling #2	10	Female	No	0	.	0	0	.	.	.	.	.	.	.	.	.	0	.
329.009.00306	Biologic Mother	28	Female	Yes	9	0	0	0	0	1	1	1	0	9	.	0	.	0	.
	Biologic Father	.	Male	Unknown	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	9	0	0	0	0	.	.	1	0	9	.	0	.	0	.
329.009.00312	Biologic Mother	48	Female	No	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	55	Male	No	.	1	.	0	.	1	1	.	.	.	.	.	.	0	0
	Sibling #1	17	Female	No	1	1	.	0	1	1	1	1	1	1	1	1	1	0	0
329.009.00327	Biologic Mother	40	Female	No	0	1	0	0	0	.	0	1	1	1	0	1	1	0	0
	Biologic Father	42	Male	No	0	.	0	0	0	1	0	.	.	.	0	.	.	0	0
	Sibling #1	18	Male	No	0	1	0	0	0	1	0	.	.	.	0	.	.	0	0
	Sibling #2	16	Female	No	0	1	0	0	0	1	0	1	.	1	0	.	.	0	0
329.009.00330	Biologic Mother	33	Female	No	1	1	1	1	1	0	0	1	1	1	1	1	1	.	0
	Biologic Father	36	Male	No	.	1	.	1	.	0	0	1	.	.	.	.	.	.	0
	Sibling #1	14	Female	No	.	1	.	.	.	0	0	.	.	.	.	.	.	.	0
	Sibling #2	12	Male	No	.	1	.	.	1	0	0	1	.	.	.	1	1	.	0
	Sibling #3	9	Male	No	.	1	.	.	.	0	0	.	.	.	.	.	.	1	0
329.010.00183	Biologic Mother	39	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	0	0	0	0	0	0	.	.	.	.	.	.	.	0	.
	Sibling #1	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	0	0	0	0	0	0	.	1	1	1	1	1	1	0	.
	Sibling #3	13	Female	No	0	0	0	0	0	0	.	.	.	.	.	.	.	0	.
329.010.00263	Biologic Mother	40	Female	No	1	1	0	0	1	.	.	1	1	1	1	1	1	0	0
	Biologic Father	60	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	21	Male	No	1	1	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #2	18	Male	No	1	1	0	0	.	1	.	1	1	1	1	1	1	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.010.00263	Sibling #3	15	Female	No	1	1	0	0	.	1	1	1	1	1	1	.	.	0	0
329.010.00277	Biologic Mother	35	Female	No	0	.	0	0	0	0	.	1	.	1	.	1	.	0	.
	Biologic Father	38	Male	No	0	.	0	0	0	0	.	.	.	.	.	.	.	0	.
	Sibling #1	14	Female	No	0	1	0	0	0	0	.	1	1	1	1	1	1	0	.
329.010.00282	Biologic Mother	45	Female	No	0	1	0	0	0	0	.	.	.	.	0	.	.	0	.
	Biologic Father	46	Male	No	0	1	0	0	0	0	.	.	.	.	0	.	.	0	.
	Sibling #1	18	Female	No	0	1	0	0	0	0	.	.	.	.	0	.	.	0	.
	Sibling #2	15	Female	No	0	1	0	0	0	0	.	1	1	1	0	1	1	0	.
	Sibling #3	12	Male	No	0	1	0	0	0	0	.	.	.	.	0	.	.	0	.
329.011.00164	Biologic Mother	43	Female	No	0	.	0	0	0	.	.	1	.	1	.	1	1	0	.
	Biologic Father	43	Male	No	0	.	0	0	0	.	.	.	.	.	.	.	.	0	.
	Sibling #1	24	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	20	Male	No	0	1	0	0	0	.	.	.	.	1	.	.	.	0	.
	Sibling #3	18	Male	No	0	.	0	0	0	.	.	1	.	1	.	.	.	0	.
	Sibling #4	15	Male	No	0	.	0	0	0	1	1	1	1	1	1	1	1	0	.
329.011.00210	Biologic Mother	32	Female	No	0	.	0	0	.	.	0	.	.	.	.	.	.	.	0
	Biologic Father	41	Male	No	0	1	0	0	1	.	0	1	1	1	1	1	1	1	0
	Sibling #1	14	Female	No	0	.	0	0	.	1	0	1	1	1	1	1	1	.	0
	Sibling #2	10	Male	No	0	1	0	0	1	.	0	.	.	.	.	.	.	.	0
329.011.00285	Biologic Mother	42	Female	No	0	.	0	0	0	.	0	.	.	.	.	.	.	0	0
	Biologic Father	44	Male	No	0	.	0	0	0	.	0	.	.	.	.	.	.	0	0
	Sibling #1	16	Male	No	0	1	0	0	0	1	0	1	1	1	1	1	1	0	0
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.011.00287	Biologic Mother	41	Female	No	0	.	0	0	0	.	.	.	.	.	.	.	.	0	0
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	.	0	0	0	.	.	1	.	.	.	.	.	0	0
	Sibling #2	14	Female	No	0	1	0	0	0	1	1	1	1	1	1	1	1	0	0
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	4	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00027	Biologic Mother	39	Female	No	.	.	.	.	.	.	.	.	.	.	0	.	.	.	0
	Biologic Father	38	Male	No	.	.	.	1	1	.	.	1	.	1	0	1	1	1	0
	Sibling #1	15	Male	No	1	1	1	.	.	1	1	1	1	1	0	1	1	1	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part I
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 2	3	4	5	6	7	7B	8	8B	9	9B	10	10B	11	11B
329.012.00217	Biologic Mother	45	Female	No	.	1	0	0	1	.	.	.	.	1	.	.	.	0	0
	Biologic Father	45	Male	No	.	1	0	0	.	.	.	.	.	.	.	1	1	0	0
	Sibling #1	22	Male	No	.	.	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Female	No	1	1	0	0	.	1	1	1	1	1	1	.	.	0	0
329.012.00218	Biologic Mother	46	Female	No	.	.	0	0	.	0	.	.	.	.	.	0	.	0	0
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	1	1	0	0	1	0	.	1	1	1	1	0	.	0	0
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00224	Biologic Mother	41	Female	No	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0
	Biologic Father	41	Male	No	.	1	0	0	.	.	.	.	.	.	.	.	.	0	0
	Sibling #1	14	Female	No	1	1	0	0	1	.	.	1	1	1	1	1	1	0	0
	Sibling #2	7	Female	No	.	1	0	0	.	.	.	.	.	.	.	1	1	0	0
329.012.00225	Biologic Mother	48	Female	No	.	1	0	0	1	0	0	.	.	1	.	1	1	0	.
	Biologic Father	48	Male	No	.	.	0	0	.	0	0	1	1	1	.	.	.	0	.
	Sibling #1	14	Male	No	1	1	0	0	1	0	0	1	1	1	1	1	1	0	.
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.001.00063	Biologic Mother	40	Female	No	0	0	0	0	0	0	1	1	0	0	0	0	.	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	.	0
	Sibling #1	14	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	.	0
	Sibling #2	13	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	1	0
	Sibling #3	10	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	.	0
	Sibling #4	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.001.00068	Biologic Mother	41	Female	No	0	.	0	.	0	.	0	.	0	.	.	.	1	.
	Biologic Father	43	Male	No	0	.	0	.	0	.	0	.	0	.	.	.	.	.
	Sibling #1	19	Female	No	0	.	0	.	0	.	0	.	0	.	1	.	.	.
	Sibling #2	13	Female	No	0	.	0	.	0	.	0	.	0	.	1	1	1	1
329.001.00072	Biologic Mother	45	Female	No	1	0	1	0	0	0	1	.	1	0	1	1	0	0
	Biologic Father	45	Male	No	.	0	1	0	0	0	1	1	.	0	1	1	0	0
	Sibling #1	15	Male	No	.	0	1	0	0	0	.	.	.	0	1	1	0	0
	Sibling #2	12	Female	No	.	0	.	0	0	0	.	.	.	0	1	1	0	0
	Sibling #3	10	Male	No	.	0	.	0	0	0	.	.	.	0	.	.	0	0
329.001.00121	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	15	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	12	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	10	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.001.00205	Biologic Mother	37	Female	No	.	0	0	.	0	.	1	0	0	.	.	0	.	0
	Biologic Father	38	Male	No	.	0	0	.	0	.	1	0	0	.	.	0	.	0
	Sibling #1	12	Male	No	.	0	0	.	0	.	.	0	0	.	1	0	1	0
	Sibling #2	10	Female	No	1	0	0	.	0	.	.	0	0	.	1	0	.	0
	Sibling #3	5	Female	No	.	0	0	.	0	.	.	0	0	.	.	0	.	0
329.001.00206	Biologic Mother	52	Female	No	0	0	0	0	.	0	0	0	0	0	.	0	0	0
	Biologic Father	54	Male	No	0	0	0	0	.	0	0	0	0	0	.	0	0	0
	Sibling #1	17	Male	No	0	0	0	0	.	0	0	0	0	0	1	0	0	0
	Sibling #2	14	Female	No	0	0	0	0	1	0	0	0	0	0	.	0	0	0
329.002.00055	Biologic Mother	48	Female	No	9	.	9	.	1	.	1	.	1	1	1	1	1	1
	Biologic Father	43	Male	No	9	.	9	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	29	Female	No	9	.	9	.	1	1	.	.	.	.	.	.	.	.
	Sibling #2	23	Male	Yes	9	.	9	.	.	.	1	1	.	.	.	.	.	.
	Sibling #3	26	Male	No	9	.	9	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.002.00055	Sibling #4	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00058	Biologic Mother	42	Female	No	0	0	1	1	.	.	1	1	.	.	.	.	1	0
	Biologic Father	36	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	0
	Sibling #1	24	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	0
	Sibling #2	22	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	0
	Sibling #3	16	Female	No	0	0	1	1	1	1	.	.	1	1	1	1	1	0
	Sibling #4	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00099	Biologic Mother	37	Female	Yes	0	.	0	.	.	9	.	0	0	.	0	.	0	.
	Biologic Father	47	Male	No	0	.	0	.	.	9	1	0	0	.	0	.	0	.
	Sibling #1	15	Male	No	0	.	0	.	.	9	1	0	0	.	0	.	0	.
	Sibling #2	9	Female	No	0	.	0	.	1	9	.	0	0	.	0	.	0	.
329.002.00102	Biologic Mother	35	Female	No	.	.	1	1	1	1	.	0	1	1	0	0	1	0
	Biologic Father	39	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	1	1	1	1	1	1	1	0	.	.	0	0	1	0
	Sibling #2	13	Female	No	.	.	1	1	1	1	.	0	1	1	0	0	1	0
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00105	Biologic Mother	43	Female	No	1	0	0	0	0	0	.	0	0	0	.	.	0	0
	Biologic Father	52	Male	Yes	.	0	0	0	0	0	.	0	0	0	1	1	0	0
	Sibling #1	17	Male	No	.	0	0	0	0	0	1	0	0	0	1	1	0	0
	Sibling #2	16	Male	Yes	1	0	0	0	0	0	1	0	0	0	1	1	0	0
329.002.00106	Biologic Mother	32	Female	No	0	.	.	.	0	.	0	.	1	.	.	.	.	0
	Biologic Father	36	Male	No	0	.	.	.	0	.	0	.	.	.	.	.	.	0
	Sibling #1	15	Female	No	0	.	1	1	0	.	0	.	1	1	1	1	1	0
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00242	Biologic Mother	36	Female	No	0	0	1	1	1	0	.	.	1	1	1	1	1	1
	Biologic Father	39	Male	No	0	0	.	.	.	0	.	.	1	1	1	1	.	.
	Sibling #1	15	Female	No	0	0	.	.	.	0	1	1	.	.	.	.	1	.
	Sibling #2	12	Male	No	0	0	.	.	.	0	1	.	1	1	.	.	.	.
329.002.00245	Biologic Mother	36	Female	No	0	0	0	0	1	0	0	0	0	0	0	.	0	0
	Biologic Father	44	Male	No	0	0	0	0	.	0	0	0	0	0	0	.	0	0
	Sibling #1	14	Female	No	0	0	0	0	.	0	0	0	0	0	0	1	0	0
	Sibling #2	18	Male	No	0	0	0	0	.	0	0	0	0	0	0	.	0	0
	Sibling #3	16	Female	No	0	0	0	0	.	0	0	0	0	0	0	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.002.00245	Sibling #4	11	Female	No	0	0	0	0	.	0	0	0	0	0	0	.	0	0
	Sibling #5	9	Male	No	0	0	0	0	.	0	0	0	0	0	0	.	0	0
329.002.00319	Biologic Mother	42	Female	No	0	.	0	.	0	.	0	.	1	0	1	0	1	0
	Biologic Father	55	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	24	Male	No	0	.	0	.	0	.	0	.	.	0	1	0	.	0
	Sibling #2	17	Male	No	0	.	0	.	0	.	0	.	.	0	1	0	.	0
	Sibling #3	16	Female	No	0	.	0	.	0	.	0	.	.	0	.	0	1	0
329.003.00077		.			1	0	.	.	.	.	.	0	0	1	0	0	.	0
	Biologic Mother	45	Female	No	.	0	1	1	1	1	1	0	0	.	0	0	1	0
	Biologic Father	55	Male	No	.	0	.	.	.	.	.	0	0	.	0	0	.	0
	Sibling #1	29	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00087	Biologic Mother	49	Female	No	.	0	.	.	1	1	.	.	.	.	.	0	1	0
	Biologic Father	50	Male	No	1	0	.	1	.	.	1	1	1	1	1	0	.	0
	Sibling #1	14	Female	Yes	.	0	1	1	1	1	1	1	1	1	.	0	.	0
329.003.00089	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	60	Male	No	0	0	0	0	0	0	0	0	0	0	.	0	0	0
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	0	0
329.003.00091	Biologic Mother	.	Female	No	0	0	1	.	1	0	.	0	1	1	0	0	0	0
	Biologic Father	.	Male	No	0	0	1	1	.	0	1	0	.	.	0	0	0	0
	Sibling #1	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	.	Male	No	0	0	.	.	.	0	.	0	.	.	0	0	0	0
	Sibling #3	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00248	Biologic Mother	43	Female	No	0	0	0	0	0	0	1	0	0	.	0	.	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	.	0	0	.	0	.	0	0
	Sibling #1	22	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	12	Female	No	0	0	0	0	0	0	.	0	0	1	0	1	0	0
	Sibling #3	8	Male	No	0	0	0	0	0	0	.	0	0	.	0	.	0	0
329.003.00250		.			.	0	9	0	0	0	9	9	.	1	1	1	.	9
	Biologic Mother	43	Female	No	.	0	9	0	0	0	9	9	.	.	.	.	.	9

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.003.00250	Biologic Father	42	Male	No	.	0	9	0	0	0	9	9	.	.	.	.	.	9
	Sibling #1	18	Female	No	1	0	9	0	0	0	9	9	1	.	.	.	1	9
	Sibling #2	15	Female	No	1	0	9	0	0	0	9	9	.	.	.	.	1	9
	Sibling #3	8	Female	No	1	0	9	0	0	0	9	9	.	.	.	.	1	9
	Sibling #4	2	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00292	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	16	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00313	Biologic Mother	36	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	37	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	Sibling #2	18	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0
329.004.00015	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.004.00017	Biologic Mother	50	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	52	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #1	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00019	Biologic Mother	.	Female	No	0	0	1	0	.	0	0	1	0	0	0	0	0	0
	Biologic Father	.	Male	No	0	0	.	0	.	0	0	.	0	0	0	0	0	0
	Sibling #1	.	Female	No	0	0	1	0	1	0	0	.	0	0	0	0	0	0
329.004.00212	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00214	Biologic Mother	41	Female	No	0	0	1	1	0	0	0	.	0	0	.	0	.	.
	Biologic Father	43	Male	No	0	0	.	.	0	0	0	.	0	0	.	0	.	.
	Sibling #1	21	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	0	0	.	.	0	0	0	.	0	0	1	0	1	1

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.005.00002	Biologic Mother	35	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	0	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00004	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	44	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Male	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00008	Biologic Mother	34	Female	No	0	0	0	0	0	0	1	0	0	0	1	1	1	0
	Biologic Father	33	Male	No	0	0	0	0	0	0	.	0	0	0	.	.	.	0
	Sibling #1	12	Male	No	0	0	0	0	0	0	1	0	0	0	1	.	1	0
	Sibling #2	9	Male	No	0	0	0	0	0	0	.	0	0	0	1	.	.	0
329.005.00109	Biologic Mother	31	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	28	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	15	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #1	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00112	Biologic Mother	61	Male	No	0	0	.	.	.	.	0	0	.	9	0	0	0	0
	Biologic Father	54	Female	No	0	0	.	.	.	.	0	0	.	9	0	0	0	0
	Sibling #1	21	Female	No	0	0	.	.	.	.	0	0	.	9	0	0	0	0
	Sibling #2	18	Male	No	0	0	1	1	1	9	0	0	1	9	0	0	0	0
	Sibling #3	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Female	No	0	0	.	.	.	.	0	0	.	9	0	0	0	0
	Sibling #5	13	Male	No	0	0	.	.	.	.	0	0	.	9	0	0	0	0
329.005.00116	Biologic Mother	39	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	51	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	25	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	24	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #4	22	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #5	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Child #1	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00119	Biologic Mother	44	Female	No	0	0	.	0	.	.	.	0	0	.	0	0	0	0
	Biologic Father	46	Male	No	0	0	.	0	.	.	1	0	0	.	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.005.00119	Sibling #1	19	Female	No	0	0	.	0	.	.	1	0	0	.	0	0	0	0
	Sibling #2	14	Female	No	0	0	1	0	1	1	.	0	0	.	0	0	0	0
	Sibling #3	7	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00151	Biologic Mother	40	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Biologic Father	40	Male	No	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	Sibling #1	17	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	Sibling #3	14	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #4	13	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
329.005.00152	Biologic Mother	37	Female	No	.	0	0	0	0	0	1	.	0	0	0	0	0	0
	Biologic Father	39	Male	No	.	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #1	15	Female	No	1	0	0	0	0	0	1	1	0	0	0	0	0	0
329.005.00257	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	.	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	1	0
	Sibling #2	12	Female	No	0	0	0	0	0	0	0	0	0	0	1	1	.	0
329.005.00258	Biologic Mother	45	Male	No	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	44	Female	No	.	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	14	Female	No	.	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	9	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00299	Biologic Mother	34	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	9	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00300	Biologic Mother	45	Female	No	0	0	1	1	0	0	1	1	0	0	.	.	0	0
	Biologic Father	50	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	0	.	.	0	0	.	.	0	0	.	.	0	0
	Sibling #2	12	Male	No	0	0	.	.	0	0	.	.	0	0	1	1	0	0
	Sibling #3	9	Male	No	0	0	.	.	0	0	.	.	0	0	.	.	0	0
329.005.00333	Biologic Mother	46	Female	No	0	0	0	0	0	0	1	.	0	0	0	0	1	0
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	19	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	.	0
	Sibling #2	16	Female	No	0	0	0	0	0	0	1	1	0	0	0	0	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.005.00336	Biologic Mother	42	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	41	Male	No	.	.	.	.	.	.	1	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	.	.	.	.	.	.	1	.	1	1	1	1	1	1
	Sibling #2	14	Female	No	1	.	.	.	.	.	.	.	1	1	1	1	1	.
	Sibling #3	7	Male	No	1	.	1	.	.	.	.	.	.	.	1	1	.	.
	Sibling #4	12	Male	No	.	.	.	.	1	.	.	.	.	.	1	1	.	.
329.006.00038	Biologic Mother	35	Female	No	.	.	.	.	1	1	1	0	0	0	0	0	1	0
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	0	0	0	0	0	1	0
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	.	.	1	1	.	.	1	0	0	0	0	0	1	0
	Sibling #3	12	Female	No	1	.	1	.	.	.	.	0	0	0	0	0	1	0
	Sibling #4	11	Female	No	.	.	.	.	.	.	.	0	0	0	0	0	1	0
	Sibling #5	5	Male	No	1	1	.	.	.	.	.	0	0	0	0	0	.	0
329.006.00039		.			0	.	.	.	.	.	.	0	0	.	.	.	.	.
	Biologic Mother	47	Female	No	0	.	1	1	1	1	1	0	0	.	.	.	1	1
	Biologic Father	48	Male	No	0	.	.	.	.	.	.	0	0	.	1	1	1	.
	Sibling #1	24	Male	No	0	.	.	.	.	.	.	0	0	.	.	.	1	1
	Sibling #2	21	Male	No	0	.	1	.	.	.	.	0	0	.	.	.	1	.
	Sibling #3	15	Female	No	0	.	1	.	.	.	.	0	0	.	.	.	1	1
329.006.00260	Biologic Mother	56	Female	No	1	0	0	.	0	.	.	0	0	.	0	.	0	.
	Biologic Father	56	Male	Yes	1	0	0	.	0	.	1	0	0	.	0	.	0	.
	Sibling #1	17	Female	No	.	0	0	.	0	.	.	0	0	.	0	.	0	.
	Sibling #2	10	Male	No	.	0	0	.	0	.	.	0	0	.	0	.	0	.
329.006.00261	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	38	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	19	Female	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	17	Male	No	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	7	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00140	Biologic Mother	32	Female	No	1	0	1	0	0	.	0	.	.	.	.	.	0	.
	Biologic Father	37	Male	No	1	0	.	0	0	.	0	.	.	.	.	.	0	.
	Sibling #1	11	Male	No	1	0	1	0	0	.	0	.	1	1	1	1	0	.
	Sibling #2	9	Male	No	1	0	.	0	0	.	0	.	.	.	.	.	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.007.00142	Biologic Mother	44	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Biologic Father	46	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #1	15	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
329.007.00145	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	41	Male	No	0	.	0	.	0	.	0	.	1	0	1	1	1	0
	Sibling #1	23	Female	No	0	.	0	.	0	.	0	.	.	0	.	.	1	0
	Sibling #2	16	Male	No	0	.	0	.	0	.	0	.	.	0	.	.	1	0
	Sibling #3	14	Female	No	0	.	0	.	0	.	0	.	.	0	.	.	1	0
329.007.00265	Biologic Mother	34	Female	No	0	.	.	.	.	0	1	0	0	.	0	.	0	.
	Biologic Father	29	Male	Yes	0	.	1	1	1	0	1	0	0	.	0	.	0	.
	Sibling #1	16	Female	No	0	.	.	.	.	0	.	0	0	.	0	.	0	.
	Sibling #2	13	Male	No	0	.	.	.	.	0	.	0	0	.	0	.	0	.
	Sibling #3	12	Male	No	0	.	.	.	.	0	.	0	0	.	0	.	0	.
	Sibling #4	6	Female	No	0	.	.	.	.	0	.	0	0	.	0	.	0	.
329.007.00268	Biologic Mother	37	Female	No	.	0	1	1	1	1	0	.	1	1	1	1	0	.
	Biologic Father	33	Male	No	.	0	.	.	.	.	0	.	.	.	.	.	0	.
	Sibling #1	13	Female	No	1	0	.	.	.	.	0	.	.	.	.	.	0	.
329.007.00294	Biologic Mother	37	Female	No	.	0	1	0	1	0	1	0	.	.	.	.	1	1
	Biologic Father	40	Male	No	.	0	.	0	.	0	.	0	.	.	.	.	.	.
	Sibling #1	15	Female	No	1	0	.	0	.	0	.	0	.	.	.	.	.	.
	Sibling #2	14	Male	No	1	0	.	0	.	0	.	0	1	1	1	1	.	.
329.007.00309	Biologic Mother	39	Female	No	0	.	.	.	.	.	.	0	0	.	.	0	0	.
	Biologic Father	44	Male	No	0	.	.	.	.	.	.	0	0	.	1	0	0	.
	Sibling #1	18	Female	No	0	.	1	1	1	1	1	0	0	.	.	0	0	.
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00310		.			.	0	.	1	0	.	0	.	.	.	.	.	.	0
	Biologic Mother	41	Female	No	.	0	.	.	0	.	0	.	1	.	1	.	1	0
	Biologic Father	41	Male	No	.	0	1	.	0	.	0	.	.	.	1	1	.	0
	Sibling #1	16	Female	No	1	0	1	.	0	.	0	.	1	1	1	.	1	0
	Sibling #2	15	Male	No	.	0	.	.	0	.	0	.	.	.	1	.	.	0
329.007.00318	Biologic Mother	44	Female	No	.	0	0	0	0	0	1	0	0	0	.	.	.	0
	Biologic Father	62	Male	No	.	0	0	0	0	0	1	0	0	0	.	.	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.007.00318	Sibling #1	15	Male	No	.	0	0	0	0	0	.	0	0	0	1	1	1	0
	Sibling #2	13	Male	No	.	0	0	0	0	0	.	0	0	0	1	1	1	0
	Sibling #3	18	Female	No	1	0	0	0	0	0	.	0	0	0	.	.	.	0
329.008.00157	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	39	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.008.00160	Biologic Mother	38	Female	No	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
329.008.00188	Biologic Mother	37	Female	No	0	0	1	1	1	1	0	0	0	0	0	0	1	1
	Biologic Father	42	Male	No	0	0	.	.	.	.	0	0	0	0	0	0	.	.
	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	0	0	.	.	.	.	0	0	0	0	0	0	.	.
	Child #1	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00271	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	41	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	10	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.008.00275	Biologic Mother	44	Female	No	0	0	1	0	0	0	1	1	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	.	0	0	0	.	.	0	0	0	0	0	0
	Sibling #1	19	Male	No	0	0	.	0	0	0	.	.	0	0	0	0	0	0
	Sibling #2	17	Female	No	0	0	.	0	0	0	.	.	0	0	0	0	0	0
329.009.00130	Biologic Mother	49	Female	No	.	0	.	.	0	0	.	.	.	.	0	0	0	0
	Biologic Father	52	Male	No	1	0	.	.	0	0	1	1	.	.	0	0	0	0
	Sibling #1	16	Male	No	1	0	.	.	0	0	1	.	.	.	0	0	0	0
	Sibling #2	15	Male	No	.	0	.	.	0	0	1	1	1	1	0	0	0	0
	Sibling #3	10	Female	No	.	0	1	1	0	0	1	.	1	1	0	0	0	0
	Sibling #4	7	Female	No	.	0	.	.	0	0	.	.	.	.	0	0	0	0
329.009.00131	Biologic Mother	.	Female	No	1	1	1	1	9	9	1	1	0	.	0	.	1	1
	Biologic Father	41	Male	No	.	.	.	.	9	9	.	.	0	.	0	.	.	.
	Sibling #1	16	Female	No	.	.	1	1	9	9	1	1	0	.	0	.	1	1
	Sibling #2	13	Female	No	1	1	.	.	9	9	1	1	0	.	0	.	.	.
329.009.00133	Biologic Mother	37	Female	No	0	.	0	.	0	.	1	1	1	1	1	1	0	0
	Biologic Father	37	Male	No	0	.	0	.	0	.	.	.	.	.	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.009.00133	Sibling #1	16	Female	No	0	.	0	.	0	.	.	.	.	.	.	.	0	0
	Sibling #2	14	Male	No	0	.	0	.	0	.	.	.	.	.	.	.	0	0
329.009.00138		.			.	0	.	.	.	.	.	.	0	.	0	.	0	.
	Biologic Mother	34	Female	No	.	0	1	1	1	1	1	.	0	.	0	.	0	.
	Biologic Father	33	Male	No	.	0	.	.	.	.	.	.	0	.	0	.	0	.
	Sibling #1	13	Female	No	1	0	1	1	1	1	1	1	0	.	0	.	0	.
	Sibling #2	10	Male	No	.	0	.	1	.	.	1	1	0	.	0	.	0	.
329.009.00170	Biologic Mother	41	Female	No	9	9	1	9	.	.	1	1	1	1	.	.	1	1
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	9	9	1	9	1	1	1	1	1	1	1	1	1	.
	Sibling #2	22	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00173	Biologic Mother	43	Female	No	.	.	0	.	1	0	1	1	0	.	0	.	0	.
	Biologic Father	45	Male	Yes	1	1	0	.	.	0	1	1	0	.	0	.	0	.
	Sibling #1	12	Female	No	.	.	0	.	.	0	1	1	0	.	0	.	0	.
329.009.00193	Biologic Mother	36	Female	No	0	.	1	1	1	1	1	0	0	.	1	0	0	0
	Biologic Father	38	Male	No	0	.	.	.	.	.	.	0	0	.	.	0	0	0
	Sibling #1	12	Female	No	0	.	1	.	1	.	1	0	0	.	1	0	0	0
	Sibling #2	3	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00196	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.
	Sibling #1	17	Female	No	0	.	0	.	0	.	0	.	0	.	1	1	0	.
	Sibling #2	9	Female	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.
329.009.00201	Biologic Mother	43	Female	No	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	Biologic Father	47	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #1	17	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #2	14	Male	No	0	0	0	0	0	0	1	1	0	0	0	0	0	0
329.009.00204	Biologic Mother	39	Female	No	.	0	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #6	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	47	Male	No	.	0	0	.	0	.	1	.	0	.	0	.	0	.
	Sibling #1	13	Male	No	.	0	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #2	12	Male	No	1	0	0	.	0	.	.	.	0	.	0	.	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.009.00204	Sibling #3	10	Female	No	.	0	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #4	9	Male	No	.	0	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #5	21	Female	No	.	0	0	.	0	.	.	.	0	.	0	.	0	.
	Child #1	.			.	0	0	.	0	.	.	.	0	.	0	.	0	.
329.009.00235	Biologic Mother	32	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	.	0
	Biologic Father	30	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	0	0	0	0	0	0	0	0	0	0	1	1	.	0
	Sibling #2	8	Male	No	0	0	0	0	0	0	0	0	0	0	1	1	1	0
329.009.00240	Biologic Mother	48	Female	No	.	0	0	0	0	0	0	0	0	0	1	0	0	0
	Biologic Father	52	Male	No	1	0	0	0	0	0	0	0	0	0	.	0	0	0
	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	.	0	0	0	0	0	0	0	0	0	.	0	0	0
	Sibling #4	13	Female	No	.	0	0	0	0	0	0	0	0	0	.	0	0	0
329.009.00303	Biologic Mother	43	Female	No	0	.	.	.	.	.	.	.	0	.	0	.	0	.
	Biologic Father	49	Male	No	0	.	.	.	.	.	.	.	0	.	0	.	0	.
	Sibling #1	17	Male	No	0	.	1	1	1	1	1	1	0	.	0	.	0	.
	Sibling #2	14	Female	No	0	.	.	.	.	.	.	.	0	.	0	.	0	.
329.009.00304	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	23	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #2	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
329.009.00324	Biologic Mother	33	Female	No	.	0	1	0	.	0	1	0	.	0	1	0	1	0
	Biologic Father	35	Female	No	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #1	13	Female	No	1	0	.	0	1	0	1	0	1	0	.	0	.	0
	Sibling #2	8	Female	No	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #3	5	Female	No	.	0	.	0	.	0	.	0	.	0	.	0	.	0
329.009.00328	Biologic Mother	45	Female	No	0	0	0	0	0	0	1	0	0	0	0	0	1	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	1	0	0	0	0	0	1	0
	Sibling #1	23	Male	No	0	0	0	0	0	0	1	0	0	0	0	0	.	0
	Sibling #2	21	Male	No	0	0	0	0	0	0	.	0	0	0	0	0	1	0
	Sibling #3	14	Male	No	0	0	0	0	0	0	.	0	0	0	0	0	1	0
	Sibling #4	12	Male	No	0	0	0	0	0	0	.	0	0	0	0	0	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.009.00329	Biologic Mother	32	Female	No	.	0	1	0	1	0	0	0	1	1	0	0	0	0
	Biologic Father	34	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Male	No	1	0	.	0	.	0	0	0	.	.	0	0	0	0
	Sibling #2	10	Male	No	.	0	.	0	.	0	0	0	.	.	0	0	0	0
	Sibling #3	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.010.00182	Biologic Mother	42	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #2	17	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.010.00278	Biologic Mother	49	Female	No	0	.	0	.	0	.	0	.	0	.	1	1	0	.
	Biologic Father	49	Male	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.
	Sibling #1	20	Female	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.
	Sibling #2	17	Female	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.
329.010.00280	Biologic Mother	33	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Biologic Father	32	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #1	13	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #2	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.011.00283	Biologic Mother	36	Female	No	.	0	1	0	.	.	.	.	0	0	.	0	.	0
	Biologic Father	42	Male	No	.	0	.	0	1	1	1	1	0	0	.	0	.	0
	Sibling #1	16	Male	No	1	0	.	0	1	1	1	1	0	0	1	0	1	0
329.011.00288	Biologic Mother	41	Female	No	.	0	0	0	.	.	1	1	1	0	1	1	1	1
	Biologic Father	45	Male	No	.	0	0	0	.	.	.	.	.	0	.	.	.	.
	Sibling #1	15	Male	No	1	0	0	0	1	1	1	1	.	0	.	.	1	1
329.012.00025	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	0	0	0	0	0	.	0	.	0	.	0	.	0	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Female	No	0	0	0	0	0	.	0	.	0	.	0	.	0	.
329.012.00220	Biologic Mother	40	Female	No	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	41	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.012.00220	Sibling #1	17	Male	No	0	0	.	.	.	.	.	.	.	.	1	.	.	.
	Sibling #2	15	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	13	Female	No	0	0	.	.	.	.	.	.	.	.	1	.	.	.
329.012.00222	Biologic Mother	37	Female	No	0	.	.	0	.	.	0	.	0	.	1	0	0	.
	Biologic Father	38	Male	No	0	.	.	0	.	.	0	.	0	.	.	0	0	.
	Sibling #1	15	Female	No	0	.	1	0	1	1	0	.	0	.	.	0	0	.
329.012.00226	Biologic Mother	50	Female	No	0	0	0	0	0	0	.	0	0	0	1	0	.	.
	Biologic Father	50	Male	No	0	0	0	0	0	0	.	0	0	0	1	0	.	.
	Sibling #1	23	Female	No	0	0	0	0	0	0	.	0	0	0	.	0	.	.
	Sibling #2	18	Male	No	0	0	0	0	0	0	.	0	0	0	.	0	1	1
	Sibling #3	16	Male	No	0	0	0	0	0	0	1	0	0	0	.	0	1	1
329.012.00228	Biologic Mother	40	Female	No	.	0	.	0	1	0	0	0	.	.	.	0	.	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	.	0	1	0	.	0	0	0	1	1	1	0	1	0
	Sibling #2	12	Female	No	1	0	.	0	.	0	0	0	.	.	.	0	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.001.00061	Biologic Mother	39	Female	No	0	0	1	0	1	1	0	0	1	1	.	.	1	.
	Biologic Father	46	Male	No	0	0	.	0	.	.	0	0	.	.	.	.	1	1
	Sibling #1	16	Female	No	0	0	1	0	1	1	0	0	.	.	1	1	.	.
	Sibling #2	14	Male	No	0	0	.	0	.	.	0	0	.	.	1	1	.	.
329.001.00066	Biologic Mother	48	Female	No	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	Biologic Father	52	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #1	17	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
	Sibling #2	13	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	0	0
329.001.00067	Biologic Mother	42	Female	No	.	.	.	.	.	.	1	0	0	.	0	.	0	.
	Biologic Father	44	Male	No	.	.	1	1	1	1	1	0	0	.	0	.	0	.
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	0	0	.	0	.	0	.
	Sibling #2	16	Female	No	1	1	.	.	.	.	.	0	0	.	0	.	0	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	0	0	.	0	.	0	.
329.001.00070	Biologic Mother	47	Female	No	.	0	1	0	0	0	1	.	0	0	1	0	0	0
	Biologic Father	46	Male	No	.	0	.	0	0	0	.	.	0	0	.	0	0	0
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	12	Male	No	1	0	.	0	0	0	1	1	0	0	.	0	0	0
329.001.00122	Biologic Mother	53	Female	No	0	0	0	0	.	.	1	.	0	0	0	0	0	0
	Sibling #6	16	Male	No	0	0	0	0	.	.	.	.	0	0	0	0	0	0
	Sibling #7	15	Male	No	0	0	0	0	1	1	1	1	0	0	0	0	0	0
	Biologic Father	58	Male	No	0	0	0	0	.	.	1	.	0	0	0	0	0	0
	Sibling #1	26	Female	No	0	0	0	0	.	.	.	.	0	0	0	0	0	0
	Sibling #2	23	Female	No	0	0	0	0	.	.	1	1	0	0	0	0	0	0
	Sibling #3	22	Female	No	0	0	0	0	.	.	.	.	0	0	0	0	0	0
	Sibling #4	20	Male	No	0	0	0	0	.	.	.	.	0	0	0	0	0	0
	Sibling #5	20	Female	No	0	0	0	0	.	.	.	.	0	0	0	0	0	0
329.002.00050	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	49	Male	No	0	0	0	0	0	0	0	0	.	0	0	0	0	0
	Sibling #1	19	Male	No	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Male	No	0	0	0	0	0	0	0	0	.	0	0	0	0	0
329.002.00056	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	41	Male	No	0	.	.	.	.	0	0	.	0	.	0	.	.	0
	Sibling #1	18	Female	No	0	.	1	1	1	0	0	.	0	.	0	.	1	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.002.00056	Sibling #2	10	Male	No	0	.	1	1	.	0	0	.	0	.	0	.	1	0
329.002.00057	Biologic Mother	33	Female	No	1	1	0	0	1	1	1	1	1	0	1	0	0	0
	Biologic Father	36	Male	No	.	.	0	0	.	.	.	.	.	0	.	0	0	0
	Sibling #1	15	Female	No	.	.	0	0	.	.	1	.	1	0	1	0	0	0
	Sibling #2	14	Female	No	.	.	0	0	.	.	.	.	.	0	.	0	0	0
	Sibling #3	12	Male	No	.	.	0	0	.	.	.	.	.	0	.	0	0	0
	Sibling #4	.			.	.	0	0	.	.	.	.	.	0	.	0	0	0
329.002.00098	Biologic Mother	43	Female	No	0	0	1	1	1	1	0	0	1	1	0	0	1	0
	Biologic Father	45	Male	No	0	0	.	.	.	.	0	0	.	.	0	0	.	0
	Sibling #1	16	Female	No	0	0	.	.	.	.	0	0	.	.	0	0	.	0
	Sibling #2	13	Female	No	0	0	.	.	.	.	0	0	1	.	0	0	.	0
	Sibling #3	9	Male	No	0	0	.	.	.	.	0	0	.	.	0	0	.	0
329.002.00100		.			.	.	0	0	0	.	0	0	0	0	0	0	0	0
	Biologic Mother	36	Female	No	.	.	0	0	0	.	0	0	0	0	0	0	0	0
	Biologic Father	35	Male	No	.	.	0	0	0	.	0	0	0	0	0	0	0	0
	Sibling #1	15	Male	No	1	1	0	0	0	.	0	0	0	0	0	0	0	0
	Sibling #2	9	Female	No	.	.	0	0	0	.	0	0	0	0	0	0	0	0
329.002.00103	Biologic Mother	39	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	0	.
	Biologic Father	38	Male	No	.	0	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Female	No	1	0	0	.	0	.	0	.	0	.	0	.	0	.
329.002.00104	Biologic Mother	41	Female	No	.	.	1	1	1	1	1	1	1	0	0	.	1	1
	Biologic Father	46	Male	No	.	.	.	.	.	.	1	.	.	0	0	.	.	.
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	0	0	.	.	.
	Sibling #2	15	Female	No	1	1	.	.	.	.	1	1	.	0	0	.	.	.
	Sibling #3	13	Male	No	.	.	.	.	.	.	.	1	.	0	0	.	.	.
329.002.00243	Biologic Mother	39	Female	No	0	.	0	.	0	.	1	1	1	.	1	1	1	1
	Biologic Father	44	Male	No	0	.	0	.	0	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	0	.	0	.	0	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	0	.	0	.	0	.	.	.	.	1	.	.	.	.
	Sibling #3	15	Female	No	0	.	0	.	0	.	.	.	.	.	.	.	.	.
329.002.00244	Biologic Mother	40	Female	No	0	0	1	0	0	0	1	1	1	1	0	0	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.002.00244	Sibling #1	17	Female	No	0	0	.	0	0	0	.	.	.	.	0	0	0	0
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00321	Biologic Mother	39	Female	No	0	.	1	.	.	0	1	0	0	.	0	.	0	.
	Biologic Father	37	Male	No	0	.	.	.	.	0	.	0	0	.	0	.	0	.
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	0	.	.	.	.	0	.	0	0	.	0	.	0	.
	Sibling #3	14	Male	No	0	.	1	1	1	0	.	0	0	.	0	.	0	.
329.002.00322	Biologic Mother	34	Female	No	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	56	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Don't	No	0	0	.	.	.	.	1	.	.	.	.	.	.	.
	Sibling #2	14	Don't	No	0	0	.	.	.	.	1	.	.	.	.	.	.	.
	Sibling #3	10	Don't	No	0	0	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	8	Don't	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	6	Don't	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00073	Biologic Mother	39	Female	No	.	0	.	.	1	1	1	0	.	.	1	1	.	0
	Biologic Father	41	Male	No	1	0	.	.	.	.	1	0	.	.	.	.	1	0
	Sibling #1	19	Female	No	.	0	1	1	.	.	.	0	.	.	.	.	.	0
	Sibling #2	17	Female	No	1	0	.	.	.	.	.	0	.	.	.	.	.	0
	Sibling #3	16	Female	No	.	0	1	1	1	1	1	0	1	1	.	.	.	0
	Sibling #4	11	Male	No	.	0	.	.	.	.	.	0	.	.	.	.	1	0
329.003.00076	Biologic Mother	35	Female	No	.	0	0	0	0	0	1	0	.	0	0	0	0	0
	Biologic Father	45	Male	No	.	0	0	0	0	0	.	0	.	0	0	0	0	0
	Sibling #1	16	Female	No	1	0	0	0	0	0	1	0	1	0	0	0	0	0
329.003.00079		.			.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Mother	.	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	.	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	.	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00088	Biologic Mother	46	Female	No	0	0	0	0	1	1	1	0	0	0	1	.	.	0
	Biologic Father	50	Male	No	0	0	0	0	.	.	.	0	0	0	.	.	.	0
	Sibling #1	24	Female	No	0	0	0	0	1	1	.	0	0	0	.	1	.	0
	Sibling #2	21	Female	No	0	0	0	0	1	1	1	0	0	0	1	.	1	0
	Sibling #3	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.003.00090	Biologic Mother	44	Female	No	0	0	0	0	0	0	.	0	0	0	0	0	9	0
	Biologic Father	51	Male	No	0	0	0	0	0	0	1	0	0	0	0	0	9	0
	Sibling #1	18	Male	No	0	0	0	0	0	0	.	0	0	0	0	0	9	0
	Sibling #2	16	Male	No	0	0	0	0	0	0	.	0	0	0	0	0	9	0
	Sibling #3	14	Female	No	0	0	0	0	0	0	.	0	0	0	0	0	9	0
329.003.00092	Biologic Mother	42	Female	No	.	.	1	1	1	0	0	.	0	.	1	1	0	.
	Biologic Father	43	Male	No	.	.	.	.	.	0	0	.	0	.	.	.	0	.
	Sibling #1	16	Female	No	1	1	1	1	.	0	0	.	0	.	1	1	0	.
	Sibling #2	12	Female	No	.	.	.	.	.	0	0	.	0	.	1	1	0	.
329.003.00093	Biologic Mother	50	Female	No	.	.	1	0	.	.	0	.	0	.	0	.	0	0
	Biologic Father	53	Male	Yes	.	.	.	0	.	.	0	.	0	.	0	.	0	0
	Sibling #1	21	Male	No	.	.	.	0	.	.	0	.	0	.	0	.	0	0
	Sibling #2	17	Female	No	1	1	1	0	1	1	0	1	0	.	0	.	0	0
329.003.00247	Biologic Mother	41	Female	No	9	9	9	9	9	9	9	9	9	9	.	0	9	9
	Biologic Father	44	Male	No	9	9	9	9	9	9	9	9	9	9	.	0	9	9
	Sibling #1	16	Male	No	9	9	9	9	9	9	9	9	9	9	1	0	9	9
	Sibling #2	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00249	Biologic Mother	46	Female	No	9	9	9	9	9	9	.	9	0	0	0	0	0	0
	Biologic Father	52	Male	No	9	9	9	9	9	9	1	9	0	0	0	0	0	0
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00289		.			0	0	.	.	.	.	.	1	.	.	.	.	.	.
	Biologic Mother	41	Female	No	0	0	1	1	1	1	1	.	1	1	1	1	1	1
	Biologic Father	45	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	1	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00290	Biologic Mother	37	Female	No	1	0	0	0	.	0	0	0	0	0	0	0	.	0
	Biologic Father	48	Male	No	1	0	0	0	.	0	0	0	0	0	0	0	.	0
	Sibling #1	3	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Male	No	.	0	0	0	.	0	0	0	0	0	0	0	1	0
	Sibling #3	10	Male	No	1	0	0	0	.	0	0	0	0	0	0	0	.	0
	Sibling #4	17	Male	No	1	0	0	0	1	0	0	0	0	0	0	0	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.003.00314	Biologic Mother	39	Female	No	0	0	0	0	0	0	.	0	0	0	0	0	0	0
	Biologic Father	36	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	Sibling #2	12	Female	No	0	0	0	0	0	0	.	0	0	0	0	0	0	0
329.003.00317		.			0	0	0	0	0	0	.	.	0	0	.	0	.	0
	Biologic Mother	50	Female	No	0	0	0	0	0	0	1	.	0	0	1	0	1	0
	Biologic Father	50	Male	No	0	0	0	0	0	0	.	.	0	0	.	0	.	0
	Sibling #1	17	Don't	No	0	0	0	0	0	0	.	.	0	0	.	0	.	0
	Sibling #2	16	Female	No	0	0	0	0	0	0	.	1	0	0	.	0	1	0
329.004.00013	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00014	Biologic Mother	52	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00211	Biologic Mother	49	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #2	18	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
329.004.00215	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00003	Biologic Mother	30	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Female	No	0	0	0	0	0	9	9	1	0	0	0	0	0	0
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	7	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	5	Male	No	0	0	0	0	0	9	9	.	0	0	0	0	0	0
	Sibling #5	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00006	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.005.00006	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00007	Biologic Mother	41	Female	No	.	.	0	0	0	0	.	0	0	0	1	1	.	.
	Biologic Father	44	Male	No	.	.	0	0	0	0	.	0	0	0	.	.	.	.
	Sibling #1	20	Female	No	1	1	0	0	0	0	.	0	0	0	.	.	.	.
	Sibling #2	15	Female	No	.	.	0	0	0	0	1	0	0	0	.	.	1	1
329.005.00009	Biologic Mother	47	Female	No	0	0	.	0	1	0	1	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	.	0	1	0	.	0	0	0	0	0	0	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	0	1	0	1	0	1	0	0	0	0	0	0	0
	Sibling #3	5	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00117	Biologic Mother	47	Female	No	.	0	.	.	.	.	.	.	.	.	1	1	1	0
	Biologic Father	49	Male	No	.	0	1	1	1	1	1	1	1	1	1	1	1	0
	Sibling #1	22	Female	No	.	0	.	.	.	.	.	.	.	.	.	.	.	0
	Sibling #2	16	Female	No	1	0	.	.	1	.	.	.	.	.	.	.	1	0
	Sibling #3	12	Male	No	.	0	.	.	.	.	.	.	.	.	.	.	1	0
329.005.00118	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	47	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	17	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00153	Biologic Mother	44	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	Biologic Father	51	Male	No	0	0	0	0	0	0	0	0	0	0	.	0	0	0
	Sibling #1	18	Female	No	0	0	0	0	0	0	0	0	0	0	.	0	0	0
329.005.00255	Biologic Mother	47	Female	No	.	0	0	0	0	0	0	0	1	1	1	1	0	0
	Biologic Father	48	Male	No	.	0	0	0	0	0	0	0	.	.	.	.	0	0
	Sibling #1	17	Male	No	.	0	0	0	0	0	0	0	.	.	.	.	0	0
	Sibling #2	15	Female	No	1	0	0	0	0	0	0	0	.	.	.	.	0	0
329.005.00256	Biologic Mother	55	Female	No	0	0	1	1	1	1	1	1	1	1	0	0	0	0
	Biologic Father	52	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	24	Female	No	0	0	.	.	.	.	.	.	.	.	0	0	0	0
	Sibling #2	23	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.005.00256	Sibling #4	16	Female	No	0	0	.	.	.	.	.	.	.	.	0	0	0	0
329.005.00295	Biologic Mother	31	Female	No	0	0	0	0	0	0	0	0	.	0	.	0	0	0
	Biologic Father	36	Male	No	0	0	0	0	0	0	0	0	1	0	1	0	0	0
	Sibling #1	13	Female	No	0	0	0	0	0	0	0	0	.	0	.	0	0	0
329.005.00297	Biologic Mother	46	Female	No	0	0	1	1	1	1	1	0	1	1	0	0	1	1
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Male	No	0	0	.	.	.	.	1	0	.	.	0	0	1	.
329.005.00332	Biologic Mother	50	Female	No	1	0	1	1	1	0	0	0	1	1	1	1	.	0
	Biologic Father	54	Male	No	.	0	.	.	.	0	0	0	.	.	.	.	.	0
	Sibling #1	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	21	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	.	0	.	.	.	0	0	0	.	.	.	.	1	0
329.005.00335	Biologic Mother	37	Female	No	.	0	1	1	0	0	1	0	0	0	0	0	1	0
	Biologic Father	39	Male	No	.	0	.	.	0	0	.	0	0	0	0	0	.	0
	Sibling #1	15	Female	No	1	0	.	.	0	0	.	0	0	0	0	0	.	0
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	6	Female	No	.	0	.	.	0	0	1	0	0	0	0	0	.	0
329.006.00040	Biologic Mother	46	Female	No	0	.	.	.	0	.	0	.	.	.	.	0	.	.
	Biologic Father	66	Male	No	0	.	.	.	0	.	0	.	.	.	.	0	.	.
	Sibling #1	28	Male	No	0	.	.	.	0	.	0	.	.	.	.	0	.	.
	Sibling #2	18	Female	No	0	.	1	1	0	.	0	.	1	1	1	0	1	1
329.006.00041	Biologic Mother	44	Female	No	.	0	.	.	.	.	.	.	9	.	.	.	.	0
	Biologic Father	50	Male	No	1	0	1	1	1	1	1	1	9	.	1	1	1	0
	Sibling #1	21	Male	No	1	0	.	.	.	.	.	.	9	.	.	.	.	0
	Sibling #2	18	Male	No	.	0	.	.	.	.	1	1	9	.	.	.	1	0
329.007.00139	Biologic Mother	38	Female	No	0	0	1	1	1	1	1	.	1	1	0	0	0	0
	Biologic Father	36	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	.	.	.	.	.	1	.	.	0	0	0	0
329.007.00143	Biologic Mother	28	Female	No	.	0	.	0	0	.	0	.	.	.	0	.	.	.
	Biologic Father	.	Male	Unknown	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Female	No	1	0	1	0	0	.	0	.	.	1	0	.	1	1

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.007.00143	Sibling #2	.			.	0	.	0	0	.	0	.	1	.	0	.	.	.
329.007.00146	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	0	.	.	0	0	.
	Biologic Father	39	Male	No	0	.	0	.	0	.	0	.	0	.	.	0	0	.
	Sibling #1	15	Female	No	0	.	0	.	0	.	0	.	0	.	1	0	0	.
329.007.00269	Biologic Mother	45	Female	No	0	.	1	0	1	0	1	0	0	.	1	1	.	0
	Biologic Father	60	Male	Yes	0	.	.	0	.	0	.	0	0	.	.	.	1	0
	Sibling #1	15	Male	No	0	.	.	0	.	0	.	0	0	.	1	1	.	0
	Sibling #2	12	Female	No	0	.	.	0	.	0	.	0	0	.	1	.	.	0
329.007.00270	Biologic Mother	34	Female	No	.	0	0	.	0	.	1	1	.	0	0	.	1	0
	Biologic Father	35	Male	No	.	0	0	.	0	.	.	.	.	0	0	.	.	0
	Sibling #1	15	Male	No	1	0	0	.	0	.	1	.	.	0	0	.	.	0
	Sibling #2	10	Male	No	.	0	0	.	0	.	.	.	1	0	0	.	.	0
	Sibling #3	8	Male	No	.	0	0	.	0	.	.	.	.	0	0	.	.	0
	Sibling #4	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00307	Biologic Mother	42	Female	No	.	0	0	.	1	0	1	0	0	.	0	.	0	.
	Biologic Father	43	Male	No	.	0	0	.	.	0	.	0	0	.	0	.	0	.
	Sibling #1	15	Female	No	1	0	0	.	.	0	.	0	0	.	0	.	0	.
	Sibling #2	14	Female	No	.	0	0	.	.	0	.	0	0	.	0	.	0	.
329.007.00308	Biologic Mother	45	Female	No	0	.	0	.	0	.	1	1	0	.	0	.	0	.
	Biologic Father	43	Male	No	0	.	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	0	.	0	.	0	.	.	.	0	.	0	.	0	.
329.008.00159	Biologic Mother	47	Female	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Biologic Father	49	Male	No	0	0	1	1	1	1	1	1	0	0	0	0	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Sibling #3	16	Female	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
329.008.00161	Biologic Mother	44	Female	No	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	Biologic Father	45	Male	No	0	0	0	0	0	0	.	0	0	0	0	0	0	0
	Sibling #1	4	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	4	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.008.00187	Biologic Mother	47	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #1	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00192	Biologic Mother	35	Female	No	0	0	1	1	1	1	0	0	0	0	0	0	0	0
	Biologic Father	40	Male	No	0	0	.	.	.	.	0	0	0	0	0	0	0	0
	Sibling #1	5	Female	No	0	0	.	.	.	.	0	0	0	0	0	0	0	0
329.008.00272	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	62	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00273	Biologic Mother	42	Female	No	0	0	1	0	1	1	1	1	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	.	0	.	.	.	.	0	0	0	0	0	0
	Sibling #1	15	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00127	Biologic Mother	31	Female	No	0	0	.	.	.	.	.	.	0	.	0	.	1	.
	Biologic Father	41	Male	No	0	0	.	.	.	.	.	.	0	.	0	.	.	.
	Sibling #1	12	Female	No	0	0	1	1	1	1	1	1	0	.	0	.	1	1
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00132	Biologic Mother	30	Female	No	0	.	.	.	0	.	1	.	0	.	0	.	.	0
	Biologic Father	31	Male	No	0	.	1	1	0	.	1	1	0	.	0	.	1	0
	Sibling #1	13	Male	No	0	.	1	.	0	.	1	1	0	.	0	.	.	0
	Sibling #2	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00134	Biologic Mother	38	Female	No	0	.	1	1	1	1	1	.	0	.	0	.	0	.
	Biologic Father	31	Male	Yes	0	.	.	.	.	.	.	.	0	.	0	.	0	.
	Sibling #1	15	Female	No	0	.	.	.	.	.	1	1	0	.	0	.	0	.
	Sibling #2	.			0	.	.	.	.	.	.	.	0	.	0	.	0	.
329.009.00137	Biologic Mother	34	Female	No	0	.	0	.	1	0	0	.	0	.	0	.	0	.
	Biologic Father	41	Male	No	0	.	0	.	.	0	0	.	0	.	0	.	0	.
	Sibling #1	20	Female	No	0	.	0	.	.	0	0	.	0	.	0	.	0	.
	Sibling #2	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	0	.	0	.	.	0	0	.	0	.	0	.	0	.
	Sibling #4	12	Female	No	0	.	0	.	.	0	0	.	0	.	0	.	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.009.00171	Biologic Mother	38	Female	No	9	9	9	9	9	9	1	9	.	9	9	9	.	0
	Biologic Father	41	Male	No	9	9	9	9	9	9	.	9	.	9	9	9	.	0
	Sibling #1	23	Male	No	9	9	9	9	9	9	.	9	.	9	9	9	.	0
	Sibling #2	16	Female	No	9	9	9	9	9	9	1	9	1	9	9	9	1	0
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	12	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	4	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00172	Biologic Mother	43	Female	No	0	.	0	.	.	0	1	0	0	.	0	.	1	0
	Biologic Father	45	Male	No	0	.	0	.	1	0	1	0	0	.	0	.	.	0
	Sibling #1	23	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	19	Female	No	0	.	0	.	.	0	.	0	0	.	0	.	.	0
	Sibling #3	13	Female	No	0	.	0	.	1	0	.	0	0	.	0	.	.	0
329.009.00194	Biologic Mother	36	Female	No	1	9	9	9	9	9	1	0	9	.	9	9	9	9
	Biologic Father	33	Male	No	.	9	9	9	9	9	.	0	9	.	9	9	9	9
	Sibling #1	12	Male	No	.	9	9	9	9	9	.	0	9	.	9	9	9	9
	Sibling #2	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	3	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00195	Biologic Mother	39	Female	No	.	.	.	.	.	.	.	.	0	.	0	.	.	.
	Biologic Father	40	Male	No	1	1	.	.	.	.	1	1	0	.	0	.	1	1
	Sibling #1	16	Female	No	.	.	.	.	.	.	.	.	0	.	0	.	.	.
	Sibling #2	14	Female	No	1	.	1	1	1	1	1	1	0	.	0	.	.	.
	Sibling #3	12	Male	No	.	.	.	.	.	.	.	.	0	.	0	.	.	.
329.009.00199	Biologic Mother	49	Female	No	.	.	0	0	0	0	.	0	0	0	0	0	0	0
	Biologic Father	56	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Female	No	1	1	0	0	0	0	1	0	0	0	0	0	0	0
	Sibling #2	14	Female	No	.	.	0	0	0	0	.	0	0	0	0	0	0	0
	Sibling #3	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00203	Biologic Mother	36	Female	No	0	.	0	.	1	1	1	1	1	1	0	.	1	0
	Biologic Father	38	Male	No	0	.	0	.	.	.	.	.	.	.	0	.	.	0
	Sibling #1	12	Female	Yes	0	.	0	.	.	.	1	.	.	.	0	.	1	0
	Sibling #2	5	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00236	Biologic Mother	45	Female	No	.	9	.	.	1	1	1	1	0	0	1	1	0	0
	Biologic Father	44	Male	No	.	9	.	.	.	.	.	.	0	0	.	.	0	0
	Sibling #1	20	Male	No	.	9	.	.	.	.	.	.	0	0	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.009.00236	Sibling #2	16	Female	No	1	9	1	1	1	1	.	.	0	0	.	.	0	0
	Sibling #3	13	Female	No	.	9	.	.	.	.	.	.	0	0	.	.	0	0
329.009.00262	Biologic Mother	38	Female	No	0	0	9	0	1	0	.	.	.	.	0	0	0	0
	Biologic Father	43	Male	No	0	0	9	0	.	0	1	1	1	1	0	0	0	0
	Sibling #1	13	Male	No	0	0	9	0	1	0	1	.	.	.	0	0	0	0
	Sibling #2	11	Male	No	0	0	9	0	1	0	.	.	.	.	0	0	0	0
329.009.00264	Biologic Mother	37	Female	No	0	0	0	0	.	.	.	0	0	0	.	0	.	.
	Biologic Father	40	Male	No	0	0	0	0	1	1	1	0	0	0	.	0	1	1
	Sibling #1	14	Female	No	0	0	0	0	1	1	1	0	0	0	1	0	1	1
329.009.00301	Biologic Mother	39	Female	No	0	.	.	.	0	.	1	0	0	.	0	.	0	.
	Biologic Father	39	Male	No	0	.	.	.	0	.	.	0	0	.	0	.	0	.
	Sibling #1	17	Male	No	0	.	.	.	0	.	1	0	0	.	0	.	0	.
	Sibling #2	10	Male	No	0	.	1	1	0	.	.	0	0	.	0	.	0	.
	Sibling #3	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00305	Biologic Mother	44	Female	No	.	0	0	.	0	.	1	1	0	.	0	.	0	.
	Biologic Father	45	Male	No	.	0	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #1	17	Female	No	.	0	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #2	14	Male	No	1	0	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #3	12	Female	No	.	0	0	.	0	.	.	.	0	.	0	.	0	.
329.009.00325	Biologic Mother	33	Female	No	.	.	.	.	.	.	.	.	.	0	.	0	0	0
	Biologic Father	38	Male	No	.	.	.	.	.	.	.	.	.	0	.	0	0	0
	Sibling #1	15	Female	No	1	1	1	1	1	1	1	1	1	0	1	0	0	0
329.009.00326	Biologic Mother	31	Female	No	.	0	1	1	0	0	.	0	0	0	0	0	.	0
	Biologic Father	34	Male	No	.	0	.	.	0	0	.	0	0	0	0	0	.	0
	Sibling #1	13	Male	No	1	0	.	.	0	0	1	0	0	0	0	0	1	0
	Sibling #2	9	Male	No	1	0	.	.	0	0	.	0	0	0	0	0	.	0
329.010.00279	Biologic Mother	37	Female	No	0	.	0	.	0	0	0	.	0	.	0	.	0	.
	Biologic Father	48	Male	No	0	.	0	.	0	0	0	.	0	.	0	.	0	.
	Sibling #1	13	Female	No	0	.	0	.	0	0	0	.	0	.	0	.	0	.
	Sibling #2	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	1	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.010.00281	Biologic Mother	43	Female	No	0	.	.	0	0	.	0	.	0	.	.	.	0	.
	Biologic Father	48	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	.	.	0	0	.	0	.	0	.	.	.	0	.
	Sibling #2	16	Male	No	0	.	1	0	0	.	0	.	0	.	1	1	0	.
	Sibling #3	14	Female	No	0	.	.	0	0	.	0	.	0	.	.	.	0	.
	Sibling #4	13	Male	No	0	.	.	0	0	.	0	.	0	.	.	.	0	.
329.011.00163	Biologic Mother	42	Female	No	.	0	.	.	.	0	1	.	0	0	.	.	1	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	1	0	1	.	1	0	1	1	0	0	1	1	.	0
	Sibling #2	9	Male	No	1	0	1	1	.	0	.	.	0	0	.	.	.	0
329.011.00208	Biologic Mother	51	Female	No	1	0	1	1	1	1	1	0	1	1	1	1	.	.
	Biologic Father	44	Male	No	.	0	.	.	.	.	.	0	.	.	.	.	1	1
	Sibling #1	13	Male	No	.	0	.	.	.	.	1	0	.	.	.	.	.	.
329.011.00209	Biologic Mother	41	Female	No	0	0	0	0	0	0	.	0	1	0	0	0	1	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Male	No	0	0	0	0	0	0	1	0	.	0	0	0	1	0
	Sibling #2	10	Female	No	0	0	0	0	0	0	.	0	1	0	0	0	.	0
329.011.00284	Biologic Mother	46	Female	No	0	0	.	0	.	0	.	0	0	0	.	.	.	0
	Biologic Father	47	Male	No	0	0	.	0	1	0	1	0	0	0	.	.	.	0
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	0	0	1	0	.	0	.	0	0	0	1	1	1	0
	Sibling #3	10	Male	No	0	0	.	0	.	0	.	0	0	0	.	.	.	0
329.011.00286	Biologic Mother	41	Female	No	0	0	0	0	0	0	1	0	.	0	1	0	.	0
	Biologic Father	44	Male	No	0	0	0	0	0	0	.	0	.	0	1	0	.	0
	Sibling #1	16	Female	No	0	0	0	0	0	0	.	0	.	0	1	0	.	0
	Sibling #2	15	Female	No	0	0	0	0	0	0	.	0	1	0	.	0	1	0
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00026	Biologic Mother	37	Female	No	.	0	0	.	0	.	0	.	1	0	1	1	0	.
	Biologic Father	36	Male	No	.	0	0	.	0	.	0	.	.	0	1	.	0	.
	Sibling #1	15	Female	No	.	0	0	.	0	.	0	.	.	0	.	.	0	.
	Sibling #2	14	Male	No	1	0	0	.	0	.	0	.	.	0	.	.	0	.
329.012.00219	Biologic Mother	42	Female	No	0	0	1	0	0	0	0	0	0	0	0	0	.	0
	Biologic Father	42	Male	No	0	0	1	0	0	0	0	0	0	0	0	0	.	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.012.00219	Sibling #1	16	Female	No	0	0	1	0	0	0	0	0	0	0	0	0	1	0
	Sibling #2	14	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	.	0
329.012.00221	Biologic Mother	44	Female	No	1	0	.	.	0	0	.	0	0	0	1	0	.	0
	Biologic Father	44	Male	No	.	0	.	.	0	0	1	0	0	0	.	0	.	0
	Sibling #1	17	Male	No	1	0	1	1	0	0	.	0	0	0	.	0	1	0
	Sibling #2	15	Male	No	.	0	.	.	0	0	.	0	0	0	.	0	1	0
	Sibling #3	14	Female	No	.	0	.	.	0	0	.	0	0	0	.	0	.	0
329.012.00223	Biologic Mother	32	Female	No	0	.	0	.	.	0	0	.	0	.	0	.	0	.
	Biologic Father	34	Male	No	0	.	0	.	.	0	0	.	0	.	0	.	0	.
	Sibling #1	13	Female	No	0	.	0	.	1	0	0	.	0	.	0	.	0	.
	Sibling #2	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00227	Biologic Mother	49	Female	No	.	0	0	0	0	0	0	0	0	0	0	0	.	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Male	No	1	0	0	0	0	0	0	0	0	0	0	0	1	0
	Sibling #2	22	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	.	0
	Sibling #3	16	Male	No	1	0	0	0	0	0	0	0	0	0	0	0	.	0
329.012.00230	Biologic Mother	36	Female	No	0	0	1	1	1	1	1	0	1	1	.	.	.	.
	Biologic Father	53	Male	Yes	0	0	.	.	.	.	1	0	.	.	1	1	.	.
	Sibling #1	15	Male	No	0	0	.	.	.	.	1	0	.	.	1	1	1	1
	Sibling #2	13	Male	No	0	0	.	.	.	.	.	0	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.001.00062	Biologic Mother	38	Female	No	1	0	1	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	37	Male	No	.	0	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Female	No	.	0	.	.	.	.	.	.	.	.	1	1	1	.
	Sibling #2	16	Female	No	1	0	1	.	1	1	.	.	1	.	.	.	1	.
	Sibling #3	15	Female	No	.	0	.	.	.	.	1	1	1	.	.	.	1	1
329.001.00064	Biologic Mother	32	Female	No	.	0	0	0	0	0	1	0	1	0	.	.	.	.
	Biologic Father	42	Male	No	.	0	0	0	0	0	.	0	.	0	.	.	1	.
	Sibling #1	13	Male	No	.	0	0	0	0	0	.	0	.	0	.	.	1	1
	Sibling #2	8	Male	No	1	0	0	0	0	0	.	0	.	0	1	1	.	.
329.001.00069	Biologic Mother	49	Female	No	.	.	.	.	.	.	.	.	0	0	.	.	.	0
	Biologic Father	55	Male	No	1	1	1	1	1	1	1	1	0	0	.	.	1	0
	Sibling #1	26	Female	No	.	.	.	.	.	.	1	1	0	0	.	.	.	0
	Sibling #2	24	Male	No	.	.	1	.	.	.	.	.	0	0	.	.	.	0
	Sibling #3	22	Female	No	.	.	.	.	.	.	.	.	0	0	1	1	.	0
	Sibling #4	16	Male	No	.	.	.	.	.	.	.	.	0	0	.	.	1	0
329.001.00071	Biologic Mother	48	Female	No	.	0	1	0	0	0	.	.	0	0	1	1	1	1
	Biologic Father	46	Male	No	.	0	.	0	0	0	1	.	0	0	.	.	.	.
	Sibling #1	18	Male		1	0	.	0	0	0	1	.	0	0	.	.	.	.
	Sibling #2	13	Female		.	0	.	0	0	0	.	.	0	0	1	1	.	.
329.001.00123	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	47	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #1	22	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #2	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
329.001.00207	Biologic Mother	48	Female	No	0	.	0	.	0	.	0	.	0	.	.	0	0	.
	Biologic Father	49	Male	No	0	.	0	.	0	.	0	.	0	.	.	0	0	.
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	0	.	0	.	0	.	0	.	0	.	1	0	0	.
329.002.00049	Biologic Mother	52	Female	No	1	1	0	0	0	0	0	0	0	0	0	0	1	1
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	23	Male	No	.	.	0	0	0	0	0	0	0	0	0	0	1	1
	Sibling #3	20	Male	No	.	.	0	0	0	0	0	0	0	0	0	0	.	.
	Sibling #4	16	Male	No	.	1	0	0	0	0	0	0	0	0	0	0	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.002.00059	Biologic Mother	46	Female	No	0	0	1	1	1	1	1	1	1	1	1	1	1	0
	Biologic Father	50	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	0
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	1	0
329.002.00060	Biologic Mother	47	Female	No	0	.	0	.	0	.	.	0	1	0	1	0	1	0
	Biologic Father	45	Male	No	0	.	0	.	0	.	1	0	.	0	.	0	.	0
	Sibling #1	16	Female	No	0	.	0	.	0	.	.	0	.	0	.	0	.	0
	Sibling #2	14	Female	No	0	.	0	.	0	.	.	0	.	0	.	0	.	0
	Sibling #3	11	Male	No	0	.	0	.	0	.	.	0	1	0	.	0	.	0
329.002.00097	Biologic Mother	43	Female	No	0	0	1	1	1	1	0	0	1	1	0	0	1	0
	Biologic Father	45	Male	No	0	0	.	.	.	.	0	0	.	.	0	0	.	0
	Sibling #1	16	Female	No	0	0	.	.	.	.	0	0	.	.	0	0	.	0
	Sibling #2	13	Female	No	0	0	.	.	.	.	0	0	1	.	0	0	.	0
	Sibling #3	9	Male	No	0	0	.	.	.	.	0	0	.	.	0	0	.	0
329.002.00101	Biologic Mother	48	Female	No	.	0	0	.	0	.	.	1	0	.	0	.	9	.
	Biologic Father	52	Male	No	.	0	0	.	0	.	1	1	0	.	0	.	9	.
	Sibling #1	26	Male	No	1	0	0	.	0	.	.	.	0	.	0	.	9	.
	Sibling #2	28	Female	No	.	0	0	.	0	.	.	.	0	.	0	.	9	.
	Sibling #3	22	Female	No	.	0	0	.	0	.	.	.	0	.	0	.	9	.
	Sibling #4	16	Male	No	.	0	0	.	0	.	1	1	0	.	0	.	9	.
329.002.00107	Biologic Mother	47	Female	No	.	0	.	.	.	.	1	0	1	1	.	.	1	0
	Biologic Father	53	Male	Yes	.	0	.	.	.	.	.	0	.	.	1	1	.	0
	Sibling #1	27	Male	No	.	0	.	.	.	.	.	0	.	.	.	.	.	0
	Sibling #2	20	Male	No	.	0	.	.	.	.	.	0	.	.	.	.	.	0
	Sibling #3	18	Male	No	1	0	1	1	1	1	.	0	1	1	1	.	.	0
	Sibling #4	15	Female	No	.	0	1	.	1	.	.	0	1	1	.	.	.	0
329.002.00241	Biologic Mother	38	Female	No	0	0	0	0	0	.	0	.	0	0	1	1	0	0
	Biologic Father	42	Male	No	0	0	0	0	0	.	0	.	0	0	.	.	0	0
	Sibling #1	15	Male	No	0	0	0	0	0	.	0	.	0	0	1	.	0	0
	Sibling #2	17	Male	No	0	0	0	0	0	.	0	.	0	0	.	.	0	0
329.002.00246	Biologic Mother	34	Female	No	1	1	1	9	9	.	1	1	9	.	9	.	.	0
	Biologic Father	35	Male	No	.	.	.	9	9	.	.	.	9	.	9	.	.	0
	Sibling #1	17	Female	No	.	.	1	9	9	.	1	1	9	.	9	.	1	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.002.00246	Sibling #2	8	Male	No	.	.	.	9	9	.	.	.	9	.	9	.	1	0
	Sibling #3	2	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00320	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	.	0	.	.	.	0	.
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	.	0	.	.	.	0	.
	Sibling #1	16	Male	No	0	0	0	0	0	0	0	.	0	.	.	.	0	.
	Sibling #2	13	Female	No	0	0	0	0	0	0	0	.	0	.	1	1	0	.
	Sibling #3	9	Female	No	0	0	0	0	0	0	0	.	0	.	.	.	0	.
329.002.00323	Biologic Mother	44	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	0	0	0	0	0	0	0	0	1	0	0	0	9	0
	Sibling #2	17	Female	No	0	0	0	0	0	0	0	0	.	0	0	0	9	0
329.003.00074	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	0	0	0	0	0	0	1	0	0	0	0	0	9	9
	Sibling #2	5	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00078		.			.	0	.	0	.	0	.	9	.	0	.	9	9	9
	Biologic Mother	40	Female	No	.	0	1	0	1	0	1	9	1	0	.	9	9	9
	Biologic Father	47	Male	No	.	0	.	0	1	0	.	9	.	0	.	9	9	9
	Sibling #1	17	Female	No	1	0	.	0	.	0	.	9	1	0	1	9	9	9
	Sibling #2	15	Female	No	.	0	.	0	.	0	.	9	.	0	.	9	9	9
	Sibling #3	12	Female	No	.	0	.	0	1	0	.	9	.	0	.	9	9	9
329.003.00080	Biologic Mother	43	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	48	Male	No	0	0	0	0	1	1	.	0	0	0	0	0	.	0
	Sibling #1	16	Female	No	0	0	0	0	.	.	1	0	0	0	0	0	1	0
	Sibling #2	14	Male	No	0	0	0	0	.	.	.	0	0	0	0	0	1	0
329.003.00085	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	1	0	1	1	0	0	1	1	1	1	1	1	1	1
	Sibling #2	14	Female	No	.	0	.	.	0	0	.	.	.	.	.	.	.	.
	Sibling #3	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00086	Biologic Mother	38	Female	No	0	0	0	0	1	1	0	0	0	0	0	0	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	0	0	0	.	.	0	0	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.003.00086	Sibling #2	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00094	Biologic Mother	55	Female	No	0	0	0	0	0	0	0	0	0	0	.	0	.	0
	Biologic Father	55	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	1	0
329.003.00252	Biologic Mother	42	Female	No	1	0	1	0	1	1	1	0	0	0	.	0	1	0
	Biologic Father	45	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	1	0	.	0	1	.	.	0	0	0	1	0	.	0
329.003.00291	Biologic Mother	38	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	35	Male	No	0	0	0	0	0	0	.	9	.	.	.	1	.	.
	Sibling #1	13	Female	No	0	0	0	0	0	0	1	9	1	1	1	.	1	1
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	.			0	0	0	0	0	0	.	9	.	.	.	.	.	.
329.003.00315	Biologic Mother	52	Female	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	52	Male	No	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	16	Female	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00316	Biologic Mother	40	Female	No	1	0	1	.	1	0	1	0	0	0	0	0	.	0
	Biologic Father	38	Male	No	.	0	1	1	.	0	1	0	0	0	0	0	.	0
	Sibling #1	18	Male	No	1	0	.	.	.	0	.	0	0	0	0	0	.	0
	Sibling #2	16	Female	No	.	0	.	.	.	0	.	0	0	0	0	0	1	0
	Sibling #3	10	Female	No	.	0	.	.	.	0	.	0	0	0	0	0	.	0
	Sibling #4	6	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00016	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	22	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.004.00018	Biologic Mother	42	Female	No	0	0	1	.	1	1	1	.	1	1	.	.	.	0
	Biologic Father	49	Male	No	0	0	.	.	.	.	.	.	.	.	.	.	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.004.00018	Sibling #1	17	Female	No	0	0	1	.	1	.	1	.	.	.	1	1	.	0
	Sibling #2	14	Male	No	0	0	1	1	1	1	1	1	1	1	1	.	1	0
329.004.00020	Biologic Mother	38	Female	No	0	.	1	0	1	1	1	0	0	.	0	.	0	.
	Biologic Father	45	Male	No	0	.	.	0	.	.	.	0	0	.	0	.	0	.
	Sibling #1	18	Male	No	0	.	.	0	.	.	.	0	0	.	0	.	0	.
	Sibling #2	14	Female	No	0	.	.	0	.	.	.	0	0	.	0	.	0	.
329.004.00213	Biologic Mother	45	Female	No	0	0	.	0	.	0	0	0	0	0	.	.	0	.
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	1	0	1	0	0	0	0	0	1	.	0	.
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00001	Biologic Mother	41	Female	No	.	.	.	.	.	.	1	0	0	0	1	0	0	9
	Biologic Father	45	Male	No	1	1	.	.	.	.	.	0	0	0	.	0	0	9
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	.	.	.	.	.	.	.	0	0	0	.	0	0	9
	Sibling #3	16	Female	No	.	.	1	1	1	1	1	0	0	0	.	0	0	9
329.005.00005	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00010	Biologic Mother	45	Female	No	0	0	.	0	0	0	.	.	.	0	0	0	0	0
	Biologic Father	47	Male	No	0	0	1	0	0	0	1	1	1	0	0	0	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Female	No	0	0	.	0	0	0	.	.	.	0	0	0	0	0
	Sibling #5	15	Female	No	0	0	.	0	0	0	.	.	.	0	0	0	0	0
	Child #1	12	Male	No	0	0	.	0	0	0	.	.	.	0	0	0	0	0
329.005.00012	Biologic Mother	41	Female	No	0	0	0	0	1	0	1	0	0	0	0	0	0	0
	Biologic Father	44	Male	No	0	0	0	0	1	0	.	0	0	0	0	0	0	0
	Sibling #1	18	Male	No	0	0	0	0	.	0	.	0	0	0	0	0	0	0
	Sibling #2	14	Female	No	0	0	0	0	.	0	.	0	0	0	0	0	0	0
329.005.00111	Biologic Mother	36	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.005.00111	Biologic Father	40	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00114	Biologic Mother	47	Female		0	0	1	1	1	1	1	1	0	0	0	0	0	0
	Biologic Father	55	Male		0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Sibling #1	22	Male	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Sibling #2	16	Male	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Sibling #3	25	Female	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
329.005.00115	Biologic Mother	41	Female	Yes	0	0	0	0	.	0	.	0	.	0	0	0	.	0
	Biologic Father	0	Male	Yes	0	0	0	0	.	0	.	0	.	0	0	0	.	0
	Sibling #1	25	Male	No	0	0	0	0	.	0	.	0	.	0	0	0	.	0
	Sibling #2	18	Female	No	0	0	0	0	1	0	1	0	1	0	0	0	1	0
	Sibling #3	17	Male	No	0	0	0	0	.	0	.	0	.	0	0	0	.	0
329.005.00120	Biologic Mother	36	Female	No	0	0	1	0	1	0	1	1	1	1	.	1	0	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	0	0	.	0	.	0	1	.	.	.	.	.	0	0
	Sibling #2	9	Male	No	0	0	.	0	.	0	.	.	.	.	1	.	0	0
329.005.00253	Biologic Mother	44	Female	No	1	1	1	0	0	0	1	0	0	0	1	1	1	0
	Biologic Father	44	Male	No	.	.	.	0	0	0	1	0	0	0	1	1	.	0
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	1	.	.	0	0	0	.	0	0	0	.	.	.	0
	Sibling #3	10	Male	No	.	.	.	0	0	0	.	0	0	0	.	.	.	0
329.005.00254	Biologic Mother	41	Female	No	.	0	1	1	1	1	1	1	.	.	.	.	.	.
	Biologic Father	45	Male	No	.	0	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	.	0	.	.	.	.	.	.	.	.	.	.	1	1
	Sibling #2	12	Female	No	.	0	1	1	.	.	.	.	1	1	1	1	.	.
	Sibling #3	9	Male	No	1	0	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00293	Biologic Mother	42	Female	No	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	41	Male	No	.	.	.	.	.	.	1	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	.	.	.	.	.	.	1	.	1	1	1	1	1	1
	Sibling #2	14	Female	No	1	.	.	.	.	.	.	.	1	1	1	1	1	.
	Sibling #3	7	Male	No	1	.	1	.	.	.	.	.	.	.	1	1	.	.
	Sibling #4	12	Male	No	.	.	.	.	1	.	.	.	.	.	1	1	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.005.00293	Child #1	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00298	Biologic Mother	42	Female	No	1	0	1	1	1	.	1	1	1	1	0	0	1	1
	Biologic Father	44	Male	No	.	0	.	.	.	.	.	.	.	.	0	0	.	.
	Sibling #1	14	Female	No	1	0	.	.	.	.	.	.	.	.	0	0	.	.
	Sibling #2	13	Female	No	1	0	1	.	1	.	.	.	.	.	0	0	.	.
	Sibling #3	8	Male	No	.	0	.	.	.	.	.	.	.	.	0	0	.	.
	Sibling #4	6	Male	No	.	0	.	.	.	.	.	.	.	.	0	0	.	.
329.005.00331	Biologic Mother	38	Female	No	.	0	1	9	1	0	.	9	9	9	.	.	1	0
	Biologic Father	48	Male	Unknown	.	0	.	9	.	0	.	9	9	9	.	.	.	0
	Sibling #1	15	Female	No	1	0	1	9	.	0	1	9	9	9	1	1	1	0
	Sibling #2	11	Female	No	.	0	.	9	.	0	1	9	9	9	.	.	.	0
329.005.00334	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	44	Male	No	.	0	0	0	0	0	0	0	1	0	1	0	0	0
	Sibling #1	15	Female	No	.	0	0	0	0	0	0	0	.	0	.	0	0	0
	Sibling #2	13	Female	No	1	0	0	0	0	0	0	0	.	0	.	0	0	0
329.006.00037	Biologic Mother	59	Female	No	1	9	.	.	.	.	1	0	1	.	1	.	.	0
	Biologic Father	55	Male	No	1	9	1	.	.	.	.	0	1	1	1	1	.	0
	Sibling #1	39	Male	No	1	9	1	.	1	1	.	0	.	.	.	.	.	0
	Sibling #2	36	Female	No	1	9	1	1	1	1	1	0	.	.	1	.	.	0
	Sibling #3	17	Female	No	1	9	1	1	.	1	.	0	.	.	.	.	1	0
329.006.00042	Biologic Mother	40	Female	No	.	.	0	.	0	.	0	.	0	.	0	.	1	.
	Biologic Father	43	Male	No	.	.	0	.	0	.	0	.	0	.	0	.	1	.
	Sibling #1	18	Male	No	.	.	0	.	0	.	0	.	0	.	0	.	1	1
	Sibling #2	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	1	1	0	.	0	.	0	.	0	.	0	.	.	.
	Sibling #4	7	Female	No	1	.	0	.	0	.	0	.	0	.	0	.	.	.
329.006.00259	Biologic Mother	49	Female	No	0	.	0	.	.	.	0	.	0	.	.	.	0	.
	Biologic Father	53	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	0	.	0	.	.	.	0	.	0	.	.	.	0	.
	Sibling #2	15	Male	No	0	.	0	.	.	.	0	.	0	.	.	.	0	.
	Sibling #3	10	Female	No	0	.	0	.	1	1	0	.	0	.	1	1	0	.
329.007.00141	Biologic Mother	32	Female	No	0	.	1	1	1	1	1	0	0	.	0	.	1	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.007.00141	Biologic Father	32	Male	No	0	.	.	.	.	.	.	0	0	.	0	.	1	0
	Sibling #1	13	Male	No	0	.	1	.	1	.	.	0	0	.	0	.	1	0
	Sibling #2	9	Female	Yes	0	.	.	.	.	.	.	0	0	.	0	.	1	0
329.007.00144	Biologic Mother	28	Female	No	0	.	0	.	0	.	1	1	0	.	0	.	0	.
	Biologic Father	39	Male	No	0	.	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #1	12	Female	No	0	.	0	.	0	.	.	.	0	.	0	.	0	.
329.007.00266	Biologic Mother	33	Female	No	1	1	1	1	0	.	1	1	0	.	0	.	.	0
	Biologic Father	34	Male	No	.	.	.	.	0	.	.	.	0	.	0	.	.	0
	Sibling #1	12	Female	No	1	1	.	.	0	.	1	.	0	.	0	.	1	0
	Sibling #2	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00267	Biologic Mother	46	Female	No	0	.	.	9	0	.	0	.	.	.	0	.	1	0
	Biologic Father	46	Male	No	0	.	.	9	0	.	0	.	.	.	0	.	.	0
	Sibling #1	16	Male	No	0	.	1	9	0	.	0	.	1	1	0	.	1	0
329.007.00311	Biologic Mother	44	Female	No	.	.	0	.	0	.	.	.	0	.	0	.	0	.
	Biologic Father	62	Male	No	.	.	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #1	18	Female	No	1	1	0	.	0	.	.	.	0	.	0	.	0	.
	Sibling #2	15	Male	No	.	.	0	.	0	.	1	1	0	.	0	.	0	.
	Sibling #3	13	Male	No	.	.	0	.	0	.	.	.	0	.	0	.	0	.
329.008.00158		.			0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Biologic Mother	47	Female	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Biologic Father	49	Male	No	0	0	1	1	1	1	1	1	0	0	0	0	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Sibling #3	16	Female	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
	Child #2	.			0	0	.	.	.	.	.	.	0	0	0	0	0	0
329.008.00162	Biologic Mother	46	Female	No	0	0	1	1	1	1	1	1	0	0	0	0	0	0
	Biologic Father	41	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Male	No	0	0	.	.	.	.	.	.	0	0	0	0	0	0
329.008.00191	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.008.00191	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	.			0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.009.00128	Biologic Mother	50	Female	No	0	0	1	0	.	0	1	1	0	0	0	0	0	0
	Biologic Father	49	Male	No	0	0	.	0	.	0	.	.	0	0	0	0	0	0
	Sibling #1	23	Male	No	0	0	.	0	.	0	.	.	0	0	0	0	0	0
	Sibling #2	13	Male	No	0	0	.	0	1	0	1	.	0	0	0	0	0	0
	Sibling #3	10	Female	No	0	0	.	0	.	0	.	.	0	0	0	0	0	0
329.009.00129	Biologic Mother	42	Female	No	1	0	1	1	1	0	1	1	0	.	0	.	1	0
	Biologic Father	47	Male	No	.	0	.	.	.	0	.	.	0	.	0	.	.	0
	Sibling #1	16	Male	No	.	0	.	.	.	0	1	1	0	.	0	.	1	0
	Sibling #2	12	Female	No	.	0	.	.	.	0	1	.	0	.	0	.	.	0
329.009.00135	Biologic Mother	48	Female	No	0	.	.	.	.	0	.	.	0	.	0	.	1	0
	Biologic Father	48	Male	No	0	.	.	.	1	0	.	.	0	.	0	.	.	0
	Sibling #1	17	Female	No	0	.	1	1	.	0	1	1	0	.	0	.	.	0
329.009.00136	Biologic Mother	39	Female	No	0	.	.	.	.	.	.	.	.	.	1	1	.	.
	Sibling #6	15	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #7	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #8	14	Female	No	0	.	.	.	.	.	1	1	.	.	.	.	1	1
	Sibling #9	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	48	Male	No	0	.	1	1	1	1	1	1	1	1	.	.	1	1
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	23	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	18	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	16	Female	No	0	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00169	Biologic Mother	27	Female	No	0	0	0	.	0	.	0	0	0	.	0	.	0	.
	Biologic Father	32	Male	No	0	0	0	.	0	.	0	0	0	.	0	.	0	.
	Sibling #1	13	Male	No	0	0	0	.	0	.	0	0	0	.	0	.	0	.
	Sibling #2	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	5	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00174	Biologic Mother	44	Female	No	0	.	0	.	1	1	1	0	0	.	0	.	0	.
	Biologic Father	48	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.009.00174	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Male	No	0	.	0	.	.	.	.	0	0	.	0	.	0	.
	Sibling #3	15	Female	No	0	.	0	.	.	.	.	0	0	.	0	.	0	.
329.009.00197	Biologic Mother	29	Female	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.
	Biologic Father	31	Male	No	0	.	0	.	0	.	.	0	0	.	0	.	0	.
	Sibling #1	12	Male	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.
	Sibling #2	4	Female	No	0	.	0	.	0	.	.	0	0	.	0	.	0	.
	Sibling #3	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00198	Biologic Mother	34	Female	No	0	.	.	.	.	.	1	1	0	.	0	.	0	.
	Biologic Father	35	Male	No	0	.	.	.	.	.	.	.	0	.	0	.	0	.
	Sibling #1	17	Female	No	0	.	1	1	1	1	1	.	0	.	0	.	0	.
	Sibling #2	15	Female	No	0	.	.	.	.	.	.	1	0	.	0	.	0	.
	Sibling #3	13	Female	No	0	.	.	.	.	.	.	.	0	.	0	.	0	.
329.009.00200	Biologic Mother	49	Female	No	0	.	0	.	.	.	1	.	0	.	.	.	0	.
	Biologic Father	53	Male	No	0	.	0	.	1	1	1	1	0	.	.	.	0	.
	Sibling #1	17	Female	No	0	.	0	.	.	.	1	1	0	.	1	1	0	.
	Sibling #2	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00202	Biologic Mother	40	Female	No	1	.	1	1	1	1	1	0	1	0	.	1	0	0
	Biologic Father	41	Male	No	1	.	.	.	.	.	.	0	.	0	.	.	0	0
	Sibling #1	19	Male	No	1	.	.	.	.	.	.	0	.	0	.	.	0	0
	Sibling #2	15	Female	No	1	.	.	.	.	.	1	0	.	0	1	1	0	0
	Sibling #3	14	Male	No	1	1	.	.	.	.	.	0	.	0	.	.	0	0
329.009.00237	Biologic Mother	43	Female	No	0	0	9	.	0	0	0	0	0	0	0	0	0	0
	Sibling #6	9	Female	No	0	0	9	.	0	0	0	0	0	0	0	0	0	0
	Biologic Father	44	Male	No	0	0	9	.	0	0	0	0	0	0	0	0	0	0
	Sibling #1	21	Male	No	0	0	9	.	0	0	0	0	0	0	0	0	0	0
	Sibling #2	19	Female	No	0	0	9	.	0	0	0	0	0	0	0	0	0	0
	Sibling #3	17	Male	No	0	0	9	.	0	0	0	0	0	0	0	0	0	0
	Sibling #4	12	Male	No	0	0	9	.	0	0	0	0	0	0	0	0	0	0
	Sibling #5	10	Male	No	0	0	9	.	0	0	0	0	0	0	0	0	0	0
329.009.00238	Biologic Mother	42	Female	No	0	0	.	.	0	0	1	1	0	0	.	0	0	0
	Biologic Father	42	Male	No	0	0	1	1	0	0	1	1	0	0	1	0	0	0
	Sibling #1	21	Male	Yes	0	0	.	.	0	0	.	.	0	0	.	0	0	0
	Sibling #2	16	Female	Yes	0	0	.	.	0	0	.	.	0	0	.	0	0	0

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.009.00238	Sibling #3	9	Female	Yes	0	0	.	.	0	0	.	.	0	0	.	0	0	0
329.009.00276	Biologic Mother	30	Female	No	.	0	0	.	0	.	1	0	0	.	0	.	0	.
	Biologic Father	32	Male	No	.	0	0	.	0	.	.	0	0	.	0	.	0	.
	Sibling #1	13	Male	No	1	0	0	.	0	.	.	0	0	.	0	.	0	.
329.009.00302	Biologic Mother	40	Female	No	0	.	0	0	1	0	0	.	0	.	.	.	0	0
	Biologic Father	41	Male	No	0	.	0	0	.	0	0	.	0	.	.	.	0	0
	Sibling #1	17	Male	No	0	.	0	0	.	0	0	.	0	.	1	1	0	0
	Sibling #2	10	Female	No	0	.	0	0	.	0	0	.	0	.	1	1	0	0
329.009.00306	Biologic Mother	28	Female	Yes	0	.	9	.	0	.	0	.	0	0	.	.	1	0
	Biologic Father	.	Male	Unknown	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	.	9	.	0	.	0	.	0	0	1	1	1	0
329.009.00312	Biologic Mother	48	Female	No	0	0	1	1	1	1	1	1	1	1	0	0	0	0
	Biologic Father	55	Male	No	0	0	1	.	1	.	1	1	.	.	0	0	0	0
	Sibling #1	17	Female	No	0	0	.	.	.	.	1	1	.	.	0	0	0	0
329.009.00327	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	1	0
	Biologic Father	42	Male	No	0	0	0	0	0	0	0	0	0	0	.	0	.	0
	Sibling #1	18	Male	No	0	0	0	0	0	0	0	0	0	0	1	0	.	0
	Sibling #2	16	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	.	0
329.009.00330	Biologic Mother	33	Female	No	.	.	0	0	0	0	1	0	0	0	0	0	1	1
	Biologic Father	36	Male	No	.	.	0	0	0	0	.	0	0	0	0	0	.	.
	Sibling #1	14	Female	No	.	.	0	0	0	0	.	0	0	0	0	0	.	.
	Sibling #2	12	Male	No	1	1	0	0	0	0	.	0	0	0	0	0	.	.
	Sibling #3	9	Male	No	.	.	0	0	0	0	.	0	0	0	0	0	.	.
329.010.00183	Biologic Mother	39	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #1	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #3	13	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
329.010.00263	Biologic Mother	40	Female	No	0	0	1	1	1	1	0	0	0	0	.	.	.	.
	Biologic Father	60	Male	No	0	0	.	.	.	.	0	0	0	0	.	.	.	.
	Sibling #1	21	Male	No	0	0	.	.	.	.	0	0	0	0	.	.	.	.
	Sibling #2	18	Male	No	0	0	.	.	.	.	0	0	0	0	1	1	1	1

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.010.00263	Sibling #3	15	Female	No	0	0	.	.	.	.	0	0	0	0	.	.	.	.
329.010.00277	Biologic Mother	35	Female	No	0	.	1	0	0	.	0	.	0	.	1	1	.	0
	Biologic Father	38	Male	No	0	.	.	0	0	.	0	.	0	.	.	.	.	0
	Sibling #1	14	Female	No	0	.	.	0	0	.	0	.	0	.	.	.	1	0
329.010.00282	Biologic Mother	45	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Biologic Father	46	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #1	18	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #2	15	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Sibling #3	12	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.
329.011.00164	Biologic Mother	43	Female	No	0	.	.	0	0	.	1	0	0	.	0	.	0	.
	Biologic Father	43	Male	No	0	.	.	0	0	.	.	0	0	.	0	.	0	.
	Sibling #1	24	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	20	Male	No	0	.	.	0	0	.	.	0	0	.	0	.	0	.
	Sibling #3	18	Male	No	0	.	.	0	0	.	.	0	0	.	0	.	0	.
	Sibling #4	15	Male	No	0	.	1	0	0	.	1	0	0	.	0	.	0	.
329.011.00210	Biologic Mother	32	Female	No	.	0	.	.	.	.	0	0	0	0	1	1	0	0
	Biologic Father	41	Male	No	1	0	.	.	.	.	0	0	0	0	.	.	0	0
	Sibling #1	14	Female	No	.	0	1	1	1	1	0	0	0	0	1	1	0	0
	Sibling #2	10	Male	No	.	0	.	.	1	1	0	0	0	0	1	1	0	0
329.011.00285	Biologic Mother	42	Female	No	0	0	0	0	.	.	.	.	.	9	.	.	.	0
	Biologic Father	44	Male	No	0	0	0	0	.	.	.	.	.	9	.	.	.	0
	Sibling #1	16	Male	No	0	0	0	0	1	1	1	1	1	9	1	1	1	0
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.011.00287	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	4	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00027	Biologic Mother	39	Female	No	0	.	.	.	.	0	.	.	9	.	1	9	0	.
	Biologic Father	38	Male	No	0	.	1	1	.	0	1	1	9	.	.	9	0	.
	Sibling #1	15	Male	No	0	.	1	1	1	0	1	1	9	.	.	9	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part II
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 12	12B	13	13B	14	14B	15	15B	16	16B	17	17B	18	18B
329.012.00217	Biologic Mother	45	Female	No	0	0	1	0	.	.	1	0	0	0	0	0	0	0
	Biologic Father	45	Male	No	0	0	1	0	1	1	1	0	0	0	0	0	0	0
	Sibling #1	22	Male	No	0	0	.	0	.	.	1	0	0	0	0	0	0	0
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Female	No	0	0	.	0	.	.	.	0	0	0	0	0	0	0
329.012.00218	Biologic Mother	46	Female	No	0	.	0	.	0	.	.	0	0	.	0	.	0	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00224	Biologic Mother	41	Female	No	0	0	1	0	0	0	1	0	0	0	0	0	0	0
	Biologic Father	41	Male	No	0	0	.	0	0	0	.	0	0	0	0	0	0	0
	Sibling #1	14	Female	No	0	0	.	0	0	0	1	0	0	0	0	0	0	0
	Sibling #2	7	Female	No	0	0	.	0	0	0	.	0	0	0	0	0	0	0
329.012.00225	Biologic Mother	48	Female	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.
	Biologic Father	48	Male	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.
	Sibling #1	14	Male	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.001.00063	Biologic Mother	40	Female	No	0	.	0	0	0	0	0	0	.	.	0	.	1	.	0
	Biologic Father	43	Male	No	0	.	0	0	0	0	0	0	1	1	0	.	1	1	0
	Sibling #1	14	Female	No	0	.	0	0	0	0	0	0	.	.	0	.	.	.	0
	Sibling #2	13	Female	No	0	.	0	0	0	0	0	0	.	.	0	.	.	.	0
	Sibling #3	10	Male	No	0	.	0	0	0	0	0	0	.	.	0	.	.	.	0
	Sibling #4	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.001.00068	Biologic Mother	41	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Biologic Father	43	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #1	19	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #2	13	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
329.001.00072	Biologic Mother	45	Female	No	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	45	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	15	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	12	Female	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	10	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.001.00121	Biologic Mother	43	Female	No	1	0	0	0	0	0	.	0	0	0	0	0	.	0	0
	Biologic Father	46	Male	No	.	0	0	0	0	0	.	0	0	0	0	0	1	0	0
	Sibling #1	15	Male	No	.	0	0	0	0	0	.	0	0	0	0	0	.	0	0
	Sibling #2	12	Male	No	.	0	0	0	0	0	1	0	0	0	0	0	.	0	0
	Sibling #3	10	Female	No	.	0	0	0	0	0	.	0	0	0	0	0	.	0	0
329.001.00205	Biologic Mother	37	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Biologic Father	38	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #1	12	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #2	10	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #3	5	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
329.001.00206	Biologic Mother	52	Female	No	0	0	0	0	0	0	0	0	1	.	0	0	.	0	.
	Biologic Father	54	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	1	0	1
	Sibling #1	17	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	.	0	.
	Sibling #2	14	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	0	.
329.002.00055	Biologic Mother	48	Female	No	.	.	0	.	9	.	9	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	0	.	9	.	9	.	1	1	1	1	1	1	.
	Sibling #1	29	Female	No	.	.	0	.	9	.	9	.	.	.	.	.	.	1	1
	Sibling #2	23	Male	Yes	1	1	0	.	9	.	9	.	.	.	.	.	1	.	1
	Sibling #3	26	Male	No	.	.	0	.	9	.	9	.	.	.	.	.	1	.	1

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.002.00055	Sibling #4	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00058	Biologic Mother	42	Female	No	1	0	1	1	.	0	0	0	.	.	.	.	0	0	.
	Biologic Father	36	Male	No	.	0	.	.	.	0	0	0	1	1	1	1	0	0	1
	Sibling #1	24	Male	No	.	0	.	.	.	0	0	0	1	1	1	1	0	0	1
	Sibling #2	22	Male	No	.	0	.	.	.	0	0	0	1	1	1	1	0	0	1
	Sibling #3	16	Female	No	.	0	.	.	1	0	0	0	.	.	.	.	0	0	.
	Sibling #4	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00099	Biologic Mother	37	Female	Yes	.	0	0	.	0	.	0	.	0	.	0	.	.	0	0
	Biologic Father	47	Male	No	1	0	0	.	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	15	Male	No	.	0	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	9	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	.	0	0
329.002.00102	Biologic Mother	35	Female	No	1	0	0	0	0	0	0	.	0	.	0	.	0	.	0
	Biologic Father	39	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	.	0	0	0	0	0	0	.	0	.	0	.	0	.	0
	Sibling #2	13	Female	No	.	0	0	0	0	0	0	.	0	.	0	.	0	.	0
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00105	Biologic Mother	43	Female	No	0	0	1	0	0	0	0	0	0	0	.	.	0	0	0
	Biologic Father	52	Male	Yes	0	0	.	0	0	0	0	0	0	0	.	.	0	0	0
	Sibling #1	17	Male	No	0	0	.	0	0	0	0	0	0	0	1	1	0	0	0
	Sibling #2	16	Male	Yes	0	0	.	0	0	0	0	0	0	0	.	.	0	0	0
329.002.00106	Biologic Mother	32	Female	No	0	.	0	.	.	0	0	.	0	.	0	.	.	.	.
	Biologic Father	36	Male	No	0	.	0	.	.	0	0	.	0	.	0	.	1	1	1
	Sibling #1	15	Female	No	0	.	0	.	1	0	0	.	0	.	0	.	.	.	.
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00242	Biologic Mother	36	Female	No	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0
	Biologic Father	39	Male	No	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0
	Sibling #1	15	Female	No	0	0	1	0	0	0	0	0	0	0	0	0	.	0	0
	Sibling #2	12	Male	No	0	0	1	0	0	0	0	0	0	0	0	0	.	0	0
329.002.00245	Biologic Mother	36	Female	No	0	0	0	0	0	0	0	0	.	.	1	0	1	0	1
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	0	1	1	1	0	1	0	1
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	.	.	1	0	.	0	.
	Sibling #2	18	Male	No	0	0	0	0	0	0	0	0	.	.	.	0	.	0	.
	Sibling #3	16	Female	No	0	0	0	0	0	0	0	0	.	.	1	0	.	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.002.00245	Sibling #4	11	Female	No	0	0	0	0	0	0	0	0	.	.	.	0	.	0	.
	Sibling #5	9	Male	No	0	0	0	0	0	0	0	0	.	.	.	0	.	0	.
329.002.00319	Biologic Mother	42	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Biologic Father	55	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	24	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #2	17	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #3	16	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
329.003.00077		.			0	0	0	0	.	0	0	0	.	0	0	0	0	0	0
	Biologic Mother	45	Female	No	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
	Biologic Father	55	Male	No	0	0	0	0	.	0	0	0	.	0	0	0	0	0	0
	Sibling #1	29	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00087	Biologic Mother	49	Female	No	.	0	0	0	0	0	0	0	0	0	0	0	.	0	0
	Biologic Father	50	Male	No	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	Sibling #1	14	Female	Yes	.	0	0	0	0	0	0	0	0	0	0	0	.	0	0
329.003.00089	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	60	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00091	Biologic Mother	.	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Biologic Father	.	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
	Sibling #1	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	.	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Sibling #3	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00248	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	.	0
	Sibling #1	22	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	12	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Sibling #3	8	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
329.003.00250		.			.	9	.	9	9	0	0	0	0	0	0	0	9	9	9
	Biologic Mother	43	Female	No	.	9	.	9	9	0	0	0	0	0	0	0	9	9	9

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.003.00250	Biologic Father	42	Male	No	.	9	.	9	9	0	0	0	0	0	0	0	9	9	9
	Sibling #1	18	Female	No	1	9	1	9	9	0	0	0	0	0	0	0	9	9	9
	Sibling #2	15	Female	No	.	9	1	9	9	0	0	0	0	0	0	0	9	9	9
	Sibling #3	8	Female	No	.	9	.	9	9	0	0	0	0	0	0	0	9	9	9
	Sibling #4	2	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00292	Biologic Mother	43	Female	No	0	.	1	0	0	0	1	9	0	0	0	0	0	9	0
	Biologic Father	43	Male	No	0	1	1	0	0	0	1	9	0	0	0	0	0	9	0
	Sibling #1	16	Male	No	0	.	1	0	0	0	1	9	0	0	0	0	0	9	0
	Sibling #2	15	Male	No	0	.	1	0	0	0	1	9	0	0	0	0	0	9	0
329.003.00313	Biologic Mother	36	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	37	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	0	0	0	.	0	.	0	0	0	0	0	0	0	.
	Sibling #2	18	Male	No	0	0	0	0	1	0	1	0	0	0	0	0	0	0	1
329.004.00015	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
329.004.00017	Biologic Mother	50	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	52	Male	No	0	.	0	.	0	.	0	.	1	1	0	.	0	.	1
	Sibling #1	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00019	Biologic Mother	.	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Biologic Father	.	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	Sibling #1	.	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
329.004.00212	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00214	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	21	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.005.00002	Biologic Mother	35	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	0	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00004	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	Biologic Father	44	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Male	Yes	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
329.005.00008	Biologic Mother	34	Female	No	.	0	0	0	0	0	0	0	0	0	0	0	1	.	0
	Biologic Father	33	Male	No	1	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	Sibling #1	12	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Sibling #2	9	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	.	.	0
329.005.00109	Biologic Mother	31	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	28	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	15	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #1	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00112	Biologic Mother	61	Male	No	0	0	0	0	.	9	0	0	.	.	9	9	0	0	.
	Biologic Father	54	Female	No	0	0	0	0	.	9	0	0	.	.	9	9	0	0	.
	Sibling #1	21	Female	No	0	0	0	0	.	9	0	0	.	.	9	9	0	0	.
	Sibling #2	18	Male	No	0	0	0	0	1	9	0	0	1	1	9	9	0	0	1
	Sibling #3	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Female	No	0	0	0	0	.	9	0	0	.	.	9	9	0	0	1
	Sibling #5	13	Male	No	0	0	0	0	.	9	0	0	.	.	9	9	0	0	.
329.005.00116	Biologic Mother	39	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	1
	Biologic Father	51	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	.
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	25	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #3	24	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #4	22	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #5	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	.
	Child #1	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00119	Biologic Mother	44	Female	No	0	0	1	.	0	0	0	0	.	.	.	0	.	.	0
	Biologic Father	46	Male	No	0	0	.	.	0	0	0	0	1	1	1	0	1	1	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.005.00119	Sibling #1	19	Female	No	0	0	.	.	0	0	0	0	.	.	.	0	.	.	0
	Sibling #2	14	Female	No	0	0	.	.	0	0	0	0	.	.	1	0	.	.	0
	Sibling #3	7	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00151	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	Biologic Father	40	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	Sibling #1	17	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Sibling #3	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Sibling #4	13	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
329.005.00152	Biologic Mother	37	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	Biologic Father	39	Male	No	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0	0	.	0	.	0	0
329.005.00257	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	12	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00258	Biologic Mother	45	Male	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	0
	Biologic Father	44	Female	No	0	0	0	0	0	0	0	0	1	1	1	1	1	1	0
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	0
	Sibling #2	9	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00299	Biologic Mother	34	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	9	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00300	Biologic Mother	45	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	50	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	12	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	9	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00333	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	19	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.005.00336	Biologic Mother	42	Female	No	0	0	.	0	1	0	0	0	.	.	.	.	.	.	0
	Biologic Father	41	Male	No	0	0	.	0	.	0	0	0	1	1	1	1	1	1	0
	Sibling #1	16	Female	No	0	0	.	0	.	0	0	0	.	.	.	.	.	.	0
	Sibling #2	14	Female	No	0	0	.	0	.	0	0	0	.	.	.	.	.	.	0
	Sibling #3	7	Male	No	0	0	1	0	.	0	0	0	.	.	.	.	.	.	0
	Sibling #4	12	Male	No	0	0	.	0	.	0	0	0	.	.	.	.	.	.	0
329.006.00038	Biologic Mother	35	Female	No	0	0	1	.	0	0	0	.	0	.	1	.	0	.	0
	Biologic Father	40	Male	No	0	0	.	.	0	0	0	.	0	.	.	.	0	.	0
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	0	0	1	1	0	0	0	.	0	.	.	.	0	.	0
	Sibling #3	12	Female	No	0	0	.	.	0	0	0	.	0	.	.	.	0	.	0
	Sibling #4	11	Female	No	0	0	.	.	0	0	0	.	0	.	.	.	0	.	0
	Sibling #5	5	Male	No	0	0	.	.	0	0	0	.	0	.	.	.	0	.	0
329.006.00039		.			.	0	.	0	0	.	0	.	0	.	0	.	0	.	.
	Biologic Mother	47	Female	No	.	0	1	0	0	.	0	.	0	.	0	.	0	.	.
	Biologic Father	48	Male	No	.	0	.	0	0	.	0	.	0	.	0	.	0	.	1
	Sibling #1	24	Male	No	.	0	.	0	0	.	0	.	0	.	0	.	0	.	1
	Sibling #2	21	Male	No	1	0	1	0	0	.	0	.	0	.	0	.	0	.	.
	Sibling #3	15	Female	No	.	0	.	0	0	.	0	.	0	.	0	.	0	.	.
329.006.00260	Biologic Mother	56	Female	No	.	.	0	.	0	.	.	.	0	.	0	.	0	.	0
	Biologic Father	56	Male	Yes	1	1	0	.	0	.	1	1	0	.	0	.	0	.	0
	Sibling #1	17	Female	No	.	.	0	.	0	.	.	.	0	.	0	.	0	.	0
	Sibling #2	10	Male	No	.	.	0	.	0	.	.	.	0	.	0	.	0	.	0
329.006.00261	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	38	Male	No	0	0	0	0	.	.	0	0	1	0	0	0	0	0	0
	Sibling #1	19	Female	No	0	0	0	0	.	.	0	0	.	0	0	0	0	0	0
	Sibling #2	17	Male	No	0	0	0	0	1	1	0	0	.	0	0	0	0	0	0
	Sibling #3	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	7	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00140	Biologic Mother	32	Female	No	1	0	0	.	.	0	0	.	.	9	9	.	.	9	.
	Biologic Father	37	Male	No	.	0	0	.	.	0	0	.	1	9	9	.	1	9	1
	Sibling #1	11	Male	No	.	0	0	.	1	0	0	.	.	9	9	.	.	9	.
	Sibling #2	9	Male	No	.	0	0	.	.	0	0	.	.	9	9	.	.	9	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
					Family History Item Number														
329.007.00142	Biologic Mother	44	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	1	0	0
	Biologic Father	46	Male	No	0	.	0	.	0	.	0	.	1	1	0	.	1	0	0
	Sibling #1	15	Male	No	0	.	0	.	0	.	0	.	.	.	0	.	.	0	0
329.007.00145	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	41	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	23	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	16	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #3	14	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
329.007.00265	Biologic Mother	34	Female	No	0	.	.	.	.	9	.	0	1	1	1	0	1	.	.
	Biologic Father	29	Male	Yes	0	.	1	1	1	9	1	0	1	1	1	0	1	1	1
	Sibling #1	16	Female	No	0	.	.	.	.	9	.	0	.	.	.	0	.	.	.
	Sibling #2	13	Male	No	0	.	.	.	.	9	.	0	.	.	.	0	.	.	.
	Sibling #3	12	Male	No	0	.	.	.	.	9	.	0	.	.	.	0	.	.	.
	Sibling #4	6	Female	No	0	.	.	.	.	9	.	0	.	.	.	0	.	.	.
329.007.00268	Biologic Mother	37	Female	No	0	.	0	.	0	.	0	.	1	.	0	.	0	.	0
	Biologic Father	33	Male	No	0	.	0	.	0	.	0	.	1	1	0	.	0	.	0
	Sibling #1	13	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	0	.	0
329.007.00294	Biologic Mother	37	Female	No	0	0	1	1	0	0	0	0	.	.	0	0	1	0	.
	Biologic Father	40	Male	No	0	0	.	.	0	0	0	0	1	1	0	0	.	0	1
	Sibling #1	15	Female	No	0	0	.	.	0	0	0	0	.	.	0	0	.	0	.
	Sibling #2	14	Male	No	0	0	.	.	0	0	0	0	.	.	0	0	.	0	.
329.007.00309	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	.	0
	Biologic Father	44	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	.	0
	Sibling #1	18	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	1	0
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00310		.			.	0	.	0	0	.	0	.	0	.	0	.	.	0	0
	Biologic Mother	41	Female	No	.	0	.	0	0	.	0	.	0	.	0	.	.	0	0
	Biologic Father	41	Male	No	1	0	1	0	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	16	Female	No	.	0	.	0	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	15	Male	No	.	0	.	0	0	.	0	.	0	.	0	.	.	0	0
329.007.00318	Biologic Mother	44	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	0	.
	Biologic Father	62	Male	No	0	0	0	0	0	0	0	0	1	1	.	.	1	0	1

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.007.00318	Sibling #1	15	Male	No	0	0	0	0	0	0	0	0	.	.	.	.	.	0	.
	Sibling #2	13	Male	No	0	0	0	0	0	0	0	0	.	.	.	.	.	0	.
	Sibling #3	18	Female	No	0	0	0	0	0	0	0	0	.	.	1	1	.	0	1
329.008.00157	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	.	.	.
	Biologic Father	39	Male	No	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1
329.008.00160	Biologic Mother	38	Female	No	0	0	0	0	0	0	0	0	0	0	1	.	1	1	.
	Biologic Father	43	Male	No	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1
329.008.00188	Biologic Mother	37	Female	No	0	0	0	0	0	0	0	0	1	1	0	0	0	0	.
	Biologic Father	42	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1
	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	.
	Child #1	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00271	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	.
	Biologic Father	41	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	Sibling #1	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	10	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	.
329.008.00275	Biologic Mother	44	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	19	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	17	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.009.00130	Biologic Mother	49	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Biologic Father	52	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	1	1	0
	Sibling #1	16	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Sibling #3	10	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Sibling #4	7	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
329.009.00131	Biologic Mother	.	Female	No	.	9	.	.	1	1	1	1	0	.	0	.	.	0	0
	Biologic Father	41	Male	No	.	9	.	.	.	.	.	.	0	.	0	.	1	0	0
	Sibling #1	16	Female	No	1	9	1	1	.	.	.	.	0	.	0	.	.	0	0
	Sibling #2	13	Female	No	.	9	.	.	.	.	.	.	0	.	0	.	.	0	0
329.009.00133	Biologic Mother	37	Female	No	0	.	0	0	0	.	0	.	0	.	0	.	1	.	0
	Biologic Father	37	Male	No	0	.	0	0	0	.	0	.	0	.	0	.	1	1	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.009.00133	Sibling #1	16	Female	No	0	.	0	0	0	.	0	.	0	.	0	.	.	.	0
	Sibling #2	14	Male	No	0	.	0	0	0	.	0	.	0	.	0	.	.	.	0
329.009.00138		.			.	.	.	.	.	1	0	.	.	.	.	.	.	.	.
	Biologic Mother	34	Female	No	1	1	1	1	1	.	0	.	1	1	.	.	.	.	.
	Biologic Father	33	Male	No	.	.	.	.	.	.	0	.	1	1	1	1	1	1	1
	Sibling #1	13	Female	No	.	.	.	.	.	.	0	.	.	.	1	1	.	.	.
	Sibling #2	10	Male	No	.	.	1	1	.	.	0	.	.	.	.	.	.	.	.
329.009.00170	Biologic Mother	41	Female	No	.	0	9	.	9	.	9	.	9	.	9	.	9	.	9
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	1	0	9	.	9	.	9	.	9	.	9	.	9	.	9
	Sibling #2	22	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00173	Biologic Mother	43	Female	No	1	1	0	.	.	.	.	.	0	.	.	0	0	.	.
	Biologic Father	45	Male	Yes	.	.	0	.	1	1	1	1	0	.	1	0	0	.	1
	Sibling #1	12	Female	No	.	.	0	.	.	.	.	.	0	.	.	0	0	.	.
329.009.00193	Biologic Mother	36	Female	No	0	.	0	.	0	.	0	.	.	.	1	1	1	1	.
	Biologic Father	38	Male	No	0	.	0	.	0	.	0	.	1	1	1	1	1	1	1
	Sibling #1	12	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	.
	Sibling #2	3	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00196	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	0	0
	Sibling #1	17	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	0	0
	Sibling #2	9	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	0	0
329.009.00201	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Biologic Father	47	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	Sibling #1	17	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Sibling #2	14	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
329.009.00204	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	0	.	.	0	.	0	0
	Sibling #6	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	47	Male	No	0	.	0	.	0	.	0	.	0	.	1	0	1	0	0
	Sibling #1	13	Male	No	0	.	0	.	0	.	0	.	0	.	.	0	.	0	0
	Sibling #2	12	Male	No	0	.	0	.	0	.	0	.	0	.	.	0	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.009.00204	Sibling #3	10	Female	No	0	.	0	.	0	.	0	.	0	.	.	0	.	0	0
	Sibling #4	9	Male	No	0	.	0	.	0	.	0	.	0	.	.	0	.	0	0
	Sibling #5	21	Female	No	0	.	0	.	0	.	0	.	0	.	.	0	.	0	0
	Child #1	.			0	.	0	.	0	.	0	.	0	.	.	0	.	0	0
329.009.00235	Biologic Mother	32	Female	No	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	30	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	.	.	.	.	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	8	Male	No	.	.	.	.	0	0	0	0	0	0	0	0	0	0	0
329.009.00240	Biologic Mother	48	Female	No	1	0	0	0	0	0	0	0	0	0	0	0	0	0	.
	Biologic Father	52	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0	.
	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	Sibling #4	13	Female	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0	.
329.009.00303	Biologic Mother	43	Female	No	0	.	.	.	0	.	0	.	0	.	0	.	1	1	.
	Biologic Father	49	Male	No	0	.	.	.	0	.	0	.	0	.	0	.	1	1	.
	Sibling #1	17	Male	No	0	.	1	1	0	.	0	.	0	.	0	.	.	.	.
	Sibling #2	14	Female	No	0	.	.	.	0	.	0	.	0	.	0	.	.	.	1
329.009.00304	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	23	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	1
	Sibling #2	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	.
329.009.00324	Biologic Mother	33	Female	No	1	0	0	0	0	0	0	0	.	0	.	0	0	0	0
	Biologic Father	35	Female	No	.	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	Sibling #1	13	Female	No	.	0	0	0	0	0	0	0	.	0	.	0	0	0	0
	Sibling #2	8	Female	No	.	0	0	0	0	0	0	0	.	0	.	0	0	0	0
	Sibling #3	5	Female	No	.	0	0	0	0	0	0	0	.	0	.	0	0	0	0
329.009.00328	Biologic Mother	45	Female	No	0	0	1	0	0	0	0	0	0	0	.	0	.	0	.
	Biologic Father	46	Male	No	0	0	.	0	0	0	0	0	0	0	.	0	1	0	.
	Sibling #1	23	Male	No	0	0	.	0	0	0	0	0	0	0	1	0	.	0	1
	Sibling #2	21	Male	No	0	0	.	0	0	0	0	0	0	0	1	0	1	0	1
	Sibling #3	14	Male	No	0	0	.	0	0	0	0	0	0	0	.	0	.	0	.
	Sibling #4	12	Male	No	0	0	.	0	0	0	0	0	0	0	.	0	.	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.009.00329	Biologic Mother	32	Female	No	0	0	1	0	0	0	0	0	1	0	0	0	0	0	1
	Biologic Father	34	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Male	No	0	0	.	0	0	0	0	0	.	0	0	0	0	0	.
	Sibling #2	10	Male	No	0	0	.	0	0	0	0	0	.	0	0	0	0	0	.
	Sibling #3	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.010.00182	Biologic Mother	42	Female	No	0	.	0	.	.	.	.	.	0	.	.	.	.	.	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	.	0	.	1	1	1	1	0	.	1	1	1	1	0
	Sibling #2	17	Female	No	0	.	0	.	.	.	.	.	0	.	.	.	.	.	0
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.010.00278	Biologic Mother	49	Female	No	0	.	0	.	0	.	0	.	.	0	0	.	0	.	0
	Biologic Father	49	Male	No	0	.	0	.	0	.	0	.	.	0	0	.	0	.	0
	Sibling #1	20	Female	No	0	.	0	.	0	.	0	.	1	0	0	.	0	.	0
	Sibling #2	17	Female	No	0	.	0	.	0	.	0	.	.	0	0	.	0	.	0
329.010.00280	Biologic Mother	33	Female	No	0	.	0	.	0	.	0	.	0	.	1	1	0	.	1
	Biologic Father	32	Male	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.	1
	Sibling #1	13	Female	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.	.
	Sibling #2	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.011.00283	Biologic Mother	36	Female	No	.	.	.	.	0	0	.	.	.	.	0	0	.	.	0
	Biologic Father	42	Male	No	1	1	1	1	0	0	1	1	1	1	0	0	1	1	0
	Sibling #1	16	Male	No	1	.	1	1	0	0	.	.	.	.	0	0	.	.	0
329.011.00288	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	1	0	.	.	0	0	0
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	1	0	1	1	0	0	0
	Sibling #1	15	Male	No	0	0	0	0	0	0	0	0	.	0	.	.	0	0	0
329.012.00025	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	0	.	0	.	0	.	0	.	0	.	9	9	0	.	0
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Female	No	0	.	0	.	0	.	0	.	0	.	9	9	0	.	0
329.012.00220	Biologic Mother	40	Female	No	.	.	0	.	1	0	0	.	1	.	0	0	1	.	0
	Biologic Father	41	Male	No	1	1	0	.	.	0	0	.	1	1	0	0	1	1	0

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.012.00220	Sibling #1	17	Male	No	.	.	0	.	.	0	0	.	.	.	0	0	.	.	0
	Sibling #2	15	Male	No	1	.	0	.	.	0	0	.	.	.	0	0	.	.	0
	Sibling #3	13	Female	No	.	.	0	.	.	0	0	.	.	.	0	0	.	.	0
329.012.00222	Biologic Mother	37	Female	No	0	.	0	.	0	.	0	.	.	.	9	0	1	0	0
	Biologic Father	38	Male	No	0	.	0	.	0	.	0	.	1	1	9	0	1	0	0
	Sibling #1	15	Female	No	0	.	0	.	0	.	0	.	.	.	9	0	.	0	0
329.012.00226	Biologic Mother	50	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	50	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	23	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	18	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	16	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.012.00228	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	0	0	.	0	0	0	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	Sibling #2	12	Female	No	0	0	0	0	0	0	0	0	0	0	.	0	0	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.001.00061	Biologic Mother	39	Female	No	0	0	0	0	0	0	0	0	1	0	1	0	1	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	.	0	.	0	1	0	0
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	.	0	.	0	.	0	0
	Sibling #2	14	Male	No	0	0	0	0	0	0	0	0	.	0	.	0	.	0	0
329.001.00066	Biologic Mother	48	Female	No	0	0	1	1	.	.	.	.	0	0	.	.	0	0	0
	Biologic Father	52	Male	No	0	0	.	.	1	1	1	1	0	0	1	1	0	0	0
	Sibling #1	17	Female	No	0	0	.	.	.	.	.	.	0	0	.	.	0	0	0
	Sibling #2	13	Male	No	0	0	.	.	.	.	.	.	0	0	.	.	0	0	0
329.001.00067	Biologic Mother	42	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	1	.	.
	Biologic Father	44	Male	No	1	0	0	.	0	.	0	.	0	.	0	.	1	1	1
	Sibling #1	21	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	1	.	.
	Sibling #2	16	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	.	.	1
	Sibling #3	14	Male	No	.	0	0	.	0	.	0	.	0	.	0	.	.	.	1
329.001.00070	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	.	0	0	0	.	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	12	Male	No	0	0	0	0	0	0	0	0	.	0	0	0	.	0	0
329.001.00122	Biologic Mother	53	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #6	16	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #7	15	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	58	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	26	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	23	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	22	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #4	20	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #5	20	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.002.00050	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	49	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
	Sibling #1	19	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
329.002.00056	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	41	Male	No	0	.	0	.	0	.	0	.	1	1	0	.	0	.	0
	Sibling #1	18	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	0	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.002.00056	Sibling #2	10	Male	No	0	.	0	.	0	.	0	.	.	.	0	.	0	.	0
329.002.00057	Biologic Mother	33	Female	No	0	0	1	1	0	0	0	0	0	0	1	1	1	0	.
	Biologic Father	36	Male	No	0	0	.	.	0	0	0	0	0	0	.	.	1	0	1
	Sibling #1	15	Female	No	0	0	.	.	0	0	0	0	0	0	.	.	.	0	.
	Sibling #2	14	Female	No	0	0	.	.	0	0	0	0	0	0	.	.	.	0	.
	Sibling #3	12	Male	No	0	0	.	.	0	0	0	0	0	0	.	.	.	0	.
	Sibling #4	.			0	0	.	.	0	0	0	0	0	0	.	.	.	0	.
329.002.00098	Biologic Mother	43	Female	No	0	0	0	.	0	.	0	.	1	1	0	.	.	0	0
	Biologic Father	45	Male	No	0	0	0	.	0	.	0	.	1	1	0	.	1	0	0
	Sibling #1	16	Female	No	0	0	0	.	0	.	0	.	1	.	0	.	.	0	0
	Sibling #2	13	Female	No	0	0	0	.	0	.	0	.	.	.	0	.	.	0	0
	Sibling #3	9	Male	No	0	0	0	.	0	.	0	.	.	.	0	.	.	0	0
329.002.00100		.			0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Biologic Mother	36	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Biologic Father	35	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
	Sibling #1	15	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Sibling #2	9	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
329.002.00103	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	1	1	0
	Biologic Father	38	Male	No	0	.	0	.	0	.	0	.	1	1	0	.	.	.	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	.	.	0
329.002.00104	Biologic Mother	41	Female	No	1	0	0	.	.	.	0	.	0	.	0	.	0	.	0
	Biologic Father	46	Male	No	1	0	0	.	.	.	0	.	0	.	0	.	0	.	0
	Sibling #1	18	Female	No	.	0	0	.	.	.	0	.	0	.	0	.	0	.	0
	Sibling #2	15	Female	No	.	0	0	.	1	1	0	.	0	.	0	.	0	.	0
	Sibling #3	13	Male	No	.	0	0	.	.	.	0	.	0	.	0	.	0	.	0
329.002.00243	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	1	0	0	.	0	.	.
	Biologic Father	44	Male	No	0	.	0	.	0	.	0	.	.	0	0	.	0	.	1
	Sibling #1	20	Female	No	0	.	0	.	0	.	0	.	.	0	0	.	0	.	1
	Sibling #2	17	Male	No	0	.	0	.	0	.	0	.	.	0	0	.	0	.	.
	Sibling #3	15	Female	No	0	.	0	.	0	.	0	.	.	0	0	.	0	.	.
329.002.00244	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
					Family History Item Number														
329.002.00244	Sibling #1	17	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00321	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	.
	Biologic Father	37	Male	No	0	.	0	.	0	.	0	.	1	1	1	1	1	1	1
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	.
329.002.00322	Biologic Mother	34	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	9	.
	Biologic Father	56	Male	No	0	0	0	0	0	0	0	0	1	1	1	1	1	9	1
	Sibling #1	14	Don't	No	0	0	0	0	0	0	0	0	.	.	.	.	.	9	.
	Sibling #2	14	Don't	No	0	0	0	0	0	0	0	0	.	.	.	.	.	9	.
	Sibling #3	10	Don't	No	0	0	0	0	0	0	0	0	.	.	.	.	.	9	.
	Sibling #4	8	Don't	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	6	Don't	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00073	Biologic Mother	39	Female	No	1	0	0	0	0	0	.	.	0	0	.	.	1	0	0
	Biologic Father	41	Male	No	.	0	0	0	0	0	.	.	0	0	.	.	.	0	0
	Sibling #1	19	Female	No	.	0	0	0	0	0	1	1	0	0	1	1	1	0	0
	Sibling #2	17	Female	No	.	0	0	0	0	0	.	.	0	0	1	.	.	0	0
	Sibling #3	16	Female	No	.	0	0	0	0	0	.	.	0	0	.	.	.	0	0
	Sibling #4	11	Male	No	.	0	0	0	0	0	.	.	0	0	.	.	.	0	0
329.003.00076	Biologic Mother	35	Female	No	.	0	1	1	.	9	0	0	0	.	0	0	1	0	0
	Biologic Father	45	Male	No	.	0	.	.	.	9	0	0	0	1	0	0	.	0	0
	Sibling #1	16	Female	No	1	0	.	.	1	9	0	0	0	.	0	0	.	0	0
329.003.00079		.			.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Mother	.	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	.	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	.	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00088	Biologic Mother	46	Female	No	0	0	1	1	0	0	0	0	0	0	0	0	1	0	.
	Biologic Father	50	Male	No	0	0	.	.	0	0	0	0	0	0	0	0	.	0	1
	Sibling #1	24	Female	No	0	0	1	.	0	0	0	0	0	0	0	0	.	0	.
	Sibling #2	21	Female	No	0	0	1	.	0	0	0	0	0	0	0	0	.	0	.
	Sibling #3	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.003.00090	Biologic Mother	44	Female	No	.	.	.	.	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	51	Male	No	.	.	.	.	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	18	Male	No	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	16	Male	No	.	.	.	.	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	14	Female	No	.	.	.	.	0	0	0	0	0	0	0	0	0	0	0
329.003.00092	Biologic Mother	42	Female	No	.	.	1	1	0	.	0	.	1	1	1	1	0	.	0
	Biologic Father	43	Male	No	.	.	.	.	0	.	0	.	1	1	1	1	0	.	0
	Sibling #1	16	Female	No	.	.	1	1	0	.	0	.	.	.	.	.	0	.	0
	Sibling #2	12	Female	No	1	1	1	1	0	.	0	.	.	.	.	.	0	.	0
329.003.00093	Biologic Mother	50	Female	No	0	0	1	0	1	1	0	.	0	.	0	.	1	1	0
	Biologic Father	53	Male	Yes	0	0	.	0	1	1	0	.	0	.	0	.	.	.	0
	Sibling #1	21	Male	No	0	0	.	0	.	.	0	.	0	.	0	.	.	.	0
	Sibling #2	17	Female	No	0	0	.	0	1	1	0	.	0	.	0	.	.	.	0
329.003.00247	Biologic Mother	41	Female	No	9	9	9	9	0	0	0	0	.	.	1	.	9	9	9
	Biologic Father	44	Male	No	9	9	9	9	0	0	0	0	1	1	1	1	9	9	9
	Sibling #1	16	Male	No	9	9	9	9	0	0	0	0	.	.	.	.	9	9	9
	Sibling #2	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00249	Biologic Mother	46	Female	No	9	9	9	9	9	9	9	9	0	0	9	9	1	1	9
	Biologic Father	52	Male	No	9	9	9	9	9	9	9	9	0	0	9	9	.	.	9
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00289		.			.	.	.	0	0	0	0	0	.	.	.	.	.	0	.
	Biologic Mother	41	Female	No	.	.	.	0	0	0	0	0	1	.	1	1	1	0	.
	Biologic Father	45	Male	No	.	.	.	0	0	0	0	0	1	1	1	1	1	0	1
	Sibling #1	16	Female	No	1	1	1	0	0	0	0	0	.	.	.	.	.	0	.
	Sibling #2	13	Male	No	.	.	.	0	0	0	0	0	.	.	.	.	.	0	.
329.003.00290	Biologic Mother	37	Female	No	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	48	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	3	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	10	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #4	17	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.003.00314	Biologic Mother	39	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	36	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	12	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00317		.			.	.	0	0	0	0	0	0	0	0	0	0	.	0	0
	Biologic Mother	50	Female	No	.	.	0	0	0	0	0	0	0	0	0	0	1	0	0
	Biologic Father	50	Male	No	.	.	0	0	0	0	0	0	0	0	0	0	1	0	0
	Sibling #1	17	Don't	No	.	.	0	0	0	0	0	0	0	0	0	0	.	0	0
	Sibling #2	16	Female	No	1	1	0	0	0	0	0	0	0	0	0	0	.	0	0
329.004.00013	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00014	Biologic Mother	52	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	.	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00211	Biologic Mother	49	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #2	18	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
329.004.00215	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00003	Biologic Mother	30	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	9	9	0
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	7	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	5	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	9	9	0
	Sibling #5	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00006	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.005.00006	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00007	Biologic Mother	41	Female	No	0	0	1	0	.	0	0	0	.	.	.	.	.	.	.
	Biologic Father	44	Male	No	0	0	.	0	.	0	0	0	1	1	1	1	1	1	1
	Sibling #1	20	Female	No	0	0	.	0	.	0	0	0	1	1	1	1	1	1	.
	Sibling #2	15	Female	No	0	0	.	0	1	0	0	0	.	.	.	.	.	.	.
329.005.00009	Biologic Mother	47	Female	No	0	0	0	0	.	0	0	0	0	0	0	0	.	0	0
	Biologic Father	46	Male	No	0	0	0	0	.	0	0	0	0	0	0	0	1	0	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	0	0	0	1	0	0	0	0	0	0	0	.	0	0
	Sibling #3	5	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00117	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Biologic Father	49	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	Sibling #1	22	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #2	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #3	12	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
329.005.00118	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
	Biologic Father	47	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	Sibling #1	17	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
	Sibling #3	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00153	Biologic Mother	44	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	0	.
	Biologic Father	51	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
	Sibling #1	18	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	.
329.005.00255	Biologic Mother	47	Female	No	0	0	1	0	.	0	0	0	1	1	1	0	.	0	0
	Biologic Father	48	Male	No	0	0	.	0	.	0	0	0	.	.	1	0	1	0	0
	Sibling #1	17	Male	No	0	0	.	0	.	0	0	0	.	.	.	0	.	0	0
	Sibling #2	15	Female	No	0	0	.	0	1	0	0	0	.	.	.	0	.	0	0
329.005.00256	Biologic Mother	55	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Biologic Father	52	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	24	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	Sibling #2	23	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.005.00256	Sibling #4	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
329.005.00295	Biologic Mother	31	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	.	0	0
	Biologic Father	36	Male	No	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	Sibling #1	13	Female	No	0	0	0	0	0	0	0	0	0	0	.	0	.	0	0
329.005.00297	Biologic Mother	46	Female	No	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Male	No	.	0	.	.	0	0	0	0	0	0	0	0	0	0	0
329.005.00332	Biologic Mother	50	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	54	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	21	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00335	Biologic Mother	37	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	0	0	.
	Biologic Father	39	Male	No	0	0	0	0	0	0	0	0	1	1	1	1	0	0	1
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	0	0	.
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	6	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	0	0	.
329.006.00040	Biologic Mother	46	Female	No	0	.	.	0	0	.	0	.	0	.	0	.	1	0	0
	Biologic Father	66	Male	No	0	.	1	0	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	28	Male	No	0	.	.	0	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	18	Female	No	0	.	1	0	0	.	0	.	0	.	0	.	.	0	0
329.006.00041	Biologic Mother	44	Female	No	.	9	.	.	0	.	0	.	.	.	0	.	1	0	0
	Biologic Father	50	Male	No	1	9	1	1	0	.	0	.	1	1	0	.	.	0	0
	Sibling #1	21	Male	No	.	9	.	.	0	.	0	.	.	.	0	.	.	0	0
	Sibling #2	18	Male	No	1	9	.	.	0	.	0	.	.	.	0	.	.	0	0
329.007.00139	Biologic Mother	38	Female	No	.	.	0	0	0	0	0	0	0	0	0	0	1	0	0
	Biologic Father	36	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	1	1	0	0	0	0	0	0	0	0	0	0	.	0	0
329.007.00143	Biologic Mother	28	Female	No	0	.	0	.	1	0	1	1	1	1	1	1	1	0	0
	Biologic Father	.	Male	Unknown	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Female	No	0	.	0	.	.	0	.	.	.	.	.	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.007.00143	Sibling #2	.			0	.	0	.	.	0	.	.	.	.	.	.	.	0	0
329.007.00146	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	1
	Biologic Father	39	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	.
	Sibling #1	15	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	.
329.007.00269	Biologic Mother	45	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	.
	Biologic Father	60	Male	Yes	0	.	0	.	0	.	0	.	0	.	0	.	1	0	1
	Sibling #1	15	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	.
	Sibling #2	12	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	.
329.007.00270	Biologic Mother	34	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	9	.	0
	Biologic Father	35	Male	No	0	.	0	.	0	.	0	.	1	1	0	.	9	.	0
	Sibling #1	15	Male	No	0	.	0	.	0	.	0	.	.	.	0	.	9	.	0
	Sibling #2	10	Male	No	0	.	0	.	0	.	0	.	.	.	0	.	9	.	0
	Sibling #3	8	Male	No	0	.	0	.	0	.	0	.	.	.	0	.	9	.	0
	Sibling #4	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00307	Biologic Mother	42	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	.
	Biologic Father	43	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	1
	Sibling #1	15	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	.
	Sibling #2	14	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	.
329.007.00308	Biologic Mother	45	Female	No	0	.	1	1	0	.	0	.	.	0	9	0	1	0	.
	Biologic Father	43	Male	No	0	.	.	.	0	.	0	.	1	0	9	0	.	0	.
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	0	.	.	.	0	.	0	.	.	0	9	0	.	0	1
329.008.00159	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Biologic Father	49	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	1	1	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Sibling #3	16	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
329.008.00161	Biologic Mother	44	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	Sibling #1	4	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	4	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.008.00187	Biologic Mother	47	Female	No	0	.	0	.	1	.	0	.	0	.	1	0	1	.	0
	Sibling #1	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00192	Biologic Mother	35	Female	No	0	0	0	0	0	0	0	0	1	.	.	.	.	.	.
	Biologic Father	40	Male	No	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	Sibling #1	5	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	.
329.008.00272	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	.	0	0	0	0	0	0
	Biologic Father	62	Male	No	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	Sibling #1	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.008.00273	Biologic Mother	42	Female	No	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	0	0	.	0	0	0	0	0	0	0	0	0	0
	Sibling #1	15	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00127	Biologic Mother	31	Female	No	0	.	0	.	0	.	0	0	.	.	0	0	.	.	0
	Biologic Father	41	Male	No	0	.	0	.	0	.	0	0	1	1	0	0	1	1	0
	Sibling #1	12	Female	No	0	.	0	.	0	.	0	0	.	.	0	0	.	.	0
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00132	Biologic Mother	30	Female	No	0	.	0	.	0	.	0	.	1	1	.	.	1	1	.
	Biologic Father	31	Male	No	0	.	0	.	0	.	0	.	1	1	1	1	1	1	1
	Sibling #1	13	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	.
	Sibling #2	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00134	Biologic Mother	38	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	1	0	0
	Biologic Father	31	Male	Yes	.	0	0	.	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	15	Female	No	1	0	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	.			.	0	0	.	0	.	0	.	0	.	0	.	.	0	0
329.009.00137	Biologic Mother	34	Female	No	.	.	.	.	.	.	.	.	1	1	.	.	0	.	.
	Biologic Father	41	Male	No	1	1	1	1	1	1	1	1	1	.	1	1	0	.	1
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	0	.	.
	Sibling #2	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	0	.	.
	Sibling #4	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	0	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.009.00171	Biologic Mother	38	Female	No	9	9	9	9	9	9	9	9	1	.	.	.	9	9	.
	Biologic Father	41	Male	No	9	9	9	9	9	9	9	9	1	1	.	.	9	9	1
	Sibling #1	23	Male	No	9	9	9	9	9	9	9	9	1	1	1	1	9	9	1
	Sibling #2	16	Female	No	9	9	9	9	9	9	9	9	.	.	.	.	9	9	.
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	12	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	4	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00172	Biologic Mother	43	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	0	.	0
	Biologic Father	45	Male	No	.	0	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #1	23	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	19	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #3	13	Female	No	.	0	0	.	0	.	0	.	0	.	0	.	0	.	0
329.009.00194	Biologic Mother	36	Female	No	9	9	9	9	9	9	9	9	9	9	1	1	.	.	9
	Biologic Father	33	Male	No	9	9	9	9	9	9	9	9	9	9	1	.	1	1	9
	Sibling #1	12	Male	No	9	9	9	9	9	9	9	9	9	9	.	.	.	.	9
	Sibling #2	6	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	3	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00195	Biologic Mother	39	Female	No	0	.	0	.	0	.	.	.	0	.	0	.	.	.	0
	Biologic Father	40	Male	No	0	.	0	.	0	.	.	.	0	.	0	.	1	1	0
	Sibling #1	16	Female	No	0	.	0	.	0	.	.	.	0	.	0	.	.	.	0
	Sibling #2	14	Female	No	0	.	0	.	0	.	1	1	0	.	0	.	.	.	0
	Sibling #3	12	Male	No	0	.	0	.	0	.	.	.	0	.	0	.	.	.	0
329.009.00199	Biologic Mother	49	Female	No	0	0	0	0	.	.	0	0	0	0	0	0	1	1	0
	Biologic Father	56	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Female	No	0	0	0	0	.	.	0	0	0	0	0	0	1	1	0
	Sibling #2	14	Female	No	0	0	0	0	1	1	0	0	0	0	0	0	.	.	0
	Sibling #3	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00203	Biologic Mother	36	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	.	0
	Biologic Father	38	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	1	1	0
	Sibling #1	12	Female	Yes	0	.	0	.	0	.	0	.	0	.	0	.	.	.	0
	Sibling #2	5	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00236	Biologic Mother	45	Female	No	1	0	1	1	.	0	0	0	.	.	.	.	0	0	.
	Biologic Father	44	Male	No	1	0	.	.	1	0	0	0	1	1	1	1	0	0	1
	Sibling #1	20	Male	No	.	0	.	.	.	0	0	0	1	.	.	.	0	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.009.00236	Sibling #2	16	Female	No	1	0	.	.	1	0	0	0	.	.	1	1	0	0	.
	Sibling #3	13	Female	No	.	0	.	.	.	0	0	0	.	.	.	.	0	0	.
329.009.00262	Biologic Mother	38	Female	No	0	0	0	0	0	0	0	0	.	.	1	0	.	0	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	0	0	1	1	1	0	1	0	0
	Sibling #1	13	Male	No	0	0	0	0	0	0	0	0	.	.	.	0	.	0	0
	Sibling #2	11	Male	No	0	0	0	0	0	0	0	0	.	.	.	0	.	0	0
329.009.00264	Biologic Mother	37	Female	No	0	0	0	0	.	0	0	0	.	.	.	.	0	0	0
	Biologic Father	40	Male	No	0	0	0	0	1	0	0	0	1	1	1	1	0	0	0
	Sibling #1	14	Female	No	0	0	0	0	.	0	0	0	.	.	.	.	0	0	0
329.009.00301	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	.	0
	Biologic Father	39	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	1	.	0
	Sibling #1	17	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	1	1	0
	Sibling #2	10	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	.	0
	Sibling #3	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00305	Biologic Mother	44	Female	No	0	.	0	.	0	.	0	.	1	1	.	.	1	0	0
	Biologic Father	45	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	0	0
	Sibling #1	17	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	.	0	0
	Sibling #2	14	Male	No	0	.	0	.	0	.	0	.	.	.	1	0	.	0	0
	Sibling #3	12	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	.	0	0
329.009.00325	Biologic Mother	33	Female	No	0	0	.	0	.	.	0	0	.	.	.	.	.	0	.
	Biologic Father	38	Male	No	0	0	.	0	.	.	0	0	1	1	1	0	1	0	1
	Sibling #1	15	Female	No	0	0	1	0	1	1	0	0	.	.	1	.	.	0	1
329.009.00326	Biologic Mother	31	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	1	0	0
	Biologic Father	34	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	.	0	0
	Sibling #1	13	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	.	0	0
	Sibling #2	9	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	.	0	0
329.010.00279	Biologic Mother	37	Female	No	0	.	0	.	0	.	.	.	.	.	0	.	0	.	0
	Biologic Father	48	Male	No	0	.	0	.	0	.	1	1	1	1	0	.	0	.	0
	Sibling #1	13	Female	No	0	.	0	.	0	.	.	.	.	.	0	.	0	.	0
	Sibling #2	2	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	1	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.010.00281	Biologic Mother	43	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Biologic Father	48	Male	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	16	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #3	14	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #4	13	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
329.011.00163	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0	0	.	0	0	0	0
	Sibling #2	9	Male	No	0	0	0	0	0	0	0	0	0	0	.	0	0	0	0
329.011.00208	Biologic Mother	51	Female	No	.	.	1	1	0	0	0	0	1	0	0	0	.	.	0
	Biologic Father	44	Male	No	1	1	.	.	0	0	0	0	.	0	0	0	1	1	0
	Sibling #1	13	Male	No	.	.	.	.	0	0	0	0	.	0	0	0	.	.	0
329.011.00209	Biologic Mother	41	Female	No	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Male	No	0	0	.	.	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	10	Female	No	0	0	.	.	0	0	0	0	0	0	0	0	0	0	0
329.011.00284	Biologic Mother	46	Female	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	47	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	10	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
329.011.00286	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	0	0	0
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	0	0	0
	Sibling #2	15	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	0	0	0
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00026	Biologic Mother	37	Female	No	0	.	0	.	.	.	0	.	.	.	0	.	1	0	0
	Biologic Father	36	Male	No	0	.	0	.	.	.	0	.	1	1	0	.	.	0	0
	Sibling #1	15	Female	No	0	.	0	.	.	.	0	.	.	.	0	.	.	0	0
	Sibling #2	14	Male	No	0	.	0	.	1	1	0	.	.	.	0	.	.	0	0
329.012.00219	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	Biologic Father	42	Male	No	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.012.00219	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	.	0	0	0	0	0	0
	Sibling #2	14	Male	No	0	0	0	0	0	0	0	0	.	0	0	0	0	0	0
329.012.00221	Biologic Mother	44	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	17	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.012.00223	Biologic Mother	32	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Biologic Father	34	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	13	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00227	Biologic Mother	49	Female	No	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	22	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	16	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
329.012.00230	Biologic Mother	36	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	0	0	0
	Biologic Father	53	Male	Yes	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0
	Sibling #1	15	Male	No	0	0	0	0	0	0	0	0	.	.	.	.	0	0	0
	Sibling #2	13	Male	No	0	0	0	0	0	0	0	0	.	.	.	.	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.001.00062	Biologic Mother	38	Female	No	1	1	1	0	0	0	0	0	.	.	0	0	.	.	.
	Biologic Father	37	Male	No	.	.	.	0	0	0	0	0	1	1	0	0	1	1	1
	Sibling #1	18	Female	No	.	.	.	0	0	0	0	0	.	.	0	0	.	.	.
	Sibling #2	16	Female	No	.	.	.	0	0	0	0	0	.	.	0	0	1	1	.
	Sibling #3	15	Female	No	.	.	.	0	0	0	0	0	.	.	0	0	.	.	.
329.001.00064	Biologic Mother	32	Female	No	0	0	1	0	0	0	0	.	0	.	0	.	1	1	0
	Biologic Father	42	Male	No	0	0	.	0	0	0	0	.	0	.	0	.	1	.	0
	Sibling #1	13	Male	No	0	0	.	0	0	0	0	.	0	.	0	.	.	.	0
	Sibling #2	8	Male	No	0	0	.	0	0	0	0	.	0	.	0	.	.	.	0
329.001.00069	Biologic Mother	49	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	.	.	0
	Biologic Father	55	Male	No	0	0	0	0	0	0	1	1	0	0	0	0	1	1	0
	Sibling #1	26	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	.	.	0
	Sibling #2	24	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	.	.	0
	Sibling #3	22	Female	No	0	0	0	0	0	0	.	.	0	0	0	0	.	.	0
	Sibling #4	16	Male	No	0	0	0	0	0	0	.	.	0	0	0	0	.	.	0
329.001.00071	Biologic Mother	48	Female	No	0	0	0	0	0	0	0	0	1	1	.	0	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	1	1	.	0	0	0	0
	Sibling #1	18	Male		0	0	0	0	0	0	0	0	.	.	1	0	0	0	0
	Sibling #2	13	Female		0	0	0	0	0	0	0	0	.	.	.	0	0	0	0
329.001.00123	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	47	Male	No	0	.	0	.	0	.	0	.	0	.	.	.	.	.	.
	Sibling #1	22	Male	No	0	.	0	.	0	.	0	.	0	.	1	1	1	1	1
	Sibling #2	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Female	No	0	.	0	.	0	.	0	.	0	.	.	.	.	.	.
329.001.00207	Biologic Mother	48	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Biologic Father	49	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
329.002.00049	Biologic Mother	52	Female	No	0	0	1	1	0	0	0	0	0	0	0	0	1	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	23	Male	No	0	0	.	.	0	0	0	0	0	0	0	0	.	0	0
	Sibling #3	20	Male	No	0	0	.	.	0	0	0	0	0	0	0	0	.	0	0
	Sibling #4	16	Male	No	0	0	.	.	0	0	0	0	0	0	0	0	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.002.00059	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Biologic Father	50	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	25	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
329.002.00060	Biologic Mother	47	Female	No	.	0	.	.	0	.	0	.	.	0	0	.	0	.	0
	Biologic Father	45	Male	No	1	0	1	1	0	.	0	.	1	0	0	.	0	.	0
	Sibling #1	16	Female	No	.	0	.	.	0	.	0	.	.	0	0	.	0	.	0
	Sibling #2	14	Female	No	.	0	.	.	0	.	0	.	.	0	0	.	0	.	0
	Sibling #3	11	Male	No	.	0	.	.	0	.	0	.	.	0	0	.	0	.	0
329.002.00097	Biologic Mother	43	Female	No	0	0	0	.	0	.	0	.	1	1	0	.	.	0	0
	Biologic Father	45	Male	No	0	0	0	.	0	.	0	.	1	1	0	.	1	0	0
	Sibling #1	16	Female	No	0	0	0	.	0	.	0	.	.	.	0	.	.	0	0
	Sibling #2	13	Female	No	0	0	0	.	0	.	0	.	.	.	0	.	.	0	0
	Sibling #3	9	Male	No	0	0	0	.	0	.	0	.	.	.	0	.	.	0	0
329.002.00101	Biologic Mother	48	Female	No	9	.	9	.	.	0	0	0	.	.	.	.	0	.	.
	Biologic Father	52	Male	No	9	.	9	.	1	0	0	0	.	.	.	.	0	.	.
	Sibling #1	26	Male	No	9	.	9	.	.	0	0	0	.	.	.	.	0	.	.
	Sibling #2	28	Female	No	9	.	9	.	.	0	0	0	.	.	.	.	0	.	.
	Sibling #3	22	Female	No	9	.	9	.	.	0	0	0	.	.	.	.	0	.	.
	Sibling #4	16	Male	No	9	.	9	.	.	0	0	0	1	1	1	1	0	.	1
329.002.00107	Biologic Mother	47	Female	No	0	.	0	.	.	0	0	.	.	.	9	.	.	.	0
	Biologic Father	53	Male	Yes	0	.	0	.	1	0	0	.	.	.	9	.	.	.	0
	Sibling #1	27	Male	No	0	.	0	.	.	0	0	.	1	1	9	.	1	1	0
	Sibling #2	20	Male	No	0	.	0	.	.	0	0	.	.	.	9	.	.	.	0
	Sibling #3	18	Male	No	0	.	0	.	.	0	0	.	.	.	9	.	.	.	0
	Sibling #4	15	Female	No	0	.	0	.	.	0	0	.	.	.	9	.	.	.	0
329.002.00241	Biologic Mother	38	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	42	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	15	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	17	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.002.00246	Biologic Mother	34	Female	No	.	.	.	0	1	1	1	1	1	1	1	1	1	1	1
	Biologic Father	35	Male	No	1	1	1	0	.	.	.	.	1	1	.	.	.	.	.
	Sibling #1	17	Female	No	.	.	.	0	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.002.00246	Sibling #2	8	Male	No	.	.	.	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	2	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.002.00320	Biologic Mother	40	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	1	.	0
	Biologic Father	44	Male	No	0	.	0	.	0	.	0	.	1	1	1	1	1	1	0
	Sibling #1	16	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	0
	Sibling #2	13	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	0
	Sibling #3	9	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	0
329.002.00323	Biologic Mother	44	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	17	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00074	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	9	9	0	0	0	0	0	0	9	0	9	9	9	0	0
	Sibling #2	5	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00078		.			.	0	9	9	9	9	0	0	0	0	0	0	0	0	0
	Biologic Mother	40	Female	No	1	0	9	9	9	9	0	0	0	0	0	0	0	0	0
	Biologic Father	47	Male	No	.	0	9	9	9	9	0	0	0	0	0	0	0	0	0
	Sibling #1	17	Female	No	1	0	9	9	9	9	0	0	0	0	0	0	0	0	0
	Sibling #2	15	Female	No	.	0	9	9	9	9	0	0	0	0	0	0	0	0	0
	Sibling #3	12	Female	No	.	0	9	9	9	9	0	0	0	0	0	0	0	0	0
329.003.00080	Biologic Mother	43	Female	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	48	Male	No	.	0	0	0	0	0	0	0	1	1	0	0	0	0	0
	Sibling #1	16	Female	No	1	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Sibling #2	14	Male	No	.	0	0	0	0	0	0	0	.	.	0	0	0	0	0
329.003.00085	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #3	8	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00086	Biologic Mother	38	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.003.00086	Sibling #2	12	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00094	Biologic Mother	55	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	55	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00252	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	45	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00291	Biologic Mother	38	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	35	Male	No	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	13	Female	No	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	.			.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00315	Biologic Mother	52	Female	No	0	0	0	0	0	0	1	1	1	1	0	0	0	0	1
	Biologic Father	52	Male	No	0	0	0	0	0	0	.	.	1	1	0	0	0	0	.
	Sibling #1	16	Female	No	0	0	0	0	0	0	.	.	.	.	0	0	0	0	.
	Sibling #2	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.003.00316	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	.
	Biologic Father	38	Male	No	0	0	0	0	0	0	0	0	1	1	1	1	.	.	.
	Sibling #1	18	Male	No	0	0	0	0	0	0	0	0	.	.	1	1	1	1	1
	Sibling #2	16	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	.
	Sibling #3	10	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	.
	Sibling #4	6	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.004.00016	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0
	Sibling #1	22	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	0	0	0	0	0	0	0	0	0	0	.	.	0	0	0
329.004.00018	Biologic Mother	42	Female	No	.	.	.	.	1	1	.	.	1	1	0	.	1	0	0
	Biologic Father	49	Male	No	.	.	.	.	.	.	.	.	.	.	0	.	1	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.004.00018	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.	.	0	.	.	0	0
	Sibling #2	14	Male	No	1	1	1	1	1	1	1	1	.	.	0	.	.	0	0
329.004.00020	Biologic Mother	38	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Biologic Father	45	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #1	18	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #2	14	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
329.004.00213	Biologic Mother	45	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00001	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	1	1	0
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Sibling #3	16	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
329.005.00005	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	1	1	1	0	0	0	.
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	.	.	.	0	0	0	1
	Sibling #1	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	0	0	0	0	0	0	0	0	.	.	.	0	0	0	.
329.005.00010	Biologic Mother	45	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	Biologic Father	47	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	21	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
	Sibling #5	15	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
	Child #1	12	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0
329.005.00012	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
	Sibling #1	18	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	Sibling #2	14	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	0
329.005.00111	Biologic Mother	36	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	1	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.005.00111	Biologic Father	40	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	1	1	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Sibling #3	13	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00114	Biologic Mother	47	Female		0	0	0	0	0	0	0	0	.	.	0	0	9	9	0
	Biologic Father	55	Male		0	0	0	0	0	0	0	0	1	1	0	0	9	9	0
	Sibling #1	22	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	9	9	0
	Sibling #2	16	Male	No	0	0	0	0	0	0	0	0	.	.	0	0	9	9	0
	Sibling #3	25	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	9	9	0
329.005.00115	Biologic Mother	41	Female	Yes	.	0	0	0	.	0	0	0	1	1	1	1	.	.	.
	Biologic Father	0	Male	Yes	.	0	0	0	.	0	0	0	1	1	1	1	.	.	.
	Sibling #1	25	Male	No	.	0	0	0	.	0	0	0	1	1	1	1	1	1	.
	Sibling #2	18	Female	No	1	0	0	0	1	0	0	0	.	.	.	.	.	.	1
	Sibling #3	17	Male	No	.	0	0	0	.	0	0	0	.	.	.	.	.	.	.
329.005.00120	Biologic Mother	36	Female	No	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	0	0	0	0	0	0	0	0	0	0	.	0	.	0	0
	Sibling #2	9	Male	No	0	0	0	0	0	0	0	0	0	0	.	0	.	0	0
329.005.00253	Biologic Mother	44	Female	No	0	0	0	0	0	0	1	0	.	.	0	0	1	1	0
	Biologic Father	44	Male	No	0	0	0	0	0	0	.	0	1	1	0	0	1	1	0
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	0	0	0	0	0	.	0	.	.	0	0	1	1	0
	Sibling #3	10	Male	No	0	0	0	0	0	0	.	0	.	.	0	0	.	.	0
329.005.00254	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	.	.	1	.	1	.	.
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	.
	Sibling #2	12	Female	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	0	0	0	0	0	0	0	0	.	.	.	.	.	.	.
329.005.00293	Biologic Mother	42	Female	No	0	0	.	0	1	0	0	0	.	.	.	.	.	.	0
	Biologic Father	41	Male	No	0	0	.	0	.	0	0	0	1	1	1	1	1	1	0
	Sibling #1	16	Female	No	0	0	.	0	.	0	0	0	.	.	.	.	.	.	0
	Sibling #2	14	Female	No	0	0	.	0	.	0	0	0	.	.	.	.	.	.	0
	Sibling #3	7	Male	No	0	0	1	0	.	0	0	0	.	.	.	.	.	.	0
	Sibling #4	12	Male	No	0	0	.	0	.	0	0	0	.	.	.	.	.	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.005.00293	Child #1	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Child #2	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.005.00298	Biologic Mother	42	Female	No	1	0	1	1	0	0	0	0	.	.	0	0	0	0	0
	Biologic Father	44	Male	No	.	0	.	.	0	0	0	0	1	1	0	0	0	0	0
	Sibling #1	14	Female	No	.	0	.	.	0	0	0	0	.	.	0	0	0	0	0
	Sibling #2	13	Female	No	.	0	.	.	0	0	0	0	.	.	0	0	0	0	0
	Sibling #3	8	Male	No	.	0	.	.	0	0	0	0	.	.	0	0	0	0	0
	Sibling #4	6	Male	No	.	0	.	.	0	0	0	0	.	.	0	0	0	0	0
329.005.00331	Biologic Mother	38	Female	No	0	0	0	0	.	.	.	.	.	.	1	0	.	.	.
	Biologic Father	48	Male	Unknown	0	0	0	0	1	1	1	1	1	1	1	0	1	1	1
	Sibling #1	15	Female	No	0	0	0	0	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	11	Female	No	0	0	0	0	.	.	.	.	.	.	.	.	.	.	.
329.005.00334	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	13	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.006.00037	Biologic Mother	59	Female	No	.	0	1	1	.	.	.	.	.	.	.	.	1	1	0
	Biologic Father	55	Male	No	1	0	1	.	1	1	1	.	1	1	1	1	1	1	0
	Sibling #1	39	Male	No	.	0	1	.	.	.	.	.	1	1	1	1	1	1	0
	Sibling #2	36	Female	No	.	0	1	.	.	.	.	.	.	.	.	.	.	.	0
	Sibling #3	17	Female	No	.	0	1	.	.	.	.	.	.	.	.	.	.	.	0
329.006.00042	Biologic Mother	40	Female	No	0	.	0	.	0	.	0	.	.	.	1	0	.	0	0
	Biologic Father	43	Male	No	0	.	0	.	0	.	0	.	1	1	1	0	1	0	0
	Sibling #1	18	Male	No	0	.	0	.	0	.	0	.	.	.	.	0	.	0	0
	Sibling #2	16	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	0	.	0	.	0	.	0	.	.	.	.	0	.	0	0
	Sibling #4	7	Female	No	0	.	0	.	0	.	0	.	.	.	.	0	.	0	0
329.006.00259	Biologic Mother	49	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Biologic Father	53	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #2	15	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #3	10	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
329.007.00141	Biologic Mother	32	Female	No	0	.	1	0	0	.	0	.	1	1	1	1	1	1	1

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.007.00141	Biologic Father	32	Male	No	0	.	.	0	0	.	0	.	.	.	.	.	1	.	.
	Sibling #1	13	Male	No	0	.	.	0	0	.	0	.	.	.	.	.	.	.	.
	Sibling #2	9	Female	Yes	0	.	.	0	0	.	0	.	.	.	.	.	.	.	.
329.007.00144	Biologic Mother	28	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Biologic Father	39	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	12	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
329.007.00266	Biologic Mother	33	Female	No	1	1	1	1	0	.	1	1	1	1	1	1	1	0	0
	Biologic Father	34	Male	No	.	.	.	.	0	.	.	.	.	.	1	.	.	0	0
	Sibling #1	12	Female	No	.	.	.	.	0	.	.	.	.	.	.	.	.	0	0
	Sibling #2	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	1	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.007.00267	Biologic Mother	46	Female	No	1	1	1	0	0	.	0	.	1	1	1	1	0	.	0
	Biologic Father	46	Male	No	.	.	.	0	0	.	0	.	1	1	1	1	0	.	0
	Sibling #1	16	Male	No	.	.	.	0	0	.	0	.	.	.	1	1	0	.	0
329.007.00311	Biologic Mother	44	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	.	0	.
	Biologic Father	62	Male	No	0	.	0	.	0	.	0	.	1	1	.	.	1	0	1
	Sibling #1	18	Female	No	0	.	0	.	0	.	0	.	.	.	1	1	.	0	1
	Sibling #2	15	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	0	.
	Sibling #3	13	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	0	.
329.008.00158		.			0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Biologic Father	49	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	1	1	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Sibling #3	16	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
	Child #2	.			0	0	0	0	0	0	0	0	.	.	0	0	.	.	0
329.008.00162	Biologic Mother	46	Female	No	1	1	1	1	0	0	0	0	1	.	.	.	0	0	.
	Biologic Father	41	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Male	No	.	.	.	.	0	0	0	0	1	1	1	1	0	0	1
329.008.00191	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.008.00191	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	.			0	0	0	0	0	0	0	0	.	.	0	0	0	0	0
329.009.00128	Biologic Mother	50	Female	No	.	0	0	0	0	0	0	0	.	0	0	0	9	0	0
	Biologic Father	49	Male	No	.	0	0	0	0	0	0	0	1	0	0	0	9	0	0
	Sibling #1	23	Male	No	.	0	0	0	0	0	0	0	.	0	0	0	9	0	0
	Sibling #2	13	Male	No	1	0	0	0	0	0	0	0	.	0	0	0	9	0	0
	Sibling #3	10	Female	No	.	0	0	0	0	0	0	0	.	0	0	0	9	0	0
329.009.00129	Biologic Mother	42	Female	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.	0
	Biologic Father	47	Male	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.	0
	Sibling #1	16	Male	No	0	.	0	.	0	.	.	0	0	.	0	.	0	.	0
	Sibling #2	12	Female	No	0	.	0	.	0	.	1	0	0	.	0	.	0	.	0
329.009.00135	Biologic Mother	48	Female	No	1	1	1	9	0	.	0	.	0	.	0	.	1	1	0
	Biologic Father	48	Male	No	.	.	.	9	0	.	0	.	0	.	0	.	1	1	0
	Sibling #1	17	Female	No	.	.	.	9	0	.	0	.	0	.	0	.	.	.	0
329.009.00136	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.	.
	Sibling #6	15	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #7	14	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #8	14	Female	No	0	.	0	.	0	.	0	.	0	.	.	.	0	.	.
	Sibling #9	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	48	Male	No	0	.	0	.	0	.	0	.	0	.	1	1	0	.	1
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	23	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	18	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #5	16	Female	No	0	.	0	.	0	.	0	.	0	.	1	1	0	.	1
329.009.00169	Biologic Mother	27	Female	No	0	.	0	.	0	.	0	.	1	1	.	.	.	.	.
	Biologic Father	32	Male	No	0	.	0	.	0	.	0	.	1	1	1	1	1	.	1
	Sibling #1	13	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	.
	Sibling #2	10	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	5	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	0	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00174	Biologic Mother	44	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Biologic Father	48	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.009.00174	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #3	15	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
329.009.00197	Biologic Mother	29	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	.
	Biologic Father	31	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	1
	Sibling #1	12	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	.
	Sibling #2	4	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	.
	Sibling #3	0	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00198	Biologic Mother	34	Female	No	0	.	0	.	.	.	.	0	.	.	0	.	0	.	0
	Biologic Father	35	Male	No	0	.	0	.	.	.	.	0	1	1	0	.	0	.	0
	Sibling #1	17	Female	No	0	.	0	.	1	1	1	0	.	.	0	.	0	.	0
	Sibling #2	15	Female	No	0	.	0	.	.	.	.	0	.	.	0	.	0	.	0
	Sibling #3	13	Female	No	0	.	0	.	.	.	.	0	.	.	0	.	0	.	0
329.009.00200	Biologic Mother	49	Female	No	0	.	0	.	.	.	0	.	1	1	1	0	.	.	0
	Biologic Father	53	Male	No	0	.	0	.	.	.	0	.	1	1	.	0	.	.	0
	Sibling #1	17	Female	No	0	.	0	.	1	1	0	.	.	.	1	0	1	.	0
	Sibling #2	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.009.00202	Biologic Mother	40	Female	No	0	0	0	.	1	1	0	0	.	.	1	0	0	.	0
	Biologic Father	41	Male	No	0	0	0	.	.	.	0	0	1	1	1	0	0	.	0
	Sibling #1	19	Male	No	0	0	0	.	.	.	0	0	1	1	1	0	0	.	0
	Sibling #2	15	Female	No	0	0	0	.	1	.	0	0	1	.	1	0	0	.	0
	Sibling #3	14	Male	No	0	0	0	.	.	.	0	0	.	.	.	0	0	.	0
329.009.00237	Biologic Mother	43	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #6	9	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #1	21	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #2	19	Female	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #3	17	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	1	.	1
	Sibling #4	12	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
	Sibling #5	10	Male	No	0	0	0	0	0	0	0	0	0	0	0	0	.	.	.
329.009.00238	Biologic Mother	42	Female	No	0	0	0	0	.	0	0	0	.	.	1	.	.	.	0
	Biologic Father	42	Male	No	0	0	0	0	1	0	0	0	1	1	1	1	1	1	0
	Sibling #1	21	Male	Yes	0	0	0	0	.	0	0	0	.	.	.	.	.	.	0
	Sibling #2	16	Female	Yes	0	0	0	0	.	0	0	0	.	.	.	.	.	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.009.00238	Sibling #3	9	Female	Yes	0	0	0	0	.	0	0	0	.	.	.	.	.	.	0
329.009.00276	Biologic Mother	30	Female	No	0	.	0	.	0	.	0	.	1	1	1	1	0	.	1
	Biologic Father	32	Male	No	0	.	0	.	0	.	0	.	.	.	1	1	0	.	.
	Sibling #1	13	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	0	.	.
329.009.00302	Biologic Mother	40	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Biologic Father	41	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	1	0	0
	Sibling #1	17	Male	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
	Sibling #2	10	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	.	0	0
329.009.00306	Biologic Mother	28	Female	Yes	0	.	0	.	9	.	0	.	0	.	9	.	9	.	0
	Biologic Father	.	Male	Unknown	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	.	0	.	9	.	0	.	0	.	9	.	9	.	0
329.009.00312	Biologic Mother	48	Female	No	.	.	.	9	.	.	0	0	0	0	0	0	1	1	0
	Biologic Father	55	Male	No	1	1	1	9	.	.	0	0	0	0	0	0	1	1	0
	Sibling #1	17	Female	No	.	.	.	9	1	1	0	0	0	0	0	0	1	.	0
329.009.00327	Biologic Mother	40	Female	No	1	0	0	0	0	0	0	0	.	.	.	.	1	.	.
	Biologic Father	42	Male	No	.	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	Sibling #1	18	Male	No	.	0	0	0	0	0	0	0	.	.	1	1	1	.	1
	Sibling #2	16	Female	No	.	0	0	0	0	0	0	0	.	.	.	.	1	.	.
329.009.00330	Biologic Mother	33	Female	No	1	1	1	0	0	0	0	0	1	1	1	1	1	0	1
	Biologic Father	36	Male	No	.	.	.	0	0	0	0	0	1	1	1	1	.	0	1
	Sibling #1	14	Female	No	.	.	.	0	0	0	0	0	.	.	.	.	.	0	.
	Sibling #2	12	Male	No	.	.	.	0	0	0	0	0	.	.	.	.	.	0	1
	Sibling #3	9	Male	No	.	.	.	0	0	0	0	0	.	.	.	.	.	0	.
329.010.00183	Biologic Mother	39	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	0	.	0	.	0	.	0	.	1	1	1	1	1	1	0
	Sibling #1	16	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	0
	Sibling #3	13	Female	No	0	.	0	.	0	.	0	.	.	.	.	.	.	.	0
329.010.00263	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	1	0	0
	Biologic Father	60	Male	No	0	0	0	0	0	0	0	0	0	0	.	.	1	0	0
	Sibling #1	21	Male	No	0	0	0	0	0	0	0	0	0	0	1	1	.	0	0
	Sibling #2	18	Male	No	0	0	0	0	0	0	0	0	0	0	.	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.010.00263	Sibling #3	15	Female	No	0	0	0	0	0	0	0	0	0	0	.	.	.	0	0
329.010.00277	Biologic Mother	35	Female	No	0	.	0	.	0	.	0	.	0	.	.	0	0	.	.
	Biologic Father	38	Male	No	0	.	0	.	0	.	0	.	0	.	1	0	0	.	1
	Sibling #1	14	Female	No	0	.	0	.	0	.	0	.	0	.	.	0	0	.	.
329.010.00282	Biologic Mother	45	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	0	.	0
	Biologic Father	46	Male	No	0	.	0	.	0	.	0	.	1	1	0	.	0	.	0
	Sibling #1	18	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	0	.	0
	Sibling #2	15	Female	No	0	.	0	.	0	.	0	.	.	.	0	.	0	.	0
	Sibling #3	12	Male	No	0	.	0	.	0	.	0	.	.	.	0	.	0	.	0
329.011.00164	Biologic Mother	43	Female	No	0	.	0	.	0	.	0	.	.	.	.	0	.	.	.
	Biologic Father	43	Male	No	0	.	0	.	0	.	0	.	1	1	1	0	.	.	.
	Sibling #1	24	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #2	20	Male	No	0	.	0	.	0	.	0	.	.	.	.	0	1	1	1
	Sibling #3	18	Male	No	0	.	0	.	0	.	0	.	.	.	.	0	.	.	.
	Sibling #4	15	Male	No	0	.	0	.	0	.	0	.	.	.	.	0	.	.	.
329.011.00210	Biologic Mother	32	Female	No	.	0	0	0	0	0	0	0	.	0	.	0	0	0	0
	Biologic Father	41	Male	No	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	Sibling #1	14	Female	No	.	0	0	0	0	0	0	0	.	0	.	0	0	0	0
	Sibling #2	10	Male	No	.	0	0	0	0	0	0	0	.	0	.	0	0	0	0
329.011.00285	Biologic Mother	42	Female	No	0	0	1	0	0	0	0	0	0	0	0	0	.	0	0
	Biologic Father	44	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	1	0	0
	Sibling #1	16	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	.	0	0
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.011.00287	Biologic Mother	41	Female	No	0	0	0	0	.	0	0	0	0	0	0	0	0	0	0
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	Sibling #2	14	Female	No	0	0	0	0	.	0	0	0	0	0	0	0	0	0	0
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #4	4	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00027	Biologic Mother	39	Female	No	.	0	0	.	9	.	0	.	.	.	.	0	.	0	0
	Biologic Father	38	Male	No	.	0	0	.	9	.	0	.	1	1	1	0	1	0	0
	Sibling #1	15	Male	No	1	0	0	.	9	.	0	.	.	.	.	0	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part III
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 19	19B	20	20B	21	21B	22	22B	23	23B	24	24B	25	25B	26
329.012.00217	Biologic Mother	45	Female	No	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	45	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	22	Male	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Female	No	0	0	.	0	0	0	0	0	0	0	0	0	0	0	0
329.012.00218	Biologic Mother	46	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
329.012.00224	Biologic Mother	41	Female	No	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	Biologic Father	41	Male	No	.	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #1	14	Female	No	.	0	.	0	0	0	0	0	0	0	0	0	0	0	0
	Sibling #2	7	Female	No	.	0	.	0	0	0	0	0	0	0	0	0	0	0	0
329.012.00225	Biologic Mother	48	Female	No	1	0	0	.	1	0	0	.	1	0	0	.	.	0	0
	Biologic Father	48	Male	No	1	0	0	.	1	0	0	.	.	0	0	.	1	0	0
	Sibling #1	14	Male	No	.	0	0	.	.	0	0	.	.	0	0	.	.	0	0
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.001.00063	Biologic Mother	40	Female	No	.	.	.	.	0	0	0	0	0
	Biologic Father	43	Male	No	.	.	1	1	0	0	0	0	0
	Sibling #1	14	Female	No	.	.	.	.	0	0	0	0	0
	Sibling #2	13	Female	No	.	.	.	.	0	0	0	0	0
	Sibling #3	10	Male	No	1	1	.	.	0	0	0	0	0
	Sibling #4	8	Male	No	.	.	.	.	.	.	.	.	.
329.001.00068	Biologic Mother	41	Female	No	.	.	1	.	0	.	.	0	.
	Biologic Father	43	Male	No	.	.	1	.	0	.	.	0	.
	Sibling #1	19	Female	No	.	.	.	.	0	.	.	0	.
	Sibling #2	13	Female	No	1	1	1	1	0	.	1	0	.
329.001.00072	Biologic Mother	45	Female	No	.	0	.	0	.	.	0	1	0
	Biologic Father	45	Male	No	.	0	.	0	.	.	0	.	0
	Sibling #1	15	Male	No	1	0	1	0	1	1	0	.	0
	Sibling #2	12	Female	No	1	0	.	0	.	.	0	.	0
	Sibling #3	10	Male	No	1	0	.	0	1	1	0	.	0
329.001.00121	Biologic Mother	43	Female	No	0	0	.	0	.	0	0	0	0
	Biologic Father	46	Male	No	0	0	.	0	.	0	0	0	0
	Sibling #1	15	Male	No	0	0	.	0	.	0	0	0	0
	Sibling #2	12	Male	No	0	0	1	0	1	0	0	0	0
	Sibling #3	10	Female	No	0	0	.	0	.	0	0	0	0
329.001.00205	Biologic Mother	37	Female	No	0	.	.	0	1	1	0	0	0
	Biologic Father	38	Male	No	0	.	1	0	1	1	0	0	0
	Sibling #1	12	Male	No	0	.	.	0	.	.	0	0	0
	Sibling #2	10	Female	No	0	.	.	0	1	1	0	0	0
	Sibling #3	5	Female	No	0	.	.	0	.	1	0	0	0
329.001.00206	Biologic Mother	52	Female	No	0	0	.	.	.	0	.	0	0
	Biologic Father	54	Male	No	0	0	1	1	.	0	1	0	0
	Sibling #1	17	Male	No	0	0	1	.	1	0	1	0	0
	Sibling #2	14	Female	No	0	0	.	.	.	0	.	0	0
329.002.00055	Biologic Mother	48	Female	No	.	.	.	0	.	9	.	.	.
	Biologic Father	43	Male	No	.	.	.	0	.	9	.	.	.
	Sibling #1	29	Female	No	.	.	1	0	1	9	1	.	.
	Sibling #2	23	Male	Yes	1	1	1	0	.	9	.	.	1
	Sibling #3	26	Male	No	.	.	1	0	.	9	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.002.00055	Sibling #4	13	Male	No	.	.	.	.	.	.	.	.	.
329.002.00058	Biologic Mother	42	Female	No	1	1	.	.	.	.	.	0	0
	Biologic Father	36	Male	No	.	.	1	.	.	.	.	0	0
	Sibling #1	24	Male	No	.	.	1	.	.	.	1	0	0
	Sibling #2	22	Male	No	.	.	1	1	.	.	1	0	0
	Sibling #3	16	Female	No	1	1	1	.	1	1	1	0	0
	Sibling #4	0	Male	No	.	.	.	.	.	.	.	.	.
329.002.00099	Biologic Mother	37	Female	Yes	.	0	0	.	.	.	0	0	.
	Biologic Father	47	Male	No	.	0	0	.	.	.	0	0	.
	Sibling #1	15	Male	No	.	0	0	.	1	1	0	0	.
	Sibling #2	9	Female	No	1	0	0	.	.	.	0	0	.
329.002.00102	Biologic Mother	35	Female	No	1	.	.	0	.	.	0	0	.
	Biologic Father	39	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	.	.	.	0	1	1	0	0	.
	Sibling #2	13	Female	No	1	1	1	0	.	.	0	0	.
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.
329.002.00105	Biologic Mother	43	Female	No	0	0	.	0	.	.	.	0	0
	Biologic Father	52	Male	Yes	0	0	.	0	.	.	.	0	0
	Sibling #1	17	Male	No	0	0	1	0	1	1	1	0	0
	Sibling #2	16	Male	Yes	0	0	.	0	.	.	.	0	0
329.002.00106	Biologic Mother	32	Female	No	0	.	.	.	.	.	.	.	0
	Biologic Father	36	Male	No	0	.	1	1	.	.	1	1	0
	Sibling #1	15	Female	No	0	.	1	.	1	1	.	.	0
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.
329.002.00242	Biologic Mother	36	Female	No	.	.	1	.	.	.	.	0	0
	Biologic Father	39	Male	No	.	.	.	.	.	.	.	0	0
	Sibling #1	15	Female	No	.	.	1	1	1	1	.	0	0
	Sibling #2	12	Male	No	1	1	1	1	1	1	1	0	0
329.002.00245	Biologic Mother	36	Female	No	9	0	1	.	.	9	.	0	0
	Biologic Father	44	Male	No	9	0	1	.	.	9	.	0	0
	Sibling #1	14	Female	No	9	0	1	.	1	9	1	0	0
	Sibling #2	18	Male	No	9	0	.	.	1	9	.	0	0
	Sibling #3	16	Female	No	9	0	1	.	.	9	1	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.002.00245	Sibling #4	11	Female	No	9	0	1	.	.	9	.	0	0
	Sibling #5	9	Male	No	9	0	.	.	1	9	.	0	0
329.002.00319	Biologic Mother	42	Female	No	0	.	0	.	0	.	0	0	.
	Biologic Father	55	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	24	Male	No	0	.	0	.	0	.	0	0	.
	Sibling #2	17	Male	No	0	.	0	.	0	.	0	0	.
	Sibling #3	16	Female	No	0	.	0	.	0	.	0	0	.
329.003.00077		.			.	0	0	0	0	0	0	.	0
	Biologic Mother	45	Female	No	1	0	0	0	0	0	0	1	0
	Biologic Father	55	Male	No	.	0	0	0	0	0	0	.	0
	Sibling #1	29	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #5	11	Male	No	.	.	.	.	.	.	.	.	.
329.003.00087	Biologic Mother	49	Female	No	.	.	0	0	.	.	0	0	0
	Biologic Father	50	Male	No	.	.	0	0	1	1	0	0	0
	Sibling #1	14	Female	Yes	1	1	0	0	.	.	0	0	0
329.003.00089	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	60	Male	No	0	0	0	0	.	.	0	0	0
	Sibling #1	14	Female	No	0	0	0	0	1	1	0	0	0
329.003.00091	Biologic Mother	.	Female	No	0	0	.	0	0	0	0	0	0
	Biologic Father	.	Male	No	0	0	.	0	0	0	0	0	0
	Sibling #1	.	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	.	Male	No	0	0	1	0	0	0	0	0	0
	Sibling #3	16	Female	No	.	.	.	.	.	.	.	.	.
329.003.00248	Biologic Mother	43	Female	No	.	.	1	1	.	.	1	0	0
	Biologic Father	46	Male	No	1	1	1	.	1	1	1	0	0
	Sibling #1	22	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	12	Female	No	.	.	.	.	.	.	.	0	0
	Sibling #3	8	Male	No	1	.	.	.	.	.	.	0	0
329.003.00250		.			9	9	9	9	9	9	0	.	0
	Biologic Mother	43	Female	No	9	9	9	9	9	9	0	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.003.00250	Biologic Father	42	Male	No	9	9	9	9	9	9	0	.	0
	Sibling #1	18	Female	No	9	9	9	9	9	9	0	1	0
	Sibling #2	15	Female	No	9	9	9	9	9	9	0	1	0
	Sibling #3	8	Female	No	9	9	9	9	9	9	0	.	0
	Sibling #4	2	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #5	1	Male	No	.	.	.	.	.	.	.	.	.
329.003.00292	Biologic Mother	43	Female	No	9	9	0	0	0	9	0	0	0
	Biologic Father	43	Male	No	9	9	0	0	0	9	0	0	0
	Sibling #1	16	Male	No	9	9	0	0	0	9	0	0	0
	Sibling #2	15	Male	No	9	9	0	0	0	9	0	0	0
329.003.00313	Biologic Mother	36	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	37	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	.	0	.	.	.	.	.	0	0
	Sibling #2	18	Male	No	1	0	1	1	1	1	1	0	0
329.004.00015	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	0
329.004.00017	Biologic Mother	50	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	52	Male	No	0	.	0	.	0	.	0	0	.
	Sibling #1	16	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	.	.	.	.	.	.	.	.	.
329.004.00019	Biologic Mother	.	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	.	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	.	Female	No	0	0	0	0	0	0	0	0	0
329.004.00212	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.
329.004.00214	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	21	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	0	0	0	0	0	0	0	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.005.00002	Biologic Mother	35	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	0	Female	Yes	.	.	.	.	.	.	.	.	.
329.005.00004	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	44	Male	Yes	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Male	Yes	0	0	0	0	0	0	0	0	0
329.005.00008	Biologic Mother	34	Female	No	0	0	0	0	1	1	.	0	0
	Biologic Father	33	Male	No	0	0	0	0	.	.	1	0	0
	Sibling #1	12	Male	No	0	0	0	0	.	.	.	0	0
	Sibling #2	9	Male	No	0	0	0	0	.	.	.	0	0
329.005.00109	Biologic Mother	31	Female	Yes	.	.	.	.	.	.	.	.	.
	Biologic Father	28	Male	Yes	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	15	Female	No	.	.	.	.	.	.	.	.	.
	Child #1	0	Female	No	.	.	.	.	.	.	.	.	.
329.005.00112	Biologic Mother	61	Male	No	0	0	.	.	0	0	0	1	0
	Biologic Father	54	Female	No	0	0	.	.	0	0	0	.	0
	Sibling #1	21	Female	No	0	0	.	.	0	0	0	.	0
	Sibling #2	18	Male	No	0	0	1	1	0	0	0	.	0
	Sibling #3	17	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Female	No	0	0	1	1	0	0	0	.	0
	Sibling #5	13	Male	No	0	0	1	.	0	0	0	.	0
329.005.00116	Biologic Mother	39	Female	No	0	0	.	0	.	.	.	.	0
	Biologic Father	51	Male	No	0	0	.	0	.	.	.	1	0
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	25	Female	No	0	0	1	0	.	.	1	.	0
	Sibling #3	24	Female	No	0	0	.	0	.	.	.	.	0
	Sibling #4	22	Male	No	0	0	1	0	.	.	1	.	0
	Sibling #5	16	Female	No	0	0	1	0	1	1	1	.	0
	Child #1	12	Female	No	.	.	.	.	.	.	.	.	.
	Child #2	10	Male	No	.	.	.	.	.	.	.	.	.
329.005.00119	Biologic Mother	44	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.005.00119	Sibling #1	19	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #2	14	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #3	7	Male	No	.	.	.	.	.	.	.	.	.
329.005.00151	Biologic Mother	40	Female	No	0	0	.	.	.	.	.	0	0
	Biologic Father	40	Male	No	0	0	.	.	1	1	.	0	0
	Sibling #1	17	Male	No	0	0	1	1	1	1	1	0	0
	Sibling #2	15	Male	No	0	0	1	.	1	1	.	0	0
	Sibling #3	14	Female	No	0	0	.	.	1	1	1	0	0
	Sibling #4	13	Female	No	0	0	1	1	1	1	1	0	0
329.005.00152	Biologic Mother	37	Female	No	0	0	0	0	0	0	0	1	0
	Biologic Father	39	Male	No	0	0	0	0	0	0	0	.	0
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	.	0
329.005.00257	Biologic Mother	43	Female	No	0	0	0	0	.	0	0	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	0	0	1	0	0	0	0
	Sibling #2	12	Female	No	0	0	0	0	.	0	0	0	0
329.005.00258	Biologic Mother	45	Male	No	0	0	0	0	0	0	0	1	0
	Biologic Father	44	Female	No	0	0	0	0	0	0	0	.	0
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	.	0
	Sibling #2	9	Male	No	.	.	.	.	.	.	.	.	.
329.005.00299	Biologic Mother	34	Female	No	0	0	0	0	.	0	0	0	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	0	0	0	0	.	0	0	0	0
	Sibling #2	9	Male	No	0	0	0	0	1	0	0	0	0
329.005.00300	Biologic Mother	45	Female	No	.	.	0	0	.	.	0	0	0
	Biologic Father	50	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	.	.	0	0	.	.	0	0	0
	Sibling #2	12	Male	No	1	1	0	0	.	.	0	0	0
	Sibling #3	9	Male	No	.	.	0	0	1	1	0	0	0
329.005.00333	Biologic Mother	46	Female	No	1	0	0	0	.	0	0	0	0
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	19	Male	No	1	0	0	0	1	0	0	0	0
	Sibling #2	16	Female	No	.	0	0	0	.	0	0	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.005.00336	Biologic Mother	42	Female	No	.	.	1	0	.	.	.	0	0
	Biologic Father	41	Male	No	.	.	.	0	.	.	.	0	0
	Sibling #1	16	Female	No	.	.	.	0	.	.	1	0	0
	Sibling #2	14	Female	No	.	.	1	0	1	.	.	0	0
	Sibling #3	7	Male	No	1	1	.	0	1	1	.	0	0
	Sibling #4	12	Male	No	.	.	.	0	1	1	.	0	0
329.006.00038	Biologic Mother	35	Female	No	1	.	.	.	.	.	.	.	0
	Biologic Father	40	Male	No	.	.	1	.	.	.	.	.	0
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	.	.	1	.	.	.	1	1	0
	Sibling #3	12	Female	No	.	.	1	1	1	1	1	.	0
	Sibling #4	11	Female	No	.	1	.	.	.	.	.	.	0
	Sibling #5	5	Male	No	.	.	.	.	1	1	.	.	0
329.006.00039		.			.	.	.	0	1	.	0	0	.
	Biologic Mother	47	Female	No	1	1	.	0	.	.	0	0	.
	Biologic Father	48	Male	No	.	.	.	0	.	.	0	0	.
	Sibling #1	24	Male	No	1	1	1	0	.	.	0	0	.
	Sibling #2	21	Male	No	1	1	1	0	.	.	0	0	.
	Sibling #3	15	Female	No	1	1	1	0	.	.	0	0	.
329.006.00260	Biologic Mother	56	Female	No	.	.	0	.	.	.	.	.	0
	Biologic Father	56	Male	Yes	.	.	0	.	.	.	.	.	0
	Sibling #1	17	Female	No	.	.	0	.	1	.	.	1	0
	Sibling #2	10	Male	No	1	1	0	.	1	1	1	1	0
329.006.00261	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	38	Male	No	0	0	.	0	0	0	0	0	0
	Sibling #1	19	Female	No	0	0	1	0	0	0	0	0	0
	Sibling #2	17	Male	No	0	0	1	0	0	0	0	0	0
	Sibling #3	16	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #4	14	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #5	7	Female	No	.	.	.	.	.	.	.	.	.
329.007.00140	Biologic Mother	32	Female	No	.	0	0	.	.	.	0	.	0
	Biologic Father	37	Male	No	.	0	0	.	.	.	0	.	0
	Sibling #1	11	Male	No	.	0	0	.	.	.	0	1	0
	Sibling #2	9	Male	No	1	0	0	.	1	1	0	.	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.007.00142	Biologic Mother	44	Female	No	1	0	1	0	0	.	0	0	.
	Biologic Father	46	Male	No	.	0	.	0	0	.	0	0	.
	Sibling #1	15	Male	No	.	0	.	0	0	.	0	0	.
329.007.00145	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	41	Male	No	.	0	.	0	.	.	.	0	.
	Sibling #1	23	Female	No	1	0	1	0	.	.	.	0	.
	Sibling #2	16	Male	No	1	0	1	0	1	1	1	0	.
	Sibling #3	14	Female	No	1	0	.	0	.	.	.	0	.
329.007.00265	Biologic Mother	34	Female	No	0	.	1	.	.	0	1	0	.
	Biologic Father	29	Male	Yes	0	.	.	.	.	0	1	0	.
	Sibling #1	16	Female	No	0	.	1	1	1	0	1	0	.
	Sibling #2	13	Male	No	0	.	1	.	.	0	.	0	.
	Sibling #3	12	Male	No	0	.	1	.	1	0	.	0	.
	Sibling #4	6	Female	No	0	.	.	.	.	0	.	0	.
329.007.00268	Biologic Mother	37	Female	No	.	.	1	1	.	.	.	1	0
	Biologic Father	33	Male	No	.	.	1	1	.	.	1	.	0
	Sibling #1	13	Female	No	1	1	.	.	1	1	.	.	0
329.007.00294	Biologic Mother	37	Female	No	.	.	0	0	.	.	.	.	0
	Biologic Father	40	Male	No	.	.	0	0	.	.	.	.	0
	Sibling #1	15	Female	No	.	.	0	0	.	.	.	.	0
	Sibling #2	14	Male	No	1	1	0	0	1	1	1	1	0
329.007.00309	Biologic Mother	39	Female	No	1	0	.	0	0	.	.	0	.
	Biologic Father	44	Male	No	.	0	1	0	0	.	.	0	.
	Sibling #1	18	Female	No	.	0	.	0	0	.	1	0	.
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	0	Female	No	.	.	.	.	.	.	.	.	.
329.007.00310		.			.	.	.	0	.	.	0	0	.
	Biologic Mother	41	Female	No	1	1	.	0	.	.	0	0	.
	Biologic Father	41	Male	No	1	.	1	0	1	.	0	0	.
	Sibling #1	16	Female	No	.	.	.	0	.	.	0	0	.
	Sibling #2	15	Male	No	.	.	.	0	1	1	0	0	.
329.007.00318	Biologic Mother	44	Female	No	.	0	.	.	.	.	.	0	0
	Biologic Father	62	Male	No	.	0	.	.	.	.	.	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.007.00318	Sibling #1	15	Male	No	1	0	1	.	1	1	1	0	0
	Sibling #2	13	Male	No	.	0	.	.	1	1	.	0	0
	Sibling #3	18	Female	No	.	0	1	1	.	.	.	0	0
329.008.00157	Biologic Mother	47	Female	No	0	0	.	.	.	.	.	0	0
	Biologic Father	39	Male	No	0	0	1	.	1	1	1	0	0
329.008.00160	Biologic Mother	38	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	0	0	0
329.008.00188	Biologic Mother	37	Female	No	0	0	1	0	0	0	.	1	0
	Biologic Father	42	Male	No	0	0	.	0	0	0	1	1	0
	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	15	Female	No	0	0	1	0	0	0	1	.	0
	Child #1	0	Female	No	.	.	.	.	.	.	.	.	.
329.008.00271	Biologic Mother	41	Female	No	0	0	0	0	.	.	0	0	0
	Biologic Father	41	Male	No	0	0	0	0	.	.	0	0	0
	Sibling #1	13	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	10	Male	No	0	0	0	0	1	1	0	0	0
329.008.00275	Biologic Mother	44	Female	No	0	0	.	0	0	0	.	0	0
	Biologic Father	46	Male	No	0	0	1	0	0	0	.	0	0
	Sibling #1	19	Male	No	0	0	1	0	0	0	.	0	0
	Sibling #2	17	Female	No	0	0	.	0	0	0	1	0	0
329.009.00130	Biologic Mother	49	Female	No	1	1	.	.	.	.	.	0	0
	Biologic Father	52	Male	No	.	.	.	.	1	1	.	0	0
	Sibling #1	16	Male	No	.	.	1	.	.	.	.	0	0
	Sibling #2	15	Male	No	1	1	1	.	1	.	.	0	0
	Sibling #3	10	Female	No	1	1	.	1	1	1	1	0	0
	Sibling #4	7	Female	No	.	.	.	.	.	.	.	0	0
329.009.00131	Biologic Mother	.	Female	No	0	.	.	.	.	.	0	.	0
	Biologic Father	41	Male	No	0	.	.	.	.	.	0	.	0
	Sibling #1	16	Female	No	0	.	.	.	1	1	0	1	0
	Sibling #2	13	Female	No	0	.	1	1	1	1	0	.	0
329.009.00133	Biologic Mother	37	Female	No	9	9	0	.	0	.	0	0	0
	Biologic Father	37	Male	No	9	9	0	.	0	.	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.009.00133	Sibling #1	16	Female	No	9	9	0	.	0	.	0	0	0
	Sibling #2	14	Male	No	9	9	0	.	0	.	0	0	0
329.009.00138		.			.	.	.	.	.	.	.	0	.
	Biologic Mother	34	Female	No	.	.	.	.	.	.	.	0	.
	Biologic Father	33	Male	No	.	.	1	1	1	1	1	0	.
	Sibling #1	13	Female	No	1	1	1	1	1	1	1	0	.
	Sibling #2	10	Male	No	1	1	.	.	.	.	.	0	.
329.009.00170	Biologic Mother	41	Female	No	.	.	9	.	9	.	9	9	.
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	1	1	9	.	9	.	9	9	.
	Sibling #2	22	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	20	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #4	18	Female	No	.	.	.	.	.	.	.	.	.
329.009.00173	Biologic Mother	43	Female	No	.	.	.	.	0	.	9	.	.
	Biologic Father	45	Male	Yes	.	.	1	1	0	.	9	1	1
	Sibling #1	12	Female	No	1	1	.	.	0	.	9	.	.
329.009.00193	Biologic Mother	36	Female	No	0	.	1	1	1	1	1	.	0
	Biologic Father	38	Male	No	0	.	1	1	1	1	.	.	0
	Sibling #1	12	Female	No	0	.	.	.	1	1	1	1	0
	Sibling #2	3	Female	No	.	.	.	.	.	.	.	.	.
329.009.00196	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	0	.	.	0	0	0	.
	Sibling #1	17	Female	No	1	1	0	.	.	0	0	0	.
	Sibling #2	9	Female	No	1	1	0	.	1	0	0	0	.
329.009.00201	Biologic Mother	43	Female	No	0	0	.	.	.	.	.	0	0
	Biologic Father	47	Male	No	0	0	.	.	1	1	.	0	0
	Sibling #1	17	Male	No	0	0	.	.	1	1	.	0	0
	Sibling #2	14	Male	No	0	0	1	1	.	.	1	0	0
329.009.00204	Biologic Mother	39	Female	No	.	0	1	0	.	.	0	0	.
	Sibling #6	8	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	47	Male	No	.	0	1	0	.	.	0	0	.
	Sibling #1	13	Male	No	.	0	1	0	1	1	0	0	.
	Sibling #2	12	Male	No	.	0	1	0	1	1	0	0	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.009.00204	Sibling #3	10	Female	No	1	0	1	0	.	.	0	0	.
	Sibling #4	9	Male	No	.	0	1	0	1	.	0	0	.
	Sibling #5	21	Female	No	.	0	1	0	.	.	0	0	.
	Child #1	.			1	0	1	0	.	.	0	0	.
329.009.00235	Biologic Mother	32	Female	No	.	.	0	0	0	0	0	0	0
	Biologic Father	30	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Female	No	.	.	0	0	0	0	0	0	0
	Sibling #2	8	Male	No	1	1	0	0	0	0	0	0	0
329.009.00240	Biologic Mother	48	Female	No	0	0	.	0	.	.	.	0	0
	Biologic Father	52	Male	No	0	0	.	0	.	.	.	0	0
	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	0	0	1	0	1	1	1	0	0
	Sibling #4	13	Female	No	0	0	.	0	1	1	.	0	0
329.009.00303	Biologic Mother	43	Female	No	0	.	0	0	.	0	0	0	.
	Biologic Father	49	Male	No	0	.	0	0	1	0	0	0	.
	Sibling #1	17	Male	No	0	.	0	0	.	0	0	0	.
	Sibling #2	14	Female	No	0	.	0	0	.	0	0	0	.
329.009.00304	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	23	Male	No	0	.	.	0	0	.	0	0	.
	Sibling #2	20	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Male	No	0	.	1	0	0	.	0	0	.
329.009.00324	Biologic Mother	33	Female	No	.	0	.	0	.	.	0	.	0
	Biologic Father	35	Female	No	.	0	.	0	.	.	0	.	0
	Sibling #1	13	Female	No	.	0	1	0	1	1	0	1	0
	Sibling #2	8	Female	No	1	0	1	0	.	.	0	.	0
	Sibling #3	5	Female	No	1	0	.	0	.	.	0	.	0
329.009.00328	Biologic Mother	45	Female	No	0	0	1	0	1	0	1	0	0
	Biologic Father	46	Male	No	0	0	1	0	1	0	1	0	0
	Sibling #1	23	Male	No	0	0	1	0	.	0	.	0	0
	Sibling #2	21	Male	No	0	0	1	0	1	0	.	0	0
	Sibling #3	14	Male	No	0	0	.	0	1	0	1	0	0
	Sibling #4	12	Male	No	0	0	.	0	.	0	.	0	0

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Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.009.00329	Biologic Mother	32	Female	No	0	0	1	0	.	0	.	0	0
	Biologic Father	34	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Male	No	0	0	.	0	.	0	1	0	0
	Sibling #2	10	Male	No	0	0	.	0	1	0	.	0	0
	Sibling #3	6	Male	No	.	.	.	.	.	.	.	.	.
329.010.00182	Biologic Mother	42	Female	No	0	.	0	.	0	.	0	0	.
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	0	.	0	.	0	.	0	0	.
	Sibling #2	17	Female	No	0	.	0	.	0	.	0	0	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.
329.010.00278	Biologic Mother	49	Female	No	0	.	0	.	0	.	0	.	0
	Biologic Father	49	Male	No	0	.	0	.	0	.	0	1	0
	Sibling #1	20	Female	No	0	.	0	.	0	.	0	.	0
	Sibling #2	17	Female	No	0	.	0	.	0	.	0	.	0
329.010.00280	Biologic Mother	33	Female	No	0	.	.	.	0	.	0	0	.
	Biologic Father	32	Male	No	0	.	.	.	0	.	0	0	.
	Sibling #1	13	Female	No	0	.	1	1	0	.	0	0	.
	Sibling #2	10	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #4	6	Male	No	.	.	.	.	.	.	.	.	.
329.011.00283	Biologic Mother	36	Female	No	1	1	.	.	.	.	.	0	0
	Biologic Father	42	Male	No	.	.	1	1	1	.	1	0	0
	Sibling #1	16	Male	No	1	1	1	1	1	1	1	0	0
329.011.00288	Biologic Mother	41	Female	No	1	1	1	1	1	1	.	.	0
	Biologic Father	45	Male	No	.	.	1	1	.	.	.	1	0
	Sibling #1	15	Male	No	.	.	1	1	1	1	1	.	0
329.012.00025	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	0	.	1	1	0	.	0	0	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Female	No	0	.	.	.	0	.	0	0	.
329.012.00220	Biologic Mother	40	Female	No	0	0	.	0	.	.	.	0	0
	Biologic Father	41	Male	No	0	0	.	0	.	.	.	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.012.00220	Sibling #1	17	Male	No	0	0	1	0	.	.	1	0	0
	Sibling #2	15	Male	No	0	0	.	0	1	1	.	0	0
	Sibling #3	13	Female	No	0	0	.	0	.	.	.	0	0
329.012.00222	Biologic Mother	37	Female	No	.	.	0	.	0	.	0	.	0
	Biologic Father	38	Male	No	.	.	0	.	0	.	0	.	0
	Sibling #1	15	Female	No	1	1	0	.	0	.	0	1	0
329.012.00226	Biologic Mother	50	Female	No	1	0	1	0	0	0	.	.	0
	Biologic Father	50	Male	No	.	0	1	0	0	0	1	.	0
	Sibling #1	23	Female	No	.	0	1	0	0	0	.	.	0
	Sibling #2	18	Male	No	.	0	1	0	0	0	.	.	0
	Sibling #3	16	Male	No	.	0	1	0	0	0	.	1	0
329.012.00228	Biologic Mother	40	Female	No	.	.	.	0	0	0	.	.	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	1	1	1	0	0	0	1	1	0
	Sibling #2	12	Female	No	.	.	.	0	0	0	.	.	0

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.001.00061	Biologic Mother	39	Female	No	1	1	1	0	0	0	0	1	0
	Biologic Father	46	Male	No	.	.	.	0	0	0	0	.	0
	Sibling #1	16	Female	No	.	.	.	0	0	0	0	.	0
	Sibling #2	14	Male	No	.	.	.	0	0	0	0	.	0
329.001.00066	Biologic Mother	48	Female	No	0	0	0	0	0	0	0	.	0
	Biologic Father	52	Male	No	0	0	0	0	0	0	0	1	0
	Sibling #1	17	Female	No	0	0	0	0	0	0	0	.	0
	Sibling #2	13	Male	No	0	0	0	0	0	0	0	.	0
329.001.00067	Biologic Mother	42	Female	No	0	.	.	.	.	.	.	.	0
	Biologic Father	44	Male	No	0	.	1	1	.	.	1	.	0
	Sibling #1	21	Female	No	0	.	1	.	.	.	.	.	0
	Sibling #2	16	Female	No	0	.	1	1	1	1	1	1	0
	Sibling #3	14	Male	No	0	.	1	1	1	1	1	.	0
329.001.00070	Biologic Mother	47	Female	No	0	0	.	0	.	.	.	.	0
	Biologic Father	46	Male	No	0	0	1	0	1	1	.	.	0
	Sibling #1	21	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	12	Male	No	0	0	.	0	1	1	1	1	0
329.001.00122	Biologic Mother	53	Female	No	.	.	.	0	.	.	0	0	0
	Sibling #6	16	Male	No	1	1	1	0	.	.	0	0	0
	Sibling #7	15	Male	No	.	.	1	0	1	1	0	0	0
	Biologic Father	58	Male	No	.	.	.	0	.	.	0	0	0
	Sibling #1	26	Female	No	1	1	1	0	.	.	0	0	0
	Sibling #2	23	Female	No	1	1	1	0	.	.	0	0	0
	Sibling #3	22	Female	No	1	1	1	0	.	.	0	0	0
	Sibling #4	20	Male	No	.	.	1	0	.	.	0	0	0
	Sibling #5	20	Female	No	.	.	1	0	.	.	0	0	0
329.002.00050	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	49	Male	No	0	0	0	0	.	.	.	0	0
	Sibling #1	19	Male	No	0	0	0	0	.	.	.	0	0
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Male	No	0	0	0	0	1	1	1	0	0
329.002.00056	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	41	Male	No	.	.	0	.	0	.	0	0	.
	Sibling #1	18	Female	No	.	.	0	.	0	.	0	0	.

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.002.00056	Sibling #2	10	Male	No	1	1	0	.	0	.	0	0	.
329.002.00057	Biologic Mother	33	Female	No	1	1	1	1	1	1	1	1	0
	Biologic Father	36	Male	No	.	.	1	1	.	.	1	.	0
	Sibling #1	15	Female	No	.	.	1	1	1	1	1	1	0
	Sibling #2	14	Female	No	.	.	.	.	.	.	1	.	0
	Sibling #3	12	Male	No	.	.	.	.	.	.	1	.	0
	Sibling #4	.			.	.	.	.	.	.	1	.	0
329.002.00098	Biologic Mother	43	Female	No	1	1	.	0	.	.	.	0	.
	Biologic Father	45	Male	No	.	.	.	0	.	.	.	0	.
	Sibling #1	16	Female	No	1	1	.	0	.	.	1	0	.
	Sibling #2	13	Female	No	.	.	.	0	1	1	.	0	.
	Sibling #3	9	Male	No	.	.	1	0	.	.	.	0	.
329.002.00100		.			0	0	.	.	.	.	0	0	0
	Biologic Mother	36	Female	No	0	0	.	.	.	.	0	0	0
	Biologic Father	35	Male	No	0	0	.	.	.	.	0	0	0
	Sibling #1	15	Male	No	0	0	1	.	.	.	0	0	0
	Sibling #2	9	Female	No	0	0	.	.	1	1	0	0	0
329.002.00103	Biologic Mother	39	Female	No	0	.	0	.	0	.	0	0	.
	Biologic Father	38	Male	No	0	.	0	.	0	.	0	0	.
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Female	No	0	.	0	.	0	.	0	0	.
329.002.00104	Biologic Mother	41	Female	No	.	.	.	.	.	0	0	1	0
	Biologic Father	46	Male	No	.	.	.	.	.	0	0	.	0
	Sibling #1	18	Female	No	.	.	.	.	.	0	0	.	0
	Sibling #2	15	Female	No	.	.	1	1	1	0	0	.	0
	Sibling #3	13	Male	No	1	1	.	.	1	0	0	.	0
329.002.00243	Biologic Mother	39	Female	No	0	.	.	.	.	.	.	.	0
	Biologic Father	44	Male	No	0	.	.	.	.	.	.	.	0
	Sibling #1	20	Female	No	0	.	1	.	.	.	1	1	0
	Sibling #2	17	Male	No	0	.	1	.	1	1	1	.	0
	Sibling #3	15	Female	No	0	.	.	.	.	.	.	.	0
329.002.00244	Biologic Mother	40	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.002.00244	Sibling #1	17	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #2	13	Male	No	.	.	.	.	.	.	.	.	.
329.002.00321	Biologic Mother	39	Female	No	.	.	.	.	.	.	.	0	.
	Biologic Father	37	Male	No	.	.	1	1	.	.	.	0	.
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	.	.	.	.	1	1	1	0	.
	Sibling #3	14	Male	No	1	1	1	.	1	1	1	0	.
329.002.00322	Biologic Mother	34	Female	No	1	1	.	0	.	.	.	0	0
	Biologic Father	56	Male	No	.	.	.	0	.	.	.	0	0
	Sibling #1	14	Don't	No	.	.	1	0	.	.	1	0	0
	Sibling #2	14	Don't	No	.	.	.	0	.	.	1	0	0
	Sibling #3	10	Don't	No	.	.	.	0	1	1	.	0	0
	Sibling #4	8	Don't	No	.	.	.	.	.	.	.	.	.
	Sibling #5	6	Don't	No	.	.	.	.	.	.	.	.	.
329.003.00073	Biologic Mother	39	Female	No	.	.	.	.	.	0	.	0	0
	Biologic Father	41	Male	No	.	.	1	1	1	0	1	0	0
	Sibling #1	19	Female	No	.	.	1	1	.	0	.	0	0
	Sibling #2	17	Female	No	.	.	1	1	.	0	1	0	0
	Sibling #3	16	Female	No	1	1	1	1	.	0	.	0	0
	Sibling #4	11	Male	No	1	1	.	.	.	0	.	0	0
329.003.00076	Biologic Mother	35	Female	No	1	9	.	0	.	0	0	9	0
	Biologic Father	45	Male	No	.	9	.	0	.	0	0	9	0
	Sibling #1	16	Female	No	1	9	1	0	1	0	0	9	0
329.003.00079		.			.	.	.	.	.	.	.	.	.
	Biologic Mother	.	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	.	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	.	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	.	Female	No	.	.	.	.	.	.	.	.	.
329.003.00088	Biologic Mother	46	Female	No	0	9	0	0	0	0	0	0	0
	Biologic Father	50	Male	No	0	9	0	0	0	0	0	0	0
	Sibling #1	24	Female	No	0	9	0	0	0	0	0	0	0
	Sibling #2	21	Female	No	0	9	0	0	0	0	0	0	0
	Sibling #3	14	Female	No	.	.	.	.	.	.	.	.	.

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.003.00090	Biologic Mother	44	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	51	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	18	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #2	16	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #3	14	Female	No	0	0	0	0	0	0	0	0	0
329.003.00092	Biologic Mother	42	Female	No	1	0	1	0	1	.	1	0	.
	Biologic Father	43	Male	No	.	0	1	0	1	1	1	0	.
	Sibling #1	16	Female	No	1	0	1	0	1	1	1	0	.
	Sibling #2	12	Female	No	1	0	.	0	1	1	.	0	.
329.003.00093	Biologic Mother	50	Female	No	.	0	0	0	0	0	0	0	0
	Biologic Father	53	Male	Yes	.	0	0	0	0	0	0	0	0
	Sibling #1	21	Male	No	1	0	0	0	0	0	0	0	0
	Sibling #2	17	Female	No	1	0	0	0	0	0	0	0	0
329.003.00247	Biologic Mother	41	Female	No	9	9	.	.	.	0	.	0	0
	Biologic Father	44	Male	No	9	9	.	.	.	0	.	0	0
	Sibling #1	16	Male	No	9	9	1	1	1	0	1	0	0
	Sibling #2	2	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	0	Male	No	.	.	.	.	.	.	.	.	.
329.003.00249	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	9	9
	Biologic Father	52	Male	No	0	0	0	0	0	0	0	9	9
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.
329.003.00289		.			0	0	0	0	0	0	0	0	0
	Biologic Mother	41	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #2	13	Male	No	0	0	0	0	0	0	0	0	0
329.003.00290	Biologic Mother	37	Female	No	9	9	9	9	9	9	9	0	0
	Biologic Father	48	Male	No	9	9	9	9	9	9	9	0	0
	Sibling #1	3	Male	Yes	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Male	No	9	9	9	9	9	9	9	0	0
	Sibling #3	10	Male	No	9	9	9	9	9	9	9	0	0
	Sibling #4	17	Male	No	9	9	9	9	9	9	9	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.003.00314	Biologic Mother	39	Female	No	0	0	.	.	0	0	0	0	0
	Biologic Father	36	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	0	0	1	1	0	0	0	0	0
	Sibling #2	12	Female	No	0	0	.	.	0	0	0	0	0
329.003.00317		.			0	0	.	0	.	.	0	.	0
	Biologic Mother	50	Female	No	0	0	.	0	.	.	0	.	0
	Biologic Father	50	Male	No	0	0	.	0	.	.	0	.	0
	Sibling #1	17	Don’t	No	0	0	.	0	.	.	0	.	0
	Sibling #2	16	Female	No	0	0	1	0	1	1	0	1	0
329.004.00013	Biologic Mother	37	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.
329.004.00014	Biologic Mother	52	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	.	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Male	No	.	.	.	.	.	.	.	.	.
329.004.00211	Biologic Mother	49	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	21	Female	No	0	.	0	.	0	.	0	0	.
	Sibling #2	18	Female	No	0	.	0	.	0	.	0	0	.
329.004.00215	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	14	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.
329.005.00003	Biologic Mother	30	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Female	No	1	1	9	9	.	.	9	9	0
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	7	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #4	5	Male	No	.	.	9	9	1	1	9	9	0
	Sibling #5	2	Female	No	.	.	.	.	.	.	.	.	.
329.005.00006	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.005.00006	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	.	.	.	.	.	.	.	.	.
329.005.00007	Biologic Mother	41	Female	No	.	.	.	.	0	0	.	.	0
	Biologic Father	44	Male	No	.	.	.	.	0	0	.	.	0
	Sibling #1	20	Female	No	.	.	1	1	0	0	1	.	0
	Sibling #2	15	Female	No	1	1	.	.	0	0	.	1	0
329.005.00009	Biologic Mother	47	Female	No	1	1	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	.	.	0	0	0	0	0	0	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	.	.	0	0	0	0	0	0	0
	Sibling #3	5	Female	No	.	.	.	.	.	.	.	.	.
329.005.00117	Biologic Mother	47	Female	No	1	.	1	.	.	.	.	0	0
	Biologic Father	49	Male	No	.	.	1	1	.	.	.	0	0
	Sibling #1	22	Female	No	.	.	1	1	.	.	1	0	0
	Sibling #2	16	Female	No	1	.	1	1	1	1	1	0	0
	Sibling #3	12	Male	No	.	.	.	.	.	.	.	0	0
329.005.00118	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	47	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	17	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #2	15	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #3	11	Male	No	.	.	.	.	.	.	.	.	.
329.005.00153	Biologic Mother	44	Female	No	0	0	.	0	.	.	.	0	0
	Biologic Father	51	Male	No	0	0	1	0	1	1	1	0	0
	Sibling #1	18	Female	No	0	0	1	0	.	.	.	0	0
329.005.00255	Biologic Mother	47	Female	No	.	.	0	0	1	1	0	1	0
	Biologic Father	48	Male	No	1	1	0	0	1	1	0	.	0
	Sibling #1	17	Male	No	.	.	0	0	1	1	0	.	0
	Sibling #2	15	Female	No	1	1	0	0	1	1	0	.	0
329.005.00256	Biologic Mother	55	Female	No	.	.	0	0	0	0	0	0	0
	Biologic Father	52	Male	Yes	.	.	.	.	.	.	.	.	.
	Sibling #1	24	Female	No	1	1	0	0	0	0	0	0	0
	Sibling #2	23	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	19	Male	No	.	.	.	.	.	.	.	.	.

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.005.00256	Sibling #4	16	Female	No	1	1	0	0	0	0	0	0	0
329.005.00295	Biologic Mother	31	Female	No	0	0	0	0	0	0	0	.	0
	Biologic Father	36	Male	No	0	0	0	0	0	0	0	.	0
	Sibling #1	13	Female	No	0	0	0	0	0	0	0	1	0
329.005.00297	Biologic Mother	46	Female	No	0	0	.	.	.	.	.	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Male	No	0	0	1	1	1	1	1	0	0
329.005.00332	Biologic Mother	50	Female	No	1	0	0	0	.	0	0	0	0
	Biologic Father	54	Male	No	1	0	0	0	.	0	0	0	0
	Sibling #1	25	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	21	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	.	0	0	0	1	0	0	0	0
329.005.00335	Biologic Mother	37	Female	No	.	.	1	0	0	0	0	1	0
	Biologic Father	39	Male	No	.	.	1	0	0	0	0	.	0
	Sibling #1	15	Female	No	.	.	.	0	0	0	0	.	0
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	6	Female	No	1	1	.	0	0	0	0	.	0
329.006.00040	Biologic Mother	46	Female	No	0	.	.	.	0	.	.	0	.
	Biologic Father	66	Male	No	0	.	1	1	0	.	1	0	.
	Sibling #1	28	Male	No	0	.	.	.	0	.	.	0	.
	Sibling #2	18	Female	No	0	.	.	.	0	.	.	0	.
329.006.00041	Biologic Mother	44	Female	No	.	.	0	.	.	.	0	0	.
	Biologic Father	50	Male	No	1	1	0	.	1	1	0	0	.
	Sibling #1	21	Male	No	.	.	0	.	.	.	0	0	.
	Sibling #2	18	Male	No	1	1	0	.	.	.	0	0	.
329.007.00139	Biologic Mother	38	Female	No	0	0	.	.	0	0	0	1	0
	Biologic Father	36	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	1	1	0	0	0	.	0
329.007.00143	Biologic Mother	28	Female	No	0	.	1	1	0	.	0	0	.
	Biologic Father	.	Male	Unknown	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Female	No	0	.	.	.	0	.	0	0	.

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.007.00143	Sibling #2	.			0	.	.	.	0	.	0	0	.
329.007.00146	Biologic Mother	39	Female	No	0	.	1	0	.	.	0	0	.
	Biologic Father	39	Male	No	0	.	1	0	.	.	0	0	.
	Sibling #1	15	Female	No	0	.	1	0	1	1	0	0	.
329.007.00269	Biologic Mother	45	Female	No	.	.	.	.	.	.	0	0	.
	Biologic Father	60	Male	Yes	.	.	.	.	.	.	0	0	.
	Sibling #1	15	Male	No	1	1	1	1	1	1	0	0	.
	Sibling #2	12	Female	No	.	.	1	.	.	.	0	0	.
329.007.00270	Biologic Mother	34	Female	No	.	.	.	9	.	9	0	0	.
	Biologic Father	35	Male	No	.	.	.	9	.	9	0	0	.
	Sibling #1	15	Male	No	.	.	.	9	1	9	0	0	.
	Sibling #2	10	Male	No	1	1	1	9	1	9	0	0	.
	Sibling #3	8	Male	No	.	.	.	9	1	9	0	0	.
	Sibling #4	1	Male	No	.	.	.	.	.	.	.	.	.
329.007.00307	Biologic Mother	42	Female	No	.	.	.	.	.	0	.	0	.
	Biologic Father	43	Male	No	.	.	1	1	.	0	1	0	.
	Sibling #1	15	Female	No	1	1	.	.	.	0	.	0	.
	Sibling #2	14	Female	No	.	.	.	.	1	0	.	0	.
329.007.00308	Biologic Mother	45	Female	No	0	.	.	.	.	0	.	0	.
	Biologic Father	43	Male	No	0	.	.	.	.	0	.	0	.
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	0	.	1	1	1	0	1	0	.
329.008.00159	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	49	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #3	16	Female	No	0	0	0	0	0	0	0	0	0
329.008.00161	Biologic Mother	44	Female	No	0	0	0	0	.	.	0	0	0
	Biologic Father	45	Male	No	0	0	0	0	1	1	0	0	0
	Sibling #1	4	Male	Yes	.	.	.	.	.	.	.	.	.
	Sibling #2	4	Male	Yes	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Female	No	.	.	.	.	.	.	.	.	.

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.008.00187	Biologic Mother	47	Female	No	0	.	0	.	0	.	0	0	.
	Sibling #1	11	Male	No	.	.	.	.	.	.	.	.	.
329.008.00192	Biologic Mother	35	Female	No	0	0	0	0	.	.	.	0	0
	Biologic Father	40	Male	No	0	0	0	0	1	1	1	0	0
	Sibling #1	5	Female	No	0	0	0	0	.	.	.	0	0
329.008.00272	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	1	0
	Biologic Father	62	Male	No	0	0	0	0	0	0	0	.	0
	Sibling #1	1	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	1	Male	No	.	.	.	.	.	.	.	.	.
329.008.00273	Biologic Mother	42	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	15	Male	No	.	.	.	.	.	.	.	.	.
329.009.00127	Biologic Mother	31	Female	No	.	.	.	.	.	.	.	.	0
	Biologic Father	41	Male	No	1	1	1	1	1	1	.	1	0
	Sibling #1	12	Female	No	1	1	.	.	1	1	1	.	0
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.
329.009.00132	Biologic Mother	30	Female	No	0	.	.	0	.	.	0	9	0
	Biologic Father	31	Male	No	0	.	1	0	1	1	0	9	0
	Sibling #1	13	Male	No	0	.	.	0	1	1	0	9	0
	Sibling #2	8	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	2	Female	No	.	.	.	.	.	.	.	.	.
329.009.00134	Biologic Mother	38	Female	No	0	.	0	.	0	.	0	0	.
	Biologic Father	31	Male	Yes	0	.	0	.	0	.	0	0	.
	Sibling #1	15	Female	No	0	.	0	.	0	.	0	0	.
	Sibling #2	.			0	.	0	.	0	.	0	0	.
329.009.00137	Biologic Mother	34	Female	No	.	.	.	.	.	.	.	.	0
	Biologic Father	41	Male	No	.	.	.	.	1	.	.	.	0
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	1	0
	Sibling #2	19	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	.	.	1	1	1	.	1	.	0
	Sibling #4	12	Female	No	1	1	.	.	.	.	.	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.009.00171	Biologic Mother	38	Female	No	9	9	.	.	9	9	.	1	0
	Biologic Father	41	Male	No	9	9	1	.	9	9	1	.	0
	Sibling #1	23	Male	No	9	9	1	1	9	9	1	.	0
	Sibling #2	16	Female	No	9	9	1	.	9	9	1	1	0
	Sibling #3	12	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #4	12	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #5	4	Female	No	.	.	.	.	.	.	.	.	.
329.009.00172	Biologic Mother	43	Female	No	.	.	0	.	0	.	0	0	.
	Biologic Father	45	Male	No	.	.	0	.	0	.	0	0	.
	Sibling #1	23	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	19	Female	No	.	.	0	.	0	.	0	0	.
	Sibling #3	13	Female	No	1	1	0	.	0	.	0	0	.
329.009.00194	Biologic Mother	36	Female	No	9	9	1	1	1	1	.	1	0
	Biologic Father	33	Male	No	9	9	.	.	.	.	.	.	0
	Sibling #1	12	Male	No	9	9	.	.	1	.	1	.	0
	Sibling #2	6	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	3	Male	No	.	.	.	.	.	.	.	.	.
329.009.00195	Biologic Mother	39	Female	No	.	.	.	0	.	.	0	0	.
	Biologic Father	40	Male	No	1	1	.	0	.	.	0	0	.
	Sibling #1	16	Female	No	.	.	.	0	.	.	0	0	.
	Sibling #2	14	Female	No	.	.	1	0	1	1	0	0	.
	Sibling #3	12	Male	No	.	.	.	0	1	1	0	0	.
329.009.00199	Biologic Mother	49	Female	No	1	1	.	.	9	9	0	.	0
	Biologic Father	56	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Female	No	1	1	1	1	9	9	0	1	0
	Sibling #2	14	Female	No	.	.	.	.	9	9	0	.	0
	Sibling #3	25	Female	No	.	.	.	.	.	.	.	.	.
329.009.00203	Biologic Mother	36	Female	No	0	.	0	.	.	.	0	0	.
	Biologic Father	38	Male	No	0	.	0	.	.	.	0	0	.
	Sibling #1	12	Female	Yes	0	.	0	.	1	1	0	0	.
	Sibling #2	5	Male	Yes	.	.	.	.	.	.	.	.	.
329.009.00236	Biologic Mother	45	Female	No	0	0	1	.	.	9	.	.	.
	Biologic Father	44	Male	No	0	0	1	.	.	9	.	.	.
	Sibling #1	20	Male	No	0	0	1	.	.	9	.	.	.

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.009.00236	Sibling #2	16	Female	No	0	0	1	1	1	9	1	1	1
	Sibling #3	13	Female	No	0	0	1	.	.	9	.	.	.
329.009.00262	Biologic Mother	38	Female	No	0	0	1	0	0	0	0	0	0
	Biologic Father	43	Male	No	0	0	1	0	0	0	0	0	0
	Sibling #1	13	Male	No	0	0	1	0	0	0	0	0	0
	Sibling #2	11	Male	No	0	0	1	0	0	0	0	0	0
329.009.00264	Biologic Mother	37	Female	No	.	.	0	0	0	0	.	0	0
	Biologic Father	40	Male	No	.	.	0	0	0	0	1	0	0
	Sibling #1	14	Female	No	1	0	0	0	0	0	.	0	0
329.009.00301	Biologic Mother	39	Female	No	0	.	0	.	.	.	0	0	.
	Biologic Father	39	Male	No	0	.	0	.	.	.	0	0	.
	Sibling #1	17	Male	No	0	.	0	.	.	.	0	0	.
	Sibling #2	10	Male	No	0	.	0	.	1	1	0	0	.
	Sibling #3	10	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #4	2	Female	No	.	.	.	.	.	.	.	.	.
329.009.00305	Biologic Mother	44	Female	No	1	1	0	.	.	.	0	0	.
	Biologic Father	45	Male	No	.	.	0	.	.	.	0	0	.
	Sibling #1	17	Female	No	.	.	0	.	.	.	0	0	.
	Sibling #2	14	Male	No	.	.	0	.	1	1	0	0	.
	Sibling #3	12	Female	No	.	.	0	.	.	.	0	0	.
329.009.00325	Biologic Mother	33	Female	No	.	.	1	.	.	.	.	.	0
	Biologic Father	38	Male	No	.	.	1	1	1	1	1	.	0
	Sibling #1	15	Female	No	1	1	1	.	1	1	.	1	0
329.009.00326	Biologic Mother	31	Female	No	1	1	1	1	.	.	1	0	0
	Biologic Father	34	Male	No	.	.	.	.	.	.	.	0	0
	Sibling #1	13	Male	No	.	.	.	.	1	1	.	0	0
	Sibling #2	9	Male	No	1	.	.	.	1	1	.	0	0
329.010.00279	Biologic Mother	37	Female	No	0	.	1	1	0	0	0	0	0
	Biologic Father	48	Male	No	0	.	.	.	0	0	0	0	0
	Sibling #1	13	Female	No	0	.	.	.	0	0	0	0	0
	Sibling #2	2	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	1	Female	No	.	.	.	.	.	.	.	.	.

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.010.00281	Biologic Mother	43	Female	No	.	.	.	0	.	.	.	0	.
	Biologic Father	48	Male	Yes	.	.	.	.	.	.	.	.	.
	Sibling #1	18	Male	No	.	.	.	0	1	1	.	0	.
	Sibling #2	16	Male	No	.	.	.	0	.	.	.	0	.
	Sibling #3	14	Female	No	.	.	1	0	.	.	.	0	.
	Sibling #4	13	Male	No	1	1	1	0	1	1	1	0	.
329.011.00163	Biologic Mother	42	Female	No	1	0	0	0	.	.	0	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	.	0	0	0	1	1	0	0	0
	Sibling #2	9	Male	No	.	0	0	0	1	1	0	0	0
329.011.00208	Biologic Mother	51	Female	No	.	0	0	0	0	0	0	1	0
	Biologic Father	44	Male	No	.	0	0	0	0	0	0	.	0
	Sibling #1	13	Male	No	1	0	0	0	0	0	0	.	0
329.011.00209	Biologic Mother	41	Female	No	.	.	0	0	0	0	0	0	0
	Biologic Father	42	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	12	Male	No	.	.	0	0	0	0	0	0	0
	Sibling #2	10	Female	No	1	1	0	0	0	0	0	0	0
329.011.00284	Biologic Mother	46	Female	No	.	0	0	0	0	0	0	0	0
	Biologic Father	47	Male	No	.	0	0	0	0	0	0	0	0
	Sibling #1	19	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	1	0	0	0	0	0	0	0	0
	Sibling #3	10	Male	No	1	0	0	0	0	0	0	0	0
329.011.00286	Biologic Mother	41	Female	No	0	0	1	0	.	0	0	0	0
	Biologic Father	44	Male	No	0	0	1	0	.	0	0	0	0
	Sibling #1	16	Female	No	0	0	.	0	.	0	0	0	0
	Sibling #2	15	Female	No	0	0	1	0	1	0	0	0	0
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.
329.012.00026	Biologic Mother	37	Female	No	.	0	.	0	.	.	.	0	.
	Biologic Father	36	Male	No	.	0	.	0	.	.	.	0	.
	Sibling #1	15	Female	No	1	0	1	0	1	1	.	0	.
	Sibling #2	14	Male	No	1	0	.	0	.	.	1	0	.
329.012.00219	Biologic Mother	42	Female	No	0	0	1	0	0	0	.	.	0
	Biologic Father	42	Male	No	0	0	1	0	0	0	.	1	0

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Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.012.00219	Sibling #1	16	Female	No	0	0	.	0	0	0	.	.	0
	Sibling #2	14	Male	No	0	0	.	0	0	0	1	1	0
329.012.00221	Biologic Mother	44	Female	No	0	0	0	0	.	0	.	0	0
	Biologic Father	44	Male	No	0	0	0	0	.	0	.	0	0
	Sibling #1	17	Male	No	0	0	0	0	.	0	.	0	0
	Sibling #2	15	Male	No	0	0	0	0	1	0	1	0	0
	Sibling #3	14	Female	No	0	0	0	0	.	0	1	0	0
329.012.00223	Biologic Mother	32	Female	No	0	.	.	.	0	.	.	0	.
	Biologic Father	34	Male	No	0	.	1	1	0	.	1	0	.
	Sibling #1	13	Female	No	0	.	.	.	0	.	.	0	.
	Sibling #2	9	Female	No	.	.	.	.	.	.	.	.	.
329.012.00227	Biologic Mother	49	Female	No	0	0	.	0	.	.	.	.	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Male	No	0	0	.	0	1	1	.	.	0
	Sibling #2	22	Male	No	0	0	1	0	.	.	1	.	0
	Sibling #3	16	Male	No	0	0	.	0	1	1	.	1	0
329.012.00230	Biologic Mother	36	Female	No	.	.	0	0	.	.	.	0	0
	Biologic Father	53	Male	Yes	.	.	0	0	.	.	.	0	0
	Sibling #1	15	Male	No	1	1	0	0	1	1	1	0	0
	Sibling #2	13	Male	No	.	.	0	0	.	.	1	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.001.00062	Biologic Mother	38	Female	No	1	.	.	.	1	.	.	.	0
	Biologic Father	37	Male	No	.	.	1	1	1	.	1	1	0
	Sibling #1	18	Female	No	1	.	.	.	1	1	.	.	0
	Sibling #2	16	Female	No	1	1	1	1	1	1	1	1	0
	Sibling #3	15	Female	No	1	1	.	.	1	.	.	.	0
329.001.00064	Biologic Mother	32	Female	No	.	0	1	0	.	.	0	0	.
	Biologic Father	42	Male	No	.	0	.	0	.	.	0	0	.
	Sibling #1	13	Male	No	1	0	.	0	1	1	0	0	.
	Sibling #2	8	Male	No	1	0	.	0	1	.	0	0	.
329.001.00069	Biologic Mother	49	Female	No	.	.	.	0	.	0	.	0	0
	Biologic Father	55	Male	No	.	.	.	0	1	0	.	0	0
	Sibling #1	26	Female	No	.	.	1	0	.	0	1	0	0
	Sibling #2	24	Male	No	.	.	.	0	.	0	.	0	0
	Sibling #3	22	Female	No	.	.	.	0	.	0	.	0	0
	Sibling #4	16	Male	No	1	1	.	0	.	0	.	0	0
329.001.00071	Biologic Mother	48	Female	No	0	0	.	0	.	.	.	0	0
	Biologic Father	46	Male	No	0	0	1	0	.	.	.	0	0
	Sibling #1	18	Male		0	0	.	0	1	1	1	0	0
	Sibling #2	13	Female		0	0	.	0	.	.	.	0	0
329.001.00123	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	47	Male	No	0	0	.	0	0	.	.	0	0
	Sibling #1	22	Male	No	0	0	1	0	0	.	1	0	0
	Sibling #2	20	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	16	Female	No	0	0	.	0	0	.	.	0	0
329.001.00207	Biologic Mother	48	Female	No	1	0	0	.	.	.	0	0	0
	Biologic Father	49	Male	No	.	0	0	.	.	.	0	0	0
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	1	0	0	.	1	1	0	0	0
329.002.00049	Biologic Mother	52	Female	No	1	0	0	0	.	.	0	0	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	23	Male	No	.	0	0	0	.	.	0	0	0
	Sibling #3	20	Male	No	.	0	0	0	.	.	0	0	0
	Sibling #4	16	Male	No	.	0	0	0	1	1	0	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.002.00059	Biologic Mother	46	Female	No	1	9	0	0	0	0	0	1	0
	Biologic Father	50	Male	No	.	9	0	0	0	0	0	.	0
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	25	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	1	9	0	0	0	0	0	.	0
329.002.00060	Biologic Mother	47	Female	No	1	0	.	0	0	.	0	0	.
	Biologic Father	45	Male	No	.	0	1	0	0	.	0	0	.
	Sibling #1	16	Female	No	.	0	.	0	0	.	0	0	.
	Sibling #2	14	Female	No	1	0	.	0	0	.	0	0	.
	Sibling #3	11	Male	No	.	0	.	0	0	.	0	0	.
329.002.00097	Biologic Mother	43	Female	No	1	1	.	0	.	.	.	0	.
	Biologic Father	45	Male	No	.	.	.	0	.	.	.	0	.
	Sibling #1	16	Female	No	1	1	.	0	.	.	1	0	.
	Sibling #2	13	Female	No	.	.	.	0	1	1	.	0	.
	Sibling #3	9	Male	No	.	.	1	0	.	.	.	0	.
329.002.00101	Biologic Mother	48	Female	No	0	.	0	.	.	.	.	0	.
	Biologic Father	52	Male	No	0	.	0	.	.	.	.	0	.
	Sibling #1	26	Male	No	0	.	0	.	.	.	.	0	.
	Sibling #2	28	Female	No	0	.	0	.	.	.	.	0	.
	Sibling #3	22	Female	No	0	.	0	.	.	.	.	0	.
	Sibling #4	16	Male	No	0	.	0	.	1	1	1	0	.
329.002.00107	Biologic Mother	47	Female	No	0	.	.	.	.	.	0	.	0
	Biologic Father	53	Male	Yes	0	.	.	.	.	.	0	.	0
	Sibling #1	27	Male	No	0	.	1	1	1	1	0	.	0
	Sibling #2	20	Male	No	0	.	1	.	.	.	0	.	0
	Sibling #3	18	Male	No	0	.	1	.	.	.	0	1	0
	Sibling #4	15	Female	No	0	.	.	.	.	.	0	.	0
329.002.00241	Biologic Mother	38	Female	No	.	0	.	0	0	0	.	0	0
	Biologic Father	42	Male	No	.	0	.	0	0	0	.	0	0
	Sibling #1	15	Male	No	.	0	.	0	0	0	.	0	0
	Sibling #2	17	Male	No	1	0	1	0	0	0	1	0	0
329.002.00246	Biologic Mother	34	Female	No	.	.	1	1	.	.	0	1	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	0	.	0
	Sibling #1	17	Female	No	.	.	.	.	.	.	0	.	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.002.00246	Sibling #2	8	Male	No	1	1	.	.	1	1	0	.	0
	Sibling #3	2	Male	No	.	.	.	.	.	.	.	.	.
329.002.00320	Biologic Mother	40	Female	No	.	0	.	0	.	.	0	0	.
	Biologic Father	44	Male	No	.	0	.	0	.	.	0	0	.
	Sibling #1	16	Male	No	1	0	1	0	.	.	0	0	.
	Sibling #2	13	Female	No	.	0	.	0	.	.	0	0	.
	Sibling #3	9	Female	No	.	0	.	0	1	1	0	0	.
329.002.00323	Biologic Mother	44	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	20	Female	No	0	0	0	0	0	0	.	0	0
	Sibling #2	17	Female	No	0	0	0	0	0	0	1	0	0
329.003.00074	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	9	0	9	0	0	0	9	0	0
	Sibling #2	5	Male	No	.	.	.	.	.	.	.	.	.
329.003.00078		.			9	9	.	1	.	9	0	0	0
	Biologic Mother	40	Female	No	9	9	1	.	1	9	0	0	0
	Biologic Father	47	Male	No	9	9	.	.	.	9	0	0	0
	Sibling #1	17	Female	No	9	9	.	.	.	9	0	0	0
	Sibling #2	15	Female	No	9	9	.	.	1	9	0	0	0
	Sibling #3	12	Female	No	9	9	.	.	1	9	0	0	0
329.003.00080	Biologic Mother	43	Female	Yes	.	.	.	.	.	.	.	.	.
	Biologic Father	48	Male	No	0	0	0	0	.	0	0	0	0
	Sibling #1	16	Female	No	0	0	0	0	.	0	0	0	0
	Sibling #2	14	Male	No	0	0	0	0	1	0	0	0	0
329.003.00085	Biologic Mother	42	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	43	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	.	0	1	1	1	1	0	0	0
	Sibling #2	14	Female	No	1	0	.	.	.	.	0	0	0
	Sibling #3	8	Female	No	.	.	.	.	.	.	.	.	.
329.003.00086	Biologic Mother	38	Female	No	0	0	.	.	0	0	.	0	0
	Biologic Father	44	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	0	0	1	1	0	0	1	0	0

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PAROXETINE - PROTOCOL 329

Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.003.00086	Sibling #2	12	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.
329.003.00094	Biologic Mother	55	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	55	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	13	Female	No	0	0	0	0	0	0	0	0	0
329.003.00252	Biologic Mother	42	Female	No	1	0	.	0	.	9	0	0	0
	Biologic Father	45	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	14	Female	No	.	0	1	0	1	9	0	0	0
329.003.00291	Biologic Mother	38	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	35	Male	No	0	0	1	.	.	.	.	0	0
	Sibling #1	13	Female	No	0	0	.	1	.	1	1	0	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	8	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #4	17	Female	No	.	.	.	.	.	.	.	.	.
	Child #2	.			0	0	.	.	1	.	.	0	0
329.003.00315	Biologic Mother	52	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	52	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	16	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #2	14	Female	No	.	.	.	.	.	.	.	.	.
329.003.00316	Biologic Mother	40	Female	No	0	0	.	.	1	1	1	0	0
	Biologic Father	38	Male	No	0	0	.	.	.	.	.	0	0
	Sibling #1	18	Male	No	0	0	1	1	1	1	1	0	0
	Sibling #2	16	Female	No	0	0	1	.	.	.	.	0	0
	Sibling #3	10	Female	No	0	0	.	.	1	1	.	0	0
	Sibling #4	6	Female	No	.	.	.	.	.	.	.	.	.
329.004.00016	Biologic Mother	46	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	46	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	22	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	17	Male	No	0	0	0	0	0	0	0	0	0
329.004.00018	Biologic Mother	42	Female	No	.	.	.	0	.	.	0	1	0
	Biologic Father	49	Male	No	.	.	.	0	.	.	0	.	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.004.00018	Sibling #1	17	Female	No	1	1	1	0	.	.	0	.	0
	Sibling #2	14	Male	No	.	.	.	0	1	1	0	.	0
329.004.00020	Biologic Mother	38	Female	No	0	.	.	0	0	.	.	.	0
	Biologic Father	45	Male	No	0	.	.	0	0	.	.	.	0
	Sibling #1	18	Male	No	0	.	.	0	0	.	1	.	0
	Sibling #2	14	Female	No	0	.	1	0	0	.	1	1	0
329.004.00213	Biologic Mother	45	Female	No	9	.	9	.	9	.	.	9	0
	Biologic Father	52	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	15	Female	No	9	.	9	.	9	.	1	9	0
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.
329.005.00001	Biologic Mother	41	Female	No	0	0	0	0	0	0	.	.	0
	Biologic Father	45	Male	No	0	0	0	0	0	0	.	1	0
	Sibling #1	19	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	17	Male	No	0	0	0	0	0	0	.	.	0
	Sibling #3	16	Female	No	0	0	0	0	0	0	1	.	0
329.005.00005	Biologic Mother	40	Female	No	0	0	.	0	.	.	0	0	0
	Biologic Father	46	Male	No	0	0	.	0	.	.	0	0	0
	Sibling #1	13	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	11	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	0	0	1	0	1	1	0	0	0
329.005.00010	Biologic Mother	45	Female	No	0	0	0	0	0	0	.	0	0
	Biologic Father	47	Male	No	0	0	0	0	0	0	.	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	21	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	20	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #4	16	Female	No	0	0	0	0	0	0	.	0	0
	Sibling #5	15	Female	No	0	0	0	0	0	0	1	0	0
	Child #1	12	Male	No	0	0	0	0	0	0	.	0	0
329.005.00012	Biologic Mother	41	Female	No	.	.	0	0	0	0	.	0	0
	Biologic Father	44	Male	No	.	.	0	0	0	0	.	0	0
	Sibling #1	18	Male	No	1	1	0	0	0	0	1	0	0
	Sibling #2	14	Female	No	.	.	0	0	0	0	.	0	0
329.005.00111	Biologic Mother	36	Female	No	0	0	0	0	0	0	0	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.005.00111	Biologic Father	40	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	18	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #3	13	Male	No	.	.	.	.	.	.	.	.	.
329.005.00114	Biologic Mother	47	Female		.	.	.	0	0	0	0	1	0
	Biologic Father	55	Male		1	1	.	0	0	0	0	.	0
	Sibling #1	22	Male	No	.	.	1	0	0	0	0	.	0
	Sibling #2	16	Male	No	.	.	1	0	0	0	0	.	0
	Sibling #3	25	Female	No	.	.	1	0	0	0	0	.	0
329.005.00115	Biologic Mother	41	Female	Yes	0	0	.	.	.	.	.	0	0
	Biologic Father	0	Male	Yes	0	0	.	.	.	.	.	0	0
	Sibling #1	25	Male	No	0	0	1	1	.	.	1	0	0
	Sibling #2	18	Female	No	0	0	1	1	1	1	1	0	0
	Sibling #3	17	Male	No	0	0	1	1	.	.	.	0	0
329.005.00120	Biologic Mother	36	Female	No	0	0	1	1	1	1	1	1	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	13	Male	No	0	0	.	.	.	.	.	.	0
	Sibling #2	9	Male	No	0	0	.	.	.	1	.	.	0
329.005.00253	Biologic Mother	44	Female	No	0	0	0	0	.	.	.	0	0
	Biologic Father	44	Male	No	0	0	0	0	.	.	.	0	0
	Sibling #1	20	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	16	Female	No	0	0	0	0	.	.	1	0	0
	Sibling #3	10	Male	No	0	0	0	0	1	1	.	0	0
329.005.00254	Biologic Mother	41	Female	No	.	.	.	.	.	.	.	0	0
	Biologic Father	45	Male	No	.	.	1	1	.	.	1	0	0
	Sibling #1	16	Female	No	.	.	1	.	1	.	.	0	0
	Sibling #2	12	Female	No	1	1	.	.	1	1	.	0	0
	Sibling #3	9	Male	No	.	.	.	.	.	.	.	0	0
329.005.00293	Biologic Mother	42	Female	No	.	.	1	0	.	.	.	0	0
	Biologic Father	41	Male	No	.	.	.	0	.	.	.	0	0
	Sibling #1	16	Female	No	.	.	.	0	.	.	1	0	0
	Sibling #2	14	Female	No	.	.	1	0	1	.	.	0	0
	Sibling #3	7	Male	No	1	1	.	0	1	1	.	0	0
	Sibling #4	12	Male	No	.	.	.	0	1	1	.	0	0

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.005.00293	Child #1	1	Male	No	.	.	.	.	.	.	.	.	.
	Child #2	0	Female	No	.	.	.	.	.	.	.	.	.
329.005.00298	Biologic Mother	42	Female	No	0	0	0	0	.	.	0	0	0
	Biologic Father	44	Male	No	0	0	0	0	.	.	0	0	0
	Sibling #1	14	Female	No	0	0	0	0	.	.	0	0	0
	Sibling #2	13	Female	No	0	0	0	0	1	1	0	0	0
	Sibling #3	8	Male	No	0	0	0	0	.	.	0	0	0
	Sibling #4	6	Male	No	0	0	0	0	.	.	0	0	0
329.005.00331	Biologic Mother	38	Female	No	.	.	1	1	9	9	0	.	0
	Biologic Father	48	Male	Unknown	.	.	1	1	9	9	0	1	0
	Sibling #1	15	Female	No	.	.	.	.	9	9	0	.	0
	Sibling #2	11	Female	No	1	1	.	.	9	9	0	.	0
329.005.00334	Biologic Mother	43	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	44	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	15	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #2	13	Female	No	0	0	0	0	0	0	0	0	0
329.006.00037	Biologic Mother	59	Female	No	1	1	.	9	.	9	9	0	0
	Biologic Father	55	Male	No	1	.	1	9	1	9	9	0	0
	Sibling #1	39	Male	No	1	1	1	9	.	9	9	0	0
	Sibling #2	36	Female	No	.	.	.	9	.	9	9	0	0
	Sibling #3	17	Female	No	1	1	.	9	1	9	9	0	0
329.006.00042	Biologic Mother	40	Female	No	0	.	.	0	.	.	0	0	.
	Biologic Father	43	Male	No	0	.	1	0	1	1	0	0	.
	Sibling #1	18	Male	No	0	.	.	0	.	.	0	0	.
	Sibling #2	16	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Male	No	0	.	.	0	1	1	0	0	.
	Sibling #4	7	Female	No	0	.	.	0	.	.	0	0	.
329.006.00259	Biologic Mother	49	Female	No	.	.	0	.	0	.	0	0	.
	Biologic Father	53	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Male	No	1	1	0	.	0	.	0	0	.
	Sibling #2	15	Male	No	1	1	0	.	0	.	0	0	.
	Sibling #3	10	Female	No	.	.	0	.	0	.	0	0	.
329.007.00141	Biologic Mother	32	Female	No	0	.	1	0	0	.	1	1	0

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Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.007.00141	Biologic Father	32	Male	No	0	.	.	0	0	.	.	.	0
	Sibling #1	13	Male	No	0	.	.	0	0	.	.	.	0
	Sibling #2	9	Female	Yes	0	.	.	0	0	.	.	.	0
329.007.00144	Biologic Mother	28	Female	No	0	.	1	1	.	.	1	0	.
	Biologic Father	39	Male	No	0	.	1	1	1	1	1	0	.
	Sibling #1	12	Female	No	0	.	.	.	.	.	.	0	.
329.007.00266	Biologic Mother	33	Female	No	0	.	1	9	.	.	0	1	0
	Biologic Father	34	Male	No	0	.	.	9	.	.	0	.	0
	Sibling #1	12	Female	No	0	.	.	9	1	1	0	.	0
	Sibling #2	10	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	9	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #4	1	Male	No	.	.	.	.	.	.	.	.	.
329.007.00267	Biologic Mother	46	Female	No	0	.	1	.	.	.	.	0	.
	Biologic Father	46	Male	No	0	.	1	.	.	.	.	0	.
	Sibling #1	16	Male	No	0	.	1	1	1	1	1	0	.
329.007.00311	Biologic Mother	44	Female	No	.	0	.	.	.	.	0	0	.
	Biologic Father	62	Male	No	.	0	.	.	.	.	0	0	.
	Sibling #1	18	Female	No	.	0	1	.	.	.	0	0	.
	Sibling #2	15	Male	No	1	0	1	.	1	.	0	0	.
	Sibling #3	13	Male	No	.	0	.	.	1	1	0	0	.
329.008.00158		.			0	0	0	0	0	0	0	0	0
	Biologic Mother	47	Female	No	0	0	0	0	0	0	0	0	0
	Biologic Father	49	Male	No	0	0	0	0	0	0	0	0	0
	Sibling #1	24	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	18	Female	No	0	0	0	0	0	0	0	0	0
	Sibling #3	16	Female	No	0	0	0	0	0	0	0	0	0
	Child #2	.			0	0	0	0	0	0	0	0	0
329.008.00162	Biologic Mother	46	Female	No	1	0	.	.	.	.	.	1	0
	Biologic Father	41	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	27	Male	No	1	0	1	1	1	1	1	.	0
329.008.00191	Biologic Mother	43	Female	No	1	.	0	0	.	.	0	0	0
	Biologic Father	45	Male	No	.	.	0	0	.	.	0	0	0
	Sibling #1	17	Female	No	.	.	.	.	.	.	.	.	.

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.008.00191	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	10	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #4	.			.	.	0	0	1	1	0	0	0
329.009.00128	Biologic Mother	50	Female	No	0	0	9	0	.	.	0	0	0
	Biologic Father	49	Male	No	0	0	9	0	.	.	0	0	0
	Sibling #1	23	Male	No	0	0	9	0	.	.	0	0	0
	Sibling #2	13	Male	No	0	0	9	0	1	1	0	0	0
	Sibling #3	10	Female	No	0	0	9	0	.	.	0	0	0
329.009.00129	Biologic Mother	42	Female	No	0	.	0	.	1	1	0	1	0
	Biologic Father	47	Male	No	0	.	0	.	1	.	0	.	0
	Sibling #1	16	Male	No	0	.	0	.	1	1	0	.	0
	Sibling #2	12	Female	No	0	.	0	.	1	1	0	.	0
329.009.00135	Biologic Mother	48	Female	No	0	0	.	0	0	.	.	0	.
	Biologic Father	48	Male	No	0	0	1	0	0	.	1	0	.
	Sibling #1	17	Female	No	0	0	.	0	0	.	.	0	.
329.009.00136	Biologic Mother	39	Female	No	.	.	.	.	.	.	.	0	.
	Sibling #6	15	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #7	14	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #8	14	Female	No	1	1	.	.	.	.	.	0	.
	Sibling #9	13	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	48	Male	No	.	.	1	1	1	1	1	0	.
	Sibling #1	26	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #3	23	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #4	18	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #5	16	Female	No	.	.	1	1	1	1	1	0	.
329.009.00169	Biologic Mother	27	Female	No	0	.	.	.	.	.	.	.	0
	Biologic Father	32	Male	No	0	.	1	.	1	1	1	.	0
	Sibling #1	13	Male	No	0	.	.	.	1	1	.	1	0
	Sibling #2	10	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	5	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #4	0	Male	No	.	.	.	.	.	.	.	.	.
329.009.00174	Biologic Mother	44	Female	No	.	.	.	0	.	.	0	0	.
	Biologic Father	48	Male	No	.	.	.	.	.	.	.	.	.

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Appendix B.6

Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.009.00174	Sibling #1	20	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	26	Male	No	.	.	1	0	.	.	0	0	.
	Sibling #3	15	Female	No	1	1	.	0	1	1	0	0	.
329.009.00197	Biologic Mother	29	Female	No	.	.	1	.	0	.	.	0	.
	Biologic Father	31	Male	No	.	.	1	.	0	.	1	0	.
	Sibling #1	12	Male	No	.	.	.	.	0	.	.	0	.
	Sibling #2	4	Female	No	1	1	.	.	0	.	.	0	.
	Sibling #3	0	Female	No	.	.	.	.	.	.	.	.	.
329.009.00198	Biologic Mother	34	Female	No	.	.	.	.	.	.	.	1	0
	Biologic Father	35	Male	No	.	.	.	.	.	.	.	.	0
	Sibling #1	17	Female	No	1	1	1	1	1	1	1	1	0
	Sibling #2	15	Female	No	.	.	.	.	.	.	.	.	0
	Sibling #3	13	Female	No	.	.	.	.	.	.	1	.	0
329.009.00200	Biologic Mother	49	Female	No	0	.	.	0	.	.	.	0	.
	Biologic Father	53	Male	No	0	.	.	0	1	1	1	0	.
	Sibling #1	17	Female	No	0	.	1	0	1	1	.	0	.
	Sibling #2	16	Male	No	.	.	.	.	.	.	.	.	.
329.009.00202	Biologic Mother	40	Female	No	0	.	.	.	.	.	.	.	0
	Biologic Father	41	Male	No	0	.	.	.	.	.	.	.	0
	Sibling #1	19	Male	No	0	.	1	1	.	.	1	1	0
	Sibling #2	15	Female	No	0	.	1	.	.	.	.	.	0
	Sibling #3	14	Male	No	0	.	.	.	1	1	.	.	0
329.009.00237	Biologic Mother	43	Female	No	0	0	.	.	.	.	.	0	0
	Sibling #6	9	Female	No	0	0	.	.	.	.	.	0	0
	Biologic Father	44	Male	No	0	0	.	.	.	.	.	0	0
	Sibling #1	21	Male	No	0	0	.	.	.	.	.	0	0
	Sibling #2	19	Female	No	0	0	.	.	.	.	.	0	0
	Sibling #3	17	Male	No	0	0	1	1	1	.	1	0	0
	Sibling #4	12	Male	No	0	0	.	.	.	.	.	0	0
	Sibling #5	10	Male	No	0	0	.	.	1	1	.	0	0
329.009.00238	Biologic Mother	42	Female	No	1	1	0	0	.	0	0	0	0
	Biologic Father	42	Male	No	.	.	0	0	.	0	0	0	0
	Sibling #1	21	Male	Yes	.	.	0	0	1	0	0	0	0
	Sibling #2	16	Female	Yes	.	.	0	0	1	0	0	0	0

0 = NO; 1 = YES; 9 = DON'T KNOW

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Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
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Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.009.00238	Sibling #3	9	Female	Yes	.	.	0	0	1	0	0	0	0
329.009.00276	Biologic Mother	30	Female	No	0	.	1	1	.	0	0	0	.
	Biologic Father	32	Male	No	0	.	.	.	.	0	0	0	.
	Sibling #1	13	Male	No	0	.	.	.	1	0	0	0	.
329.009.00302	Biologic Mother	40	Female	No	1	.	0	.	.	0	0	0	.
	Biologic Father	41	Male	No	.	.	0	.	.	0	0	0	.
	Sibling #1	17	Male	No	.	.	0	.	1	0	0	0	.
	Sibling #2	10	Female	No	1	.	0	.	.	0	0	0	.
329.009.00306	Biologic Mother	28	Female	Yes	0	.	1	0	1	0	0	0	.
	Biologic Father	.	Male	Unknown	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	.	.	0	.	0	0	0	.
329.009.00312	Biologic Mother	48	Female	No	0	0	0	0	0	0	0	1	0
	Biologic Father	55	Male	No	0	0	0	0	0	0	0	.	0
	Sibling #1	17	Female	No	0	0	0	0	0	0	0	.	0
329.009.00327	Biologic Mother	40	Female	No	0	0	.	.	0	0	.	0	0
	Biologic Father	42	Male	No	0	0	1	1	0	0	.	0	0
	Sibling #1	18	Male	No	0	0	1	1	0	0	1	0	0
	Sibling #2	16	Female	No	0	0	1	1	0	0	.	0	0
329.009.00330	Biologic Mother	33	Female	No	0	0	.	.	.	.	.	.	0
	Biologic Father	36	Male	No	0	0	.	.	.	.	.	.	0
	Sibling #1	14	Female	No	0	0	.	.	.	.	1	.	0
	Sibling #2	12	Male	No	0	0	1	1	1	1	1	1	0
	Sibling #3	9	Male	No	0	0	.	.	.	.	.	.	0
329.010.00183	Biologic Mother	39	Female	No	.	.	.	.	.	.	.	.	.
	Biologic Father	45	Male	No	.	.	0	.	.	.	.	.	0
	Sibling #1	16	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	14	Male	No	1	1	0	.	1	1	.	1	0
	Sibling #3	13	Female	No	.	.	0	.	.	.	1	.	0
329.010.00263	Biologic Mother	40	Female	No	.	.	.	.	.	.	.	.	0
	Biologic Father	60	Male	No	.	.	.	.	.	.	.	.	0
	Sibling #1	21	Male	No	.	.	1	1	.	.	1	1	0
	Sibling #2	18	Male	No	1	1	.	.	1	1	.	.	0

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Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.010.00263	Sibling #3	15	Female	No	.	.	1	.	.	.	1	.	0
329.010.00277	Biologic Mother	35	Female	No	0	.	0	.	.	.	.	0	.
	Biologic Father	38	Male	No	0	.	0	.	.	.	.	0	.
	Sibling #1	14	Female	No	0	.	0	.	1	1	1	0	.
329.010.00282	Biologic Mother	45	Female	No	0	.	0	.	.	.	0	0	.
	Biologic Father	46	Male	No	0	.	0	.	.	.	0	0	.
	Sibling #1	18	Female	No	0	.	0	.	.	.	0	0	.
	Sibling #2	15	Female	No	0	.	0	.	1	1	0	0	.
	Sibling #3	12	Male	No	0	.	0	.	1	1	0	0	.
329.011.00164	Biologic Mother	43	Female	No	0	.	.	.	0	.	0	0	.
	Biologic Father	43	Male	No	0	.	.	.	0	.	0	0	.
	Sibling #1	24	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #2	20	Male	No	0	.	.	.	0	.	0	0	.
	Sibling #3	18	Male	No	0	.	1	.	0	.	0	0	.
	Sibling #4	15	Male	No	0	.	1	1	0	.	0	0	.
329.011.00210	Biologic Mother	32	Female	No	1	1	1	1	.	.	0	0	0
	Biologic Father	41	Male	No	.	.	.	.	.	.	0	0	0
	Sibling #1	14	Female	No	.	.	.	.	1	.	0	0	0
	Sibling #2	10	Male	No	.	.	.	.	1	1	0	0	0
329.011.00285	Biologic Mother	42	Female	No	0	0	1	.	.	0	.	0	0
	Biologic Father	44	Male	No	0	0	1	1	.	0	1	0	0
	Sibling #1	16	Male	No	0	0	1	.	1	0	.	0	0
	Sibling #2	13	Female	No	.	.	.	.	.	.	.	.	.
329.011.00287	Biologic Mother	41	Female	No	0	0	.	0	1	1	.	.	0
	Biologic Father	40	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	16	Female	No	0	0	1	0	.	.	1	1	0
	Sibling #2	14	Female	No	0	0	.	0	.	.	.	1	0
	Sibling #3	10	Female	No	.	.	.	.	.	.	.	.	.
	Sibling #4	4	Male	No	.	.	.	.	.	.	.	.	.
329.012.00027	Biologic Mother	39	Female	No	0	.	1	0	.	.	0	0	.
	Biologic Father	38	Male	No	0	.	.	0	.	.	0	0	.
	Sibling #1	15	Male	No	0	.	.	0	1	1	0	0	.

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Listing of Family History - Epidemiologic by Treatment Group and Patient: Part IV
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Treatment Group=PLACEBO

Patient ID	Family Member	Age	Sex	Deceased	Family History Item Number 27	27B	28	28B	29	29B	30	31	31B
329.012.00217	Biologic Mother	45	Female	No	0	0	.	0	0	0	0	0	0
	Biologic Father	45	Male	No	0	0	.	0	0	0	0	0	0
	Sibling #1	22	Male	No	0	0	.	0	0	0	0	0	0
	Sibling #2	19	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Female	No	0	0	1	0	0	0	0	0	0
329.012.00218	Biologic Mother	46	Female	No	0	.	1	0	0	.	0	0	.
	Biologic Father	46	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #1	17	Female	No	0	.	1	0	0	.	0	0	.
	Sibling #2	14	Male	No	.	.	.	.	.	.	.	.	.
	Sibling #3	14	Male	No	.	.	.	.	.	.	.	.	.
329.012.00224	Biologic Mother	41	Female	No	1	1	.	0	0	0	0	0	0
	Biologic Father	41	Male	No	.	.	.	0	0	0	0	0	0
	Sibling #1	14	Female	No	1	1	.	0	0	0	0	0	0
	Sibling #2	7	Female	No	1	1	1	0	0	0	0	0	0
329.012.00225	Biologic Mother	48	Female	No	.	0	1	0	.	.	0	0	.
	Biologic Father	48	Male	No	.	0	.	0	.	1	0	0	.
	Sibling #1	14	Male	No	1	0	.	0	1	.	0	0	.
	Sibling #2	11	Female	No	.	.	.	.	.	.	.	.	.

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Listing of Medical/Surgical History and Physical Examination
by Treatment Group and Patient
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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.001.00063	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
	ALLERGY POLLEN	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
	PAIN LEFT WRIST(POSSIBLE SPRAIN)	SPRAINS/STRAINS	INJURY/POISONING	CUR	1994
	SLIGHTLY OBESE	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1994
329.001.00065	DIZZINESS UPON CHANGING POSITIONS	DIZZINESS, POSTURAL	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	HAND TREMORS	TREMOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1989
	STOMACH UPSET(NAUSEA)	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	OSGOOD SCHLATTER DISEASE	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1991
329.001.00068	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1993
	FEVER BLISTERS	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	CUR	1990
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
	NAUSEA STOMACH UPSET	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
	INFECTED {BIOPSY MARK RIGHT SUPRACLAVICULAR ARM}	COMPLIC OF MED CARE	INJURY/POISONING	PRV	1991
	LYMPH NODE BIOPSY (ENLARGED NODES)	OPERATION, LYMPH	OPERATIONS	PRV	1991
329.001.00072	STRESS FRACTURE BACK	BONE/CARTIL DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1993
329.001.00121	DECREASED WHITE BLOOD CELL	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1995

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.001.00121	BIRTHMARK REMOVED	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1989
	CHICKEN POX	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	PRV	1987
	CYST REMOVED FROM CHEST	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1981
329.001.00205	SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1984
	FACIAL LACERATIONS{DOG BITE}	OPEN WOUND	INJURY/POISONING	PRV	1986
	PLASTIC SURGERY FOR FACIAL SCARS	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1994
329.001.00206	ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
329.002.00055	ALLERGIES-BEE STING	TOXIC EFFECTS, VENOM	INJURY/POISONING	CUR	1987
	ALLERGY-CAT FUR(MILD)	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1987
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
329.002.00058	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	ATTENTION DEFICIT DISORDER	MENTAL STATUS, IMPAIRED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1983
329.002.00099	SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
329.002.00105	ALLERGIES{CATS,POLLEN}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1990
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	HEARTBURN	HEARTBURN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.002.00242	HEADACHES {RECURRENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.002.00245	MIGRAINE HEADACHES {ACCORDING TO PATIENT}	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
329.002.00319	HEADACHES {FRONTAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.003.00075	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
329.003.00081	HEADACHES{DAILY}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.003.00087	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1994
329.003.00313	OVERWEIGHT	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	
	TUBERCULOSIS	TUBERCULOSIS	INFECTIOUS/PARASITIC DIS	PRV	
329.004.00015	ENURESIS	INCONTINENCE, URINARY	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1990
	URETERS BILATERALLY REEMBEDDED	OPERATION, OTHER URINARY	OPERATIONS	PRV	1990
329.004.00212	ALLERGIES{ENVIRONMENTAL}	ALLERGY, NEC	INJURY/POISONING	CUR	1995
	AMENORRHEA	AMENORRHEA	GENITOURINARY SYST DIS	CUR	1996
329.004.00214	COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
	JOINT PAIN - FLEXIBLE JOINTS	PAIN, JOINT	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
	HEAD LACERATION	OPEN WOUND	INJURY/POISONING	PRV	1987
329.005.00002	CANNABIS USE	DRUG ABUSE	MENTAL DISORD	CUR	1994

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.005.00109	POSTPARTUM - NOT BREAST FEEDING	POSTPARTUM CARE	FAMILY/PERSONAL HISTORY	CUR	1994
	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1979
	BLEEDING ULCER {NOS}	CONDITIONS, OTHER, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993
329.005.00112	BURNING STOMACH	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.005.00119	STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
329.005.00151	BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1989
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991
329.005.00152	BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1985
329.005.00257	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
329.005.00258	OCCULT BLOOD IN URINE - PATIENT MENSTRUATING	HEMATURIA	GENITOURINARY SYST DIS	CUR	1996
	PROTEIN IN URINE - PATIENT MENSTRUATING	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.005.00299	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
	KNEE PAIN {RIGHT-MILD AFTER RUNNING}	PAIN, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
329.005.00333	ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
	TONSILLECTOMY AND ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1990

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.005.00336	BACKACHE	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1997
329.006.00038	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
329.006.00039	HEADACHES-FREQUENT	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
329.006.00260	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
	HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.006.00261	ASTHMA {VERY MILD}	ASTHMA	RESPIRATORY SYST DIS	CUR	1984
	DYSHYDROSIS {MILD ON HAND AND PENIS}	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
	TINEA PEDIS {BOTH FEET}	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1996
329.007.00140	OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	VESICULAR DYSHIDROSIS	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
	TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989
329.007.00142	MILD LYMPHADENOPATHY,LEFT ANTERIOR CERVICAL,PERSISTENT	LYMPHADENOPATHY	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1985
	CAT SCRATCH FEVER	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993
	INGUINAL HERNIA	HERNIA, ABDOMINAL	DIGESTIVE SYST	PRV	1983
	SORE THROAT	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1995
329.007.00145	ELEVATED MONOCYTES	MONOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.007.00145	LOW WHITE BLOOD CELL COUNT	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
	BROKEN LEFT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1991
329.007.00265	ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.007.00268	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
	LYMPH NODE INFECTION{BILATERAL GROIN NODES}	LYMPHADENITIS, ACUTE	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	1991
329.007.00294	BACKACHES	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	RASH, PLANTAR SURFACE RIGHT FOOT	RASH/OTHER SKIN ERUPTION	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
	WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
	10 BONE FUSIONS IN BACK	OPERATION, BONE/JOINT	OPERATIONS	PRV	1995
	ROD PLACEMENT {BACK}	OPERATION, BONE/JOINT	OPERATIONS	PRV	1995
	SCOLIOSIS	DEFORMITY, ACQUIRED	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1995
329.007.00309	"ULCER-LIKE" SYMPTOMS (BURNING, INDIGESTION), NO ULCER	DYSPEPSIA	DIGESTIVE SYST	CUR	1996
	HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	NAUSEA {CHRONIC}	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.007.00310	HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
	TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1994
329.007.00318	ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	PRV	1984
	EUSTACHIAN TUBE {BILATERAL}	OPERATION, EAR	OPERATIONS	PRV	1985
329.008.00157	SURGERY TO REPAIR A HERNIA	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980
329.008.00160	EPIGLOTTITIS	EPIGLOTTITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1990
329.008.00271	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1984
329.008.00275	ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1994
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
329.009.00130	NERVOUS STOMACH	STOMACH/DUODENUM DISORD	DIGESTIVE SYST	CUR	1989
329.009.00131	OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	HEART MURMUR, GRADE 1, ASYMPTOMATIC	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1984
329.009.00133	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993

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329.009.00133	PREMENSTRUAL TENSION(OCCASIONAL)	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993
	SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1985
	FEVER OF UNKNOWN ORIGIN	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993
	STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	PRV	1985
329.009.00138	OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	OCCASIONAL STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
329.009.00170	BILATERAL LEG PAIN:MUSCULAR ORIGIN	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
	OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	SCOLIOSIS	DEFORMITY, ACQUIRED	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1989
329.009.00173	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	UPPER RESPIRATORY TRACT INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1995
329.009.00193	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.009.00196	ALLERGIES TO ASPIRIN	ADVERSE EFF/ANALGESIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
	ALLERGIES TO SULFA DRUGS	ADVERSE EFF/ANTI-INFECT	EXT CAUSES OF INJURY/POISONING	CUR	1995
	ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1995
	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1993
	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

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329.009.00196	MENSTRUAL CRAMPS{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
	OBESITY{MILD}	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
329.009.00201	FEVER	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	CUR	1996
329.009.00204	ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1986
	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1996
329.009.00235	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
	OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	FLU SYMPTOMS	INFLUENZA	RESPIRATORY SYST DIS	PRV	1996
329.009.00240	HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	SLEEP DISTURBANCE	DISTURBANCE, SLEEP, UNSPEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1984
329.009.00303	HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1996
329.009.00304	HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

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329.009.00324	HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
	SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1996
	UNCONSCIOUS AT AGE 1 - HIT HEAD IN FALL	COMA AND STUPOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1984
329.009.00328	BIVENTRICULAR HYPERTROPHY	CARDIOMEGALY	CIRCULATORY SYST	CUR	1996
	HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	STOMACH ACHES {OCCASIONAL}	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
329.009.00329	HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	REPOLARIZATION ON ECG {EARLY}	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	SINUS BRADYCARDIA {MARKED}	BRADYCARDIA	CIRCULATORY SYST	CUR	1996
329.010.00182	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.010.00278	ABDOMINAL PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	POLYCYSTIC OVARY	OVARIAN DYSFUNC	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
	ACUTE PANCREATITIS	PANCREATITIS	DIGESTIVE SYST	PRV	1994
329.010.00280	ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	ASTHMA ATTACK	ASTHMA	RESPIRATORY SYST DIS	PRV	
329.011.00288	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1987

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329.011.00288	PROTEINURIA	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.012.00025	ALLERGIES(SKIN)	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
329.012.00220	ALLERGIC TO SUDAFED	ADVERSE EFF ON AUTONOMIC NS	EXT CAUSES OF INJURY/POISONING	CUR	1984
	ATTENTION DEFICIT HYPERACTIVE DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1987
	BED-WETTING	INCONTINENCE, URINARY	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1986
	BLADDER INFECTIONS	CYSTITIS	GENITOURINARY SYST DIS	PRV	1986
	OBSESSIVE COMPULSIVE SYMPTOMS	NEUROSES	MENTAL DISORD	PRV	1994
	TOURETTES (TIC DISORDER).	TICS	MENTAL DISORD	PRV	1987
329.012.00222	HAYFEVER-LATE SPRING,SUMMER MONTHS ONLY	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994
329.012.00226	MILD RECURRENT HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
	FRACTURE RIGHT LEG	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1988
	SURGERY FOR STRABISMUS	OPERATION, EYE	OPERATIONS	PRV	1983
329.012.00231	ECZEMA	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996

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329.001.00061	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
	INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
	REPEATED SINUS INFECTIONS ABOUT ONE TIME PER MONTH	SINUSITIS, OTHER	RESPIRATORY SYST DIS	CUR	1989
	FOOT CASTED	THERAPY, REHAB	PROCEDURES	PRV	1977
	FOOT TURNED AT BIRTH	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1977
	REPEATED STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	PRV	1978
	RESPIRATORY DIFFICULTIES AT BIRTH	CONDITIONS, PERINATAL	PERINATAL COND	PRV	1977
	TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989
329.001.00066	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
	MILD ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
	MOLE LEFT KNEE-RAISED	NEOPLASMS BENIGN	NEOPLASMS	CUR	1994
	STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
	MOLE EXCISED BELOW UMBILICUS/BENIGN	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1984
	SUTURES IN CHIN	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1980
329.001.00070	ALLERGIC TO CAFFEINE	ADVERSE EFF/PSYCHOTROPICS	EXT CAUSES OF INJURY/POISONING	CUR	1992
	ALLERGIC TO CHOCOLATE	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1992
	ALLERGIC TO MOLD	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1992
	ENLARGED LYMPH NODES	LYMPHADENOPATHY	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991

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329.001.00070	BRUISED FOOT	CONTUSION	INJURY/POISONING	PRV	1990
	BRUISED HAND	CONTUSION	INJURY/POISONING	PRV	1993
	EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1983
	SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1991
	SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1992
	SPRAINED FOOT	SPRAINS/STRAINS	INJURY/POISONING	PRV	1990
329.001.00122	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
	HEAVY PERSPIRATION	HYPERHIDROSIS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	HERNIA REPAIR	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1988
	RIGHT FOOT INFECTION {TOENAILS}	CELLULITIS/ABSCESS	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	1985
329.002.00050	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1991
	INTERMITTENT GLUCOSE(DECREASED)	HYPOGLYCEMIA	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
	HYPOSPADIAS {MALE}	CONG ANOM, GU	ANOMALIES	PRV	1978
	LEFT URETERAL DUPLICATION	CONG ANOM, GU	ANOMALIES	PRV	1978
	RIGHT VESICOURETERAL REFLUX	KIDNEY DISORD	GENITOURINARY SYST DIS	PRV	1978
329.002.00056	MISCARRIAGE	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994
	PREGNANCY	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1994
329.002.00057	HEARTBURN	HEARTBURN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

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329.002.00057	OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	SCHEUERMANN'S KYPHOSIS	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
	STOMACH PROBLEMS	STOMACH/DUODENUM DISORD	DIGESTIVE SYST	CUR	1994
	CHILDHOOD MIGRAINES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	PRV	1984
	CONCUSSION	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1985
	HERNIA OPERATION	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1985
	TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1983
	TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1983
329.002.00100	DEPRESSION	DEPRESSION	MENTAL DISORD	CUR	1995
	HAND TREMOR	TREMOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	SWEATING AT BROW	HYPERHIDROSIS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
329.002.00103	HEADACHES(DAILY)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.002.00104	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
329.002.00243	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	SHAKINESS	NERVOUSNESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	SORE THROAT-TONSILLITIS	TONSILLITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
329.002.00244	HEAVY CRAMPS DUE TO MENSES	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	P&C	1990
	NAUSEA DUE TO MENSES	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	P&C	1990

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329.002.00321	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.003.00073	SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	CUR	1995
329.003.00076	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	
	GLASSES FOR DISTANCE SINCE GRADE 4	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	PRV	1988
	HISTORY FUNCTIONAL HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	
	SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1994
329.003.00090	IRRITABLE BOWEL SYNDROME	DIGESTIVE DISORD, OTHER	DIGESTIVE SYST	CUR	1987
329.003.00093	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1989
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
329.003.00249	CIGARETTE SMOKER	TOBACCO USE	MENTAL DISORD	CUR	
	DYSMENORRHEA	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1991
	NEAR-SIGHTED	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	CUR	
	SCARS LEFT AND RIGHT FOREARM	SCARRING	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	
329.003.00289	ALLERGIES {TO POLLEN, TREES, DUST}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
	DYSMENORRHEA	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993

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329.003.00289	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
	ASTHMA {AS YOUNG CHILD}	ASTHMA	RESPIRATORY SYST DIS	PRV	1981
329.003.00290	NEARSIGHTED	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	CUR	
	SORE THROATS {FREQUENT}	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1994
	TONSILLECTOMY AND ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1994
329.003.00314	PHARYNGITIS	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996
329.003.00317	ALLERGIC RHINITIS	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	
329.004.00013	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
329.004.00215	LOW ENERGY	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.005.00003	EAR INFECTION	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1994
	ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1988
	HISTORY OF HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	
329.005.00006	HISTORY OF ENVIRONMENTAL ALLERGIES-DUST	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	
	HISTORY OF ENVIRONMENTAL ALLERGIES-POLLEN	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	
	HISTORY OF RECURRENT TONSILLITIS	TONSILS/ADENOIDS DIS	RESPIRATORY SYST DIS	PRV	

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329.005.00006	STATUS POST MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1994
329.005.00007	QUESTIONABLE OVARIAN CYST	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
329.005.00009	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	HAY FEVER	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	1984
329.005.00110	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1984
329.005.00113	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1985
	ABORTION	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994
329.005.00117	HISTORY OF CHRONIC OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1979
	MILD HEARING LOSS	HEARING LOSS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1979
	STATUS POST HIP SURGERY	OPERATION, BONE/JOINT	OPERATIONS	PRV	1989
329.005.00118	GYNECOMASTIA	GYNECOMASTIA	GENITOURINARY SYST DIS	CUR	
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.005.00153	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
	COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
	INCREASED LYMPHOCYTES	LYMPHOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
	INCREASED NEUTROPHIL SEGS	LEUCOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
	TRACE PROTEIN IN URINE	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.005.00255	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1986
	ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
	URINARY TRACT INFECTION	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	CUR	1996
	STRABISMUS	EYE DISORD, OTHER	NERVOUS SYST/SENSE ORGAN DIS	PRV	
329.005.00256	DECREASED LYMPHOCYTES	LYMPHOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
329.005.00295	BODY ACHES	PAIN, GENERAL	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
	DIARRHEA	DIARRHEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	FLU	INFLUENZA	RESPIRATORY SYST DIS	CUR	1996
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.005.00335	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1997
329.006.00040	ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1985
	OVARIAN CYST	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
329.006.00041	RIGHTWARD AXIS ON ELECTROCARDIOGRAM	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.007.00139	FRACTURED RIGHT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	CUR	1995
329.007.00143	COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1995
	MILD OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1994

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.007.00143	STATUS POST HOSPITALIZATION FOR DEPRESSION	DEPRESSION	MENTAL DISORD	PRV	1994
	URINARY TRACT INFECTION	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	PRV	1994
329.007.00146	COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
	HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	JOINT PAIN{RIGHT WRIST}	PAIN, JOINT	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
	SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
	SWELLING{LEFT CALF}	SWELLING, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
329.007.00269	HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	RECURRENT SINUSITIS{SEASONAL ALLERGIES}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996
	UPSET STOMACH	DYSPEPSIA	DIGESTIVE SYST	CUR	1996
	ACHILLES TENDON CASTED TIMES 6 WEEKS	THERAPY, REHAB	PROCEDURES	PRV	1994
	BILATERAL HERNIA REPAIR	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980
	SEVER'S DISEASE	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1994
329.007.00270	FOOD ALLERGIES{MILK PRODUCTS}	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1985
	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
	RINGWORM	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1996

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329.007.00270	STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	CUR	1996
	BROKEN LEFT FEMUR{FELL OUT OF TREE}	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1994
329.007.00307	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
	INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1993
	SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1995
329.007.00308	URINE {1+ PROTEIN}	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	SPINAL MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1982
329.008.00161	NECROTIZING ENTEROCOLITIS AT BIRTH-NO COMPLICATIONS	CONDITIONS, PERINATAL	PERINATAL COND	PRV	1978
329.008.00187	COLITIS	ENTERITIS/COLITIS	DIGESTIVE SYST	CUR	1981
	OCCASIONAL MILD HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	VAGINAL WARTS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	CUR	1995
329.008.00192	ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	PRV	1996
329.008.00272	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1996
329.008.00273	TEMPOROMANDIBULAR JOINT PAIN	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1996
329.009.00127	INITIAL INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

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329.009.00127	SEPARATION ANXIETY	STRESS REACTION	MENTAL DISORD	CUR	1995
329.009.00132	HEADACHES(OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
329.009.00134	DERMATOLOGICAL FUNGUS	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1995
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993
	OCCASIONAL STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
	SPRAINED ARM MUSCLES	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995
329.009.00171	ALLERGY TO IODINE	ADVERSE EFF/OTHER DRUG	EXT CAUSES OF INJURY/POISONING	CUR	1994
	PREGNANCY	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1994
	SEXUAL ASSAULT{STATUS POST,NO POST-TRAUMATIC STRESS DISORDER SYNDROME}	RAPE	EXT CAUSES OF INJURY/POISONING	PRV	1992
	SUICIDE ATTEMPT{NOT IN CURRENT EPISODE}	SUICIDE	EXT CAUSES OF INJURY/POISONING	PRV	1994
	WEIGHT LOSS{52LBS.-PLANNED}	WEIGHT LOSS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1995
	{CHILDBIRTH}	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994
329.009.00172	OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.009.00194	ALLERGIES TO MILK	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1993
	ANKLE PAIN{SECONDARY TO SURGICAL CORRECTION RIGHT FOOT(CLUB)}	OPERATION, MUSCLE/TENDON	OPERATIONS	CUR	1984

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329.009.00194	HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	MYALGIA{UNSPECIFIED}	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
329.009.00195	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
	SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1995
329.009.00199	ALLERGY TO CECLOR	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	MUSCULAR NECK PAIN	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
329.009.00203	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
	LEFT AXIS DEVIATION	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994
329.009.00236	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
	STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.009.00239	MIGRAINES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1991
	SINUS ARRHYTHMIA	ARRHYTHMIA	CIRCULATORY SYST	CUR	1996
	SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	CUR	1996
	DRUG ALLERGY - PENICILLIN	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	P&C	1995

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329.009.00239	MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995
329.009.00262	ENCOPRETIC	PSYCHOGENIC PHYSIOL DYSFUNC	MENTAL DISORD	CUR	1993
	EYE INFECTION (LEFT AND RIGHT EYE)	EYE DISORD, OTHER	NERVOUS SYST/SENSE ORGAN DIS	CUR	1997
	OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
	STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
	CHRONIC EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1986
	TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1986
329.009.00264	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	ASTHMA - NO PROBLEMS FOR 2 YRS	ASTHMA	RESPIRATORY SYST DIS	PRV	1991
329.009.00301	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1983
	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	ASTHMA ATTACKS{HOSPITALIZED}	ASTHMA	RESPIRATORY SYST DIS	PRV	1990
	BROKEN LEFT ARM{X2}	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1988
	BROKEN RIGHT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1989
329.009.00325	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
	HEADACHE {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995

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329.009.00325	NAUSEA {STOMACH UPSET}	DYSPEPSIA	DIGESTIVE SYST	CUR	1995
329.009.00326	COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996
329.010.00279	THYROID-STIMULATING HORMONE DECREASE	THYROID FUNCTION, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	WBC DECREASE	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
329.010.00281	BILATERAL TUBE PLACEMENT IN EARS	OPERATION, EAR	OPERATIONS	PRV	1984
	CHICKEN POX	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	PRV	1987
	JAUNDICE DUE TO ABO INCOMPATIBILTY {NOS}	COMPLIC OF MED CARE	INJURY/POISONING	PRV	1983
	REMOVAL OF BAKER'S CYST FROM RIGHT LEG	OPERATION, SOFT TISSUE	OPERATIONS	PRV	1989
329.011.00163	MIGRAINE HEADACHES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1989
	STRESS INDUCED ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1994
	TEMPOROMANDIBULAR JOINT SYNDROME	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1994
	CORRECTIVE SURGERY(BOTH EYES)FOR STRABISMUS	OPERATION, EYE	OPERATIONS	PRV	1985
329.011.00208	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
	ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989
	TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989
329.011.00209	ALLERGIES {ENVIRONMENTAL}	ALLERGY, NEC	INJURY/POISONING	CUR	1996

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329.011.00209	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.011.00284	LOW NEUTROPHILS	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
	LOW WHITE BLOOD CELLS	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
	CROUP	LARYNGITIS/TRACH, ACUTE	RESPIRATORY SYST DIS	PRV	1979
	PECTUS EXCAVATUM	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1978
	PSEUDOMONAS INFECTION	BACT DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1988
329.011.00286	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
	SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	
329.012.00219	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1985
329.012.00221	HEADACHES {MODERATE}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1989
329.012.00223	ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1996
	BENIGN LUMP LEFT FOOT	SWELLING, MASS, LOCALIZED	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	BRONCHOSPASM	RESP DIS, OTHER	RESPIRATORY SYST DIS	CUR	1996
	HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	FATTY INFILTRATION OF THE LIVER {CLINICALLY NORMAL}	LIVER DISORD	DIGESTIVE SYST	PRV	1996
	HISTORY OF HIGH AVERAGE/BORDERLINE HIGH BLOOD PRESSURE	BLOOD PRESSURE, ELEVATED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1995

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.012.00223	PYELONEPHRITIS	KIDNEY INFECT	GENITOURINARY SYST DIS	PRV	1995
	RADIAL FRACTURE	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
	URINARY TRACT INFECTION'S {FREQUENT}	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	PRV	1984
329.012.00230	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1993

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.001.00062	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1979
	STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1988
329.001.00064	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
	SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1994
	BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
	BROKEN RIGHT WRIST	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
	COLD(HEAD)	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1994
	EAR INFECTION	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1983
	MYRINGOTOMY	OPERATION, EAR	OPERATIONS	PRV	1983
	PNEUMONIA	PNEUMONIA, OTHER	RESPIRATORY SYST DIS	PRV	1981
329.001.00069	PHARYNGITIS	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1995
	RIGHT OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
	SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1985
	FEVER	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994
	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994
	PNEUMONIA	PNEUMONIA, OTHER	RESPIRATORY SYST DIS	PRV	1994
329.001.00071	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
	FLU	INFLUENZA	RESPIRATORY SYST DIS	PRV	1995
	PRESSURE EQUALIZATION TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1983
	SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1995

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.001.00123	BACTERIAL VAGINAL RASH	VAGINITIS	GENITOURINARY SYST DIS	CUR	1995
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1992
	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1993
	BROKEN ANKLE	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
	BROKEN WRIST	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1988
	FEMORAL EPIPHYSIS RIGHT HIP{JOINT DISORDER}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1989
	HIP LEFT FEMORAL EPIPHYSIS{JOINT DISORDER}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1990
	SURGERY PINNING LEFT HIP	OPERATION, BONE/JOINT	OPERATIONS	PRV	1990
	SURGERY REMOVAL OF PINS IN RIGHT,LEFT HIPS	OPERATION, BONE/JOINT	OPERATIONS	PRV	1991
	SURGERY-PLACEMENT OF CANNULATED LOG SCREW RIGHT HIP	OPERATION, BONE/JOINT	OPERATIONS	PRV	1989
329.001.00207	OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
	MUSCLE STRAIN	SPRAINS/STRAINS	INJURY/POISONING	PRV	1996
	SORE THROAT WITH COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996
329.002.00049	BILATERAL HERNIORRHAPHY	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980
329.002.00059	HISTORY OF MITRAL VALVE PROLAPSE-NO FUNCTIONAL IMPAIRMENT	MITRAL VALVE DISORD	CIRCULATORY SYST	CUR	1987

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.002.00097	HEADACHES,DAILY 2-3 TIMES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	UPPER RESPIRATORY INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1994
329.002.00101	HISTORY OF APNEA AND RESUSCITATION IN FIRST YEAR OF LIFE(SIDS)	SUDDEN INFANT DEATH SYNDROME	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1979
329.002.00107	EPIGASTRIC DISTRESS	DYSPEPSIA	DIGESTIVE SYST	CUR	1995
	FAINTING{OCCASIONAL}	SYNCOPE AND COLLAPSE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	MISSED MENSES	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
329.002.00241	ALLERGIES {TO PENICILLIN}	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	1991
	ALLERGIES {TO POLLEN, POULTRY DUST}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1991
	NASAL CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1996
	SINUS RHYTHM ALTERNATING WITH ECTOPIC ATRIAL RHYTHM	EXTRASYSTOLES, ATRIAL	CIRCULATORY SYST	CUR	1996
329.002.00246	GASTROINTESTINAL DISTRESS	GASTROINTEST PROB, NEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	{PAST} ALCOHOL USE	ALCOHOL INGESTION, OTHER	FAMILY/PERSONAL HISTORY	PRV	1994
	{PAST} MARIJUANA USE	DRUG ABUSE	MENTAL DISORD	PRV	1994
329.002.00320	BILATERAL KNEE PAIN	PAIN, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995

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329.002.00320	CHRONIC BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
	DIZZINESS	DIZZINESS AND GIDDINESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
	STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	FRACTURED LEFT FEMUR	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
	FRACTURED RIGHT TIBIA	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
	FRACTURED SKULL	FRACTURE, SKULL	INJURY/POISONING	PRV	1990
	LYME DISEASE	ARTHROPOD-BORNE DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995
	SPRAINED WRIST	SPRAINS/STRAINS	INJURY/POISONING	PRV	1990
	SUBDURAL HEMATOMA	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1990
329.002.00323	BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
	ELEVATED CHOLESTEROL	CHOLEST/TRIGLYCERIDE, ELEVATED	ENDOCR/METAB/IMMUNITY DISORD	PRV	
	HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993
329.003.00074	STATUS POST ACUTE APPENDICITIS	APPENDICITIS	DIGESTIVE SYST	PRV	1994
329.003.00080	FATIGUE	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
329.003.00085	EKG SHOWS RAPID HEART RATE DUE TO PREVIOUS BLOOD DRAWING-NORMAL	TACHYCARDIA, UNSPEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1988

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.003.00086	ABDOMINAL PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	RHINORRHEA	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1993
329.003.00094	ALLERGY TO PENICILLIN {PATIENT GETS A RASH}	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	
	SKIN CUTS MULTIPLE {SUPERFICIAL ON LEFT FOREARM}	OPEN WOUND	INJURY/POISONING	CUR	1995
	SKIN CUTS MULTIPLE {SUPERFICIAL ON RIGHT THIGH}	OPEN WOUND	INJURY/POISONING	CUR	1995
	TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989
329.003.00251	MYRINGOTOMY {TUBE PLACEMENT}	OPERATION, EAR	OPERATIONS	.	
	DIZZINESS	DIZZINESS AND GIDDINESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	SHORTNESS OF BREATH	DYSPNEA, OTHER	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.003.00252	ALLERGIC TO SULFA DRUGS	ADVERSE EFF/ANTI-INFECT	EXT CAUSES OF INJURY/POISONING	CUR	
	ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	
	FACIAL CYSTIC ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	
	MURMUR {I/VI SYSTOLIC EJECTION MURMUR}	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
329.004.00016	ALLERGIES-ANIMAL HAIR & POLLENS	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1988
329.004.00018	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991

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329.004.00018	UPPER RESPIRATORY TRACT INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1995
329.004.00020	ANXIETY	ANXIETY	MENTAL DISORD	CUR	1995
329.004.00213	BACKACHES	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.005.00001	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
329.005.00010	DISLOCATED RIGHT HIP AT BIRTH	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1978
	HERNIA REPAIR AT AGE 7	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1987
	RUPTURED RIGHT EAR DRUM AT BIRTH	CONGEN ANOM, HEAD/NECK	ANOMALIES	PRV	1978
329.005.00012	TOXOPLASMOSIS{RIGHT EYE}	INFECT/PARASIT DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1994
329.005.00114	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1993
329.005.00115	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1984
329.005.00120	RASH ON ARMS AND CHEST{FOLLICULITIS}	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
329.005.00253	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
	BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	CUR	1996

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.005.00253	POSITIVE URINE DRUG SCREEN FOR CODEINE AND MORPHINE.	DRUG DEPEND	MENTAL DISORD	CUR	1996
329.005.00254	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.005.00293	RBC IN URINE POST PARTUM	HEMATURIA	GENITOURINARY SYST DIS	CUR	1997
	SQUAMOUS CELLS IN URINE POST PARTUM	URINARY CASTS/WBC'S	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
	2 VAGINAL DELIVERY BIRTHS	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1996
329.005.00298	ALLERGIES {SEASONAL}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1988
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
329.005.00331	25% HEARING LOSS RIGHT EAR	HEARING LOSS	NERVOUS SYST/SENSE ORGAN DIS	CUR	1982
	ALLERGIES {CAT AND DOG HAIR, DUST, TREES}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
	RECURRENT EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1982
	SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1996
	TUBES PLACED IN RIGHT EAR X6	OPERATION, EAR	OPERATIONS	CUR	1982
329.005.00334	ABNORMAL LAB VALUES URINALYSIS +3 OCCULT BLOOD/RED	HEMATURIA	GENITOURINARY SYST DIS	CUR	1997
	ABNORMAL LAB VALUES URINALYSIS MODERATE BACTERIA/CLOUDY	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	CUR	1997

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.005.00334	REPAIR OF LEFT FOOT - BONE REALIGNMENT	OPERATION, BONE/JOINT	OPERATIONS	CUR	1997
	BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1995
329.006.00042	ECG-SINUS ARRHYTHMIA(MILD)	ARRHYTHMIA	CIRCULATORY SYST	CUR	1995
	OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1990
329.006.00259	FACIAL ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
	FATIGUE	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	NORMAL SINUS RHYTHM WITH SHORT PR ON EKG	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	LOW THYROID FUNCTION	HYPOTHYROIDISM	ENDOCR/METAB/IMMUNITY DISORD	PRV	1996
329.007.00141	ANGINA	ANGINA PECTORIS	CIRCULATORY SYST	CUR	1995
	INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	EUSTACHIAN TUBE PLACEMENT	OPERATION, EAR	OPERATIONS	PRV	1982
	HYPERTENSION	HYPERTENSION	CIRCULATORY SYST	PRV	1994
329.007.00267	HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	OBESE{MILDLY}	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
	POSITIVE DRUG SCREEN{CANNABINOIDS}	DRUG ABUSE	MENTAL DISORD	CUR	1996
	TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1981
329.007.00311	PROTEIN IN URINE	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	PRV	1996

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329.007.00311	CONCUSSION	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1994
	EUSTACHIAN TUBES LEFT EAR {FOR SEVERE, CHRONIC EAR INFECTION}	OPERATION, EAR	OPERATIONS	PRV	1984
	EUSTACHIAN TUBES RIGHT EAR {FOR SEVERE, CHRONIC EAR INFECTION}	OPERATION, EAR	OPERATIONS	PRV	1987
329.008.00158	GASTRIC REFLUX	ESOPHAGITIS	DIGESTIVE SYST	CUR	
	APPENDICITIS	APPENDICITIS	DIGESTIVE SYST	PRV	1989
329.008.00191	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
329.009.00128	GENERALIZED ANXIETY DISORDER	NEUROSES	MENTAL DISORD	CUR	1994
	SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1993
	ATTENTION DEFICIT DISORDER	MENTAL STATUS, IMPAIRED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994
329.009.00129	BROKEN COLLAR BONE	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1992
329.009.00135	DYSMENORRHEA{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	HYPOTHYROID	HYPOTHYROIDISM	ENDOCR/METAB/IMMUNITY DISORD	CUR	1992
	MENSTRUAL CRAMPS{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
	PARTIAL THYROIDECTOMY	OPERATION, ENDOCR	OPERATIONS	PRV	1991

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329.009.00136	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1992
	SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1995
	SPRAINED LEFT ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995
329.009.00174	ALLERGIES(SEASONAL)	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994
	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
	MILD OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
	TEMPOROMANDIBULAR JOINT SYNDROME	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1995
329.009.00197	OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	STOMACH PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.009.00198	ALLERGY TO CODEINE	ADVERSE EFF/ANALGESIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	OTITIS MEDIA BILATERAL{PROBABLE}	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
	UPPER RESPIRATORY TRACT INFECTION(FLU)	INFLUENZA	RESPIRATORY SYST DIS	CUR	1994
	GRAVIDA 1,PARA 0,ABORTION {PREGNANCY}	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1993
329.009.00200	ANEMIC	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.009.00200	{COMMON} COLD	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996
329.009.00202	HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
	SEASONAL ALLERGY	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1995
329.009.00237	ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	P&C	
	OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	P&C	
	SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	P&C	1996
329.009.00238	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.009.00276	EARLY REPOLARIZATION {EKG}	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
	HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
	STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
329.009.00302	ABDOMINAL CYST-SURGERY	OPERATION, OTHER ABDOM	OPERATIONS	PRV	1990
	TENDONITIS	RHEUMATIC DISORD	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1996
329.009.00306	NON MALIGNANT LUMP REMOVED FROM(LEFT)BREAST	OPERATION, BREAST	OPERATIONS	PRV	1996
329.009.00312	ALLERGIES TO ERYTHROCIN	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	
	OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	SINUS ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996

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PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.009.00312	STOMACH ULCER	ULCER, GASTRIC	DIGESTIVE SYST	CUR	1996
329.009.00327	HEADACHE {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
	INSECT BITES	INJURY, SUPERFICIAL	INJURY/POISONING	CUR	1996
	MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
	SINUS ALLERGIES {CONGESTION}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996
	STOMACHACHE {OCCASIONAL}	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
329.009.00330	ATTENTION-DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1996
	BROKEN EAR DRUM	EAR/MASTOID DISORD	NERVOUS SYST/SENSE ORGAN DIS	CUR	1996
	POSSIBLE VENTRICULAR HYPERTROPHY	CARDIOMEGALY	CIRCULATORY SYST	CUR	1996
	SINUS ARRHYTHMIA	ARRHYTHMIA	CIRCULATORY SYST	CUR	1996
	SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	CUR	1996
329.010.00183	INCREASED CREATININE	CREATININE, INCREASED	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	INCREASED URINE NITROGEN	URINE, ABN, OTHER	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	ASTHMATIC REACTION{BRIEF}	ASTHMA	RESPIRATORY SYST DIS	PRV	1994
	SEIZURE{UNKNOWN ETIOLOGY 1X}	CONVULSIONS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1989
329.010.00263	MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1996
329.010.00277	HEADACHES{FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.010.00277	PROTEINURIA	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
329.010.00282	BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	CUR	1996
	MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1980
	TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1996
329.011.00164	LYME DISEASE	ARTHROPOD-BORNE DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993
	MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1993
329.011.00210	HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
329.011.00285	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
	KNEE PROBLEMS{RIGHT}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
	EPSTEIN BARR VIRUS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993
329.012.00027	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1985
	OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
	TENSION HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
329.012.00217	HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1995
	INJURY TO LEFT KNEE{PARAGLIDING}	TRAUMA/INJURIES, UNSPEC	INJURY/POISONING	PRV	1993
	LIGAMENT TEARS{LEFT FOOT,ANKLE}	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
329.012.00217	MONONUCLEOSIS{(2 EPISODES IN ONE YEAR)}	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995
329.012.00218	ANXIETY	ANXIETY	MENTAL DISORD	CUR	1996
	ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1986

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TREATMENT GROUP: PAROXETINE

DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
BLOOD/BLOOD FORMING ORGAN DIS	ANEMIA, OTHER	ANEMIA	329.007.00265	CUR	1996
	ANEMIA, OTHER	ANEMIA	329.009.00196	CUR	1995
	LEUKOPENIA	DECREASED WHITE BLOOD CELL	329.001.00121	CUR	1995
	LEUKOPENIA	LOW WHITE BLOOD CELL COUNT	329.007.00145	CUR	1996
	MONOCYTOSIS	ELEVATED MONOCYTES	329.007.00145	CUR	1996
CIRCULATORY SYST	BRADYCARDIA	SINUS BRADYCARDIA {MARKED}	329.009.00329	CUR	1996
	CARDIOMEGALY	BIVENTRICULAR HYPERTROPHY	329.009.00328	CUR	1996
DIGESTIVE SYST	DYSPEPSIA	"ULCER-LIKE" SYMPTOMS (BURNING, INDIGESTION), NO ULCER	329.007.00309	CUR	1996
	HERNIA, ABDOMINAL	INGUINAL HERNIA	329.007.00142	PRV	1983
	PANCREATITIS	ACUTE PANCREATITIS	329.010.00278	PRV	1994
	STOMACH/DUODENUM DISORD	NERVOUS STOMACH	329.009.00130	CUR	1989
ENDOCR/METAB/IMMUNITY DISORD	OBESITY	OBESITY{MILD}	329.009.00196	CUR	1995
	OBESITY	OVERWEIGHT	329.003.00313	CUR	
	OBESITY	SLIGHTLY OBESE	329.001.00063	CUR	1994
	OVARIAN DYSFUNC	POLYCYSTIC OVARY	329.010.00278	CUR	1995
EXT CAUSES OF INJURY/POISONING	ADVERSE EFF ON AUTONOMIC NS	ALLERGIC TO SUDAFED	329.012.00220	CUR	1984
	ADVERSE EFF/ANALGESIC	ALLERGIES TO ASPIRIN	329.009.00196	CUR	1995
	ADVERSE EFF/ANTI-INFECT	ALLERGIES TO SULFA DRUGS	329.009.00196	CUR	1995

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TREATMENT GROUP: PAROXETINE

DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
FAMILY/PERSONAL HISTORY	POSTPARTUM CARE	POSTPARTUM - NOT BREAST FEEDING	329.005.00109	CUR	1994
GENITOURINARY SYST DIS	AMENORRHEA	AMENORRHEA	329.004.00212	CUR	1996
	CYSTITIS	BLADDER INFECTIONS	329.012.00220	PRV	1986
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.007.00268	CUR	1995
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.007.00310	CUR	1996
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS{OCCASIONAL}	329.009.00196	CUR	1994
	GENITAL FEMALE DISORD, OTHER	PREMENSTRUAL TENSION(OCCASIONAL)	329.009.00133	CUR	1993
	HEMATURIA	OCCULT BLOOD IN URINE - PATIENT MENSTRUATING	329.005.00258	CUR	1996
INFECTIOUS/PARASITIC DIS	INFECTION, BACTERIAL	STREP THROAT	329.009.00133	PRV	1985
	INFECTION, BACTERIAL	STREP THROAT	329.009.00201	CUR	1996
	MYCOSES	TINEA PEDIS {BOTH FEET}	329.006.00261	CUR	1996
	TUBERCULOSIS	TUBERCULOSIS	329.003.00313	PRV	
	VIRAL DIS/EXANTHEM	CHICKEN POX	329.001.00121	PRV	1987
	VIRAL DIS/EXANTHEM	FEVER BLISTERS	329.001.00068	CUR	1990
	VIRUS/CHLAMYD DIS, OTHER	CAT SCRATCH FEVER	329.007.00142	PRV	1993
INJURY/POISONING	ALLERGY, NEC	ALLERGIES	329.008.00275	CUR	1994
	ALLERGY, NEC	ALLERGIES	329.010.00280	CUR	

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DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
INJURY/POISONING	ALLERGY, NEC	ALLERGIES{ENVIRONMENTAL}	329.004.00212	CUR	1995
	ALLERGY, NEC	ENVIRONMENTAL ALLERGIES	329.001.00206	CUR	
	ALLERGY, NEC	ENVIRONMENTAL ALLERGIES	329.005.00333	CUR	
	COMPLIC OF MED CARE	INFECTED {BIOPSY MARK RIGHT SUPRACLAVICULAR ARM}	329.001.00068	PRV	1991
	FRACTURE, LOWER LIMB	FRACTURE RIGHT LEG	329.012.00226	PRV	1988
	FRACTURE, UPPER LIMB	BROKEN ARM	329.005.00152	PRV	1985
	FRACTURE, UPPER LIMB	BROKEN LEFT ARM	329.007.00145	PRV	1991
	OPEN WOUND	FACIAL LACERATIONS{DOG BITE}	329.001.00205	PRV	1986
	OPEN WOUND	HEAD LACERATION	329.004.00214	PRV	1987
	SPRAINS/STRAINS	PAIN LEFT WRIST(POSSIBLE SPRAIN)	329.001.00063	CUR	1994
	TOXIC EFFECTS, VENOM	ALLERGIES-BEE STING	329.002.00055	CUR	1987
MENTAL DISORD	CONDUCT DISORD	ATTENTION DEFICIT HYPERACTIVE DISORDER	329.012.00220	CUR	1987
	CONDUCT DISORD	ATTENTION DEFICIT HYPERACTIVITY DISORDER	329.007.00318	PRV	1984
	CONDUCT DISORD	ATTENTION DEFICIT HYPERACTIVITY DISORDER	329.009.00204	CUR	1986
	DRUG ABUSE	CANNABIS USE	329.005.00002	CUR	1994
	NEUROSES	OBSESSIVE COMPULSIVE SYMPTOMS	329.012.00220	PRV	1994
	TICS	TOURETTES (TIC DISORDER).	329.012.00220	PRV	1987

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MUSCULOSKEL/CONNECT TISSUE DIS	BACK PAIN	BACK PAIN	329.005.00151	CUR	1989
	BACK PAIN	BACKACHE	329.005.00336	PRV	1997
	BACK PAIN	BACKACHES	329.007.00294	CUR	1994
	BONE/CARTIL DISORD, OTHER	STRESS FRACTURE BACK	329.001.00072	PRV	1993
	DEFORMITY, ACQUIRED	SCOLIOSIS	329.007.00294	PRV	1995
	DEFORMITY, ACQUIRED	SCOLIOSIS	329.009.00170	CUR	1989
	MYALGIA	BILATERAL LEG PAIN:MUSCULAR ORIGIN	329.009.00170	CUR	1995
	OSTEOCHONDROPATHIES	OSGOOD SCHLATTER DISEASE	329.001.00065	PRV	1991
	PAIN, JOINT	JOINT PAIN - FLEXIBLE JOINTS	329.004.00214	CUR	1996
	PAIN, LIMB	KNEE PAIN {RIGHT-MILD AFTER RUNNING}	329.005.00299	CUR	1996
NERVOUS SYST/SENSE ORGAN DIS	MENINGITIS	MENINGITIS	329.009.00240	PRV	1984
	MIGRAINE	MIGRAINE HEADACHES {ACCORDING TO PATIENT}	329.002.00245	CUR	1995
OPERATIONS	OPERATION, BONE/JOINT	10 BONE FUSIONS IN BACK	329.007.00294	PRV	1995
	OPERATION, BONE/JOINT	ROD PLACEMENT {BACK}	329.007.00294	PRV	1995
	OPERATION, EAR	EUSTACHIAN TUBE {BILATERAL}	329.007.00318	PRV	1985
	OPERATION, EYE	SURGERY FOR STRABISMUS	329.012.00226	PRV	1983
	OPERATION, HERNIA REPAIR	SURGERY TO REPAIR A HERNIA	329.008.00157	PRV	1980
	OPERATION, LYMPH	LYMPH NODE BIOPSY (ENLARGED NODES)	329.001.00068	PRV	1991

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OPERATIONS	OPERATION, NOSE/MOUTH	TONSILLECTOMY	329.007.00140	PRV	1989
	OPERATION, NOSE/MOUTH	TONSILLECTOMY	329.007.00310	PRV	1994
	OPERATION, NOSE/MOUTH	TONSILLECTOMY AND ADENOIDECTOMY	329.005.00333	PRV	1990
	OPERATION, OTHER URINARY	URETERS BILATERALLY REEMBEDDED	329.004.00015	PRV	1990
	OPERATION, SKIN/SUBCUT	BIRTHMARK REMOVED	329.001.00121	PRV	1989
	OPERATION, SKIN/SUBCUT	CYST REMOVED FROM CHEST	329.001.00121	PRV	1981
	OPERATION, SKIN/SUBCUT	PLASTIC SURGERY FOR FACIAL SCARS	329.001.00205	PRV	1994
RESPIRATORY SYST DIS	ASTHMA	ASTHMA	329.003.00075	CUR	
	ASTHMA	ASTHMA	329.003.00087	PRV	1994
	ASTHMA	ASTHMA	329.005.00109	PRV	1979
	ASTHMA	ASTHMA	329.006.00038	CUR	1990
	ASTHMA	ASTHMA	329.008.00271	CUR	1984
	ASTHMA	ASTHMA	329.009.00196	CUR	1993
	ASTHMA	ASTHMA	329.011.00288	CUR	1987
	ASTHMA	ASTHMA ATTACK	329.010.00280	PRV	
	ASTHMA	ASTHMA {VERY MILD}	329.006.00261	CUR	1984
	EPIGLOTTITIS, ACUTE	EPIGLOTTITIS	329.008.00160	PRV	1990
	INFLUENZA	FLU SYMPTOMS	329.009.00235	PRV	1996
	NASOPHARYNGITIS, ACUTE	COLD {COMMON}	329.004.00214	CUR	1996
	PHARYNGITIS, ACUTE	SORE THROAT	329.007.00142	PRV	1995

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RESPIRATORY SYST DIS	RHINITIS, ALLERGIC	ALLERGIES{CATS,POLLEN}	329.002.00105	CUR	1990
	RHINITIS, ALLERGIC	ALLERGY POLLEN	329.001.00063	CUR	1983
	RHINITIS, ALLERGIC	ALLERGY-CAT FUR(MILD)	329.002.00055	CUR	1987
	RHINITIS, ALLERGIC	HAYFEVER-LATE SPRING,SUMMER MONTHS ONLY	329.012.00222	CUR	1994
	RHINITIS, ALLERGIC	SEASONAL ALLERGIES	329.002.00099	CUR	
	RHINITIS, ALLERGIC	SEASONAL ALLERGIES	329.009.00324	CUR	
	SINUSITIS,NOS	SINUS INFECTION	329.009.00303	CUR	1996
	SINUSITIS,NOS	SINUS INFECTIONS	329.009.00133	CUR	1985
	UPPER RESP DISORD, OTHER	SINUS CONGESTION	329.001.00205	CUR	1984
	UPPER RESP DISORD, OTHER	SINUS CONGESTION	329.009.00324	CUR	1996
	UPPER RESP INFECT, ACUTE	UPPER RESPIRATORY TRACT INFECTION	329.009.00173	CUR	1995
SIGNS,SYMPTOMS,ILL-DEFINED CON	CARDIAC MURMURS	HEART MURMUR, GRADE 1, ASYMPTOMATIC	329.009.00131	PRV	1984
	CARDIOVAS FUNCTIONS/ECG, ABN	REPOLARIZATION ON ECG {EARLY}	329.009.00329	CUR	1996
	COMA AND STUPOR	UNCONSCIOUS AT AGE 1 - HIT HEAD IN FALL	329.009.00324	PRV	1984
	CONDITIONS, OTHER, ABN	BLEEDING ULCER {NOS}	329.005.00109	PRV	1993
	DISTURBANCE, SLEEP, UNSPEC	SLEEP DISTURBANCE	329.009.00240	CUR	1996
	DIZZINESS, POSTURAL	DIZZINESS UPON CHANGING POSITIONS	329.001.00065	CUR	1994
	HEADACHE	HEADACHE	329.007.00265	CUR	1996

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SIGNS,SYMPTOMS,ILL-DEFINED CON	HEADACHE	HEADACHE	329.009.00133	CUR	1993
	HEADACHE	HEADACHE	329.009.00173	CUR	1995
	HEADACHE	HEADACHE	329.009.00193	CUR	1995
	HEADACHE	HEADACHE	329.009.00201	CUR	1996
	HEADACHE	HEADACHES	329.001.00063	CUR	1990
	HEADACHE	HEADACHES	329.001.00065	CUR	1989
	HEADACHE	HEADACHES	329.001.00068	CUR	1992
	HEADACHE	HEADACHES	329.002.00055	CUR	1993
	HEADACHE	HEADACHES	329.002.00058	CUR	1994
	HEADACHE	HEADACHES	329.002.00105	CUR	1995
	HEADACHE	HEADACHES	329.003.00075	CUR	
	HEADACHE	HEADACHES	329.005.00151	CUR	1991
	HEADACHE	HEADACHES	329.005.00299	CUR	
	HEADACHE	HEADACHES	329.007.00294	CUR	1994
	HEADACHE	HEADACHES	329.008.00275	CUR	1995
	HEADACHE	HEADACHES	329.010.00182	CUR	1995
	HEADACHE	HEADACHES	329.010.00280	CUR	1996
	HEADACHE	HEADACHES (OCCASIONAL)	329.009.00240	CUR	1996
	HEADACHE	HEADACHES (OCCASIONAL)	329.009.00324	CUR	1996
	HEADACHE	HEADACHES {FREQUENT}	329.007.00309	CUR	1996
	HEADACHE	HEADACHES {FREQUENT}	329.007.00310	CUR	1995
	HEADACHE	HEADACHES {FRONTAL}	329.002.00319	CUR	1995

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SIGNS,SYMPTOMS,ILL-DEFINED CON	HEADACHE	HEADACHES {OCCASIONAL}	329.006.00260	CUR	1996
	HEADACHE	HEADACHES {OCCASIONAL}	329.009.00328	CUR	1994
	HEADACHE	HEADACHES {OCCASIONAL}	329.009.00329	CUR	1995
	HEADACHE	HEADACHES {RECURRENT}	329.002.00242	CUR	1995
	HEADACHE	HEADACHES-FREQUENT	329.006.00039	CUR	1992
	HEADACHE	HEADACHES{DAILY}	329.003.00081	CUR	1995
	HEADACHE	HEADACHES{OCCASIONAL}	329.007.00268	CUR	1994
	HEADACHE	HEADACHES{OCCASIONAL}	329.009.00196	CUR	1994
	HEADACHE	HEADACHES{OCCASIONAL}	329.009.00204	CUR	1994
	HEADACHE	HEADACHE{OCCASIONAL}	329.009.00303	CUR	1994
	HEADACHE	HEADACHE{OCCASIONAL}	329.009.00304	CUR	1995
	HEADACHE	MILD RECURRENT HEADACHES	329.012.00226	CUR	1993
	HEADACHE	OCCASIONAL HEADACHE	329.007.00142	CUR	1985
	HEADACHE	OCCASIONAL HEADACHE	329.009.00131	CUR	1995
	HEADACHE	OCCASIONAL HEADACHE	329.009.00138	CUR	1995
	HEADACHE	OCCASIONAL HEADACHE	329.009.00170	CUR	1994
	HEADACHE	OCCASIONAL HEADACHES	329.007.00140	CUR	1994
	HEADACHE	OCCASIONAL HEADACHES	329.009.00235	CUR	1996
	HEARTBURN	HEARTBURN	329.002.00105	CUR	1995
	INCONTINENCE, URINARY	BED-WETTING	329.012.00220	PRV	1986
	INCONTINENCE, URINARY	ENURESIS	329.004.00015	PRV	1990
	INSOMNIA	INSOMNIA	329.008.00275	CUR	1994

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SIGNS,SYMPTOMS,ILL-DEFINED CON	LYMPHADENOPATHY	MILD LYMPHADENOPATHY,LEFT ANTERIOR CERVICAL,PERSISTENT	329.007.00142	CUR	1995
	MENTAL STATUS, IMPAIRED	ATTENTION DEFICIT DISORDER	329.002.00058	PRV	1983
	NAUSEA	NAUSEA STOMACH UPSET	329.001.00068	CUR	1992
	NAUSEA	NAUSEA {CHRONIC}	329.007.00309	CUR	1995
	NAUSEA	STOMACH UPSET(NAUSEA)	329.001.00065	CUR	1994
	PAIN, ABDOMINO-PELVIC	ABDOMINAL PAIN	329.010.00278	CUR	1994
	PAIN, ABDOMINO-PELVIC	BURNING STOMACH	329.005.00112	CUR	1995
	PAIN, ABDOMINO-PELVIC	OCCASIONAL STOMACH ACHE	329.009.00138	CUR	1990
	PAIN, ABDOMINO-PELVIC	STOMACH ACHE	329.009.00173	CUR	1995
	PAIN, ABDOMINO-PELVIC	STOMACH ACHES	329.005.00119	CUR	1993
	PAIN, ABDOMINO-PELVIC	STOMACH ACHES {OCCASIONAL}	329.009.00328	CUR	1994
	PROTEINURIA	PROTEIN IN URINE - PATIENT MENSTRUATING	329.005.00258	CUR	1996
	PROTEINURIA	PROTEINURIA	329.011.00288	CUR	1996
	PYREXIA	FEVER	329.009.00201	CUR	1996
	PYREXIA	FEVER OF UNKNOWN ORIGIN	329.009.00133	PRV	1993
	RASH/OTHER SKIN ERUPTION	RASH, PLANTAR SURFACE RIGHT FOOT	329.007.00294	CUR	1997
	TREMOR	HAND TREMORS	329.001.00065	CUR	1994
	WEIGHT GAIN	WEIGHT GAIN	329.007.00294	CUR	1997
	WEIGHT GAIN	WEIGHT GAIN	329.009.00204	PRV	1996

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SKIN/SUBCUTANEOUS TISSUE DIS	INFLAM SKIN/SUBCUT	ALLERGIES(SKIN)	329.012.00025	CUR	1995
	INFLAM SKIN/SUBCUT	ECZEMA	329.012.00231	CUR	1996
	LYMPHADENITIS, ACUTE	LYMPH NODE INFECTION{BILATERAL GROIN NODES}	329.007.00268	PRV	1991
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.001.00063	CUR	1994
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.001.00068	CUR	1993
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.005.00257	CUR	1995
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.006.00260	CUR	1996
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.009.00235	CUR	1996
	SKIN/SUBCUT DISORD, OTHER	DYSHYDROSIS {MILD ON HAND AND PENIS}	329.006.00261	CUR	1996
	SKIN/SUBCUT DISORD, OTHER	VESICULAR DYSHIDROSIS	329.007.00140	CUR	1995

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ANOMALIES	CONG ANOM, GU	HYPOSPADIAS {MALE}	329.002.00050	PRV	1978
	CONG ANOM, GU	LEFT URETERAL DUPLICATION	329.002.00050	PRV	1978
	CONG ANOM, MUSCULOSKEL	FOOT TURNED AT BIRTH	329.001.00061	PRV	1977
	CONG ANOM, MUSCULOSKEL	PECTUS EXCAVATUM	329.011.00284	PRV	1978
BLOOD/BLOOD FORMING ORGAN DIS	LEUCOCYTOSIS	INCREASED NEUTROPHIL SEGS	329.005.00153	CUR	1996
	LEUKOPENIA	LOW NEUTROPHILS	329.011.00284	CUR	1996
	LEUKOPENIA	LOW WHITE BLOOD CELLS	329.011.00284	CUR	1996
	LEUKOPENIA	WBC DECREASE	329.010.00279	CUR	1996
	LYMPHOCYTOSIS	INCREASED LYMPHOCYTES	329.005.00153	CUR	1996
	LYMPHOPENIA	DECREASED LYMPHOCYTES	329.005.00256	CUR	1996
CIRCULATORY SYST	ARRHYTHMIA	SINUS ARRHYTHMIA	329.009.00239	CUR	1996
	BRADYCARDIA	SINUS BRADYCARDIA	329.009.00239	CUR	1996
COMPLIC OF PREGNANCY/BIRTH	PREGNANCY, COMPLICATIONS	ABORTION	329.005.00113	PRV	1994
	PREGNANCY, COMPLICATIONS	MISCARRIAGE	329.002.00056	PRV	1994
	PREGNANCY, COMPLICATIONS	{CHILDBIRTH}	329.009.00171	PRV	1994
DIGESTIVE SYST	DENTOFACIAL ANOM	TEMPOROMANDIBULAR JOINT PAIN	329.008.00273	CUR	1996
	DENTOFACIAL ANOM	TEMPOROMANDIBULAR JOINT SYNDROME	329.011.00163	CUR	1994
	DIGESTIVE DISORD, OTHER	IRRITABLE BOWEL SYNDROME	329.003.00090	CUR	1987
	DYSPEPSIA	NAUSEA {STOMACH UPSET}	329.009.00325	CUR	1995

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DIGESTIVE SYST	DYSPEPSIA	UPSET STOMACH	329.007.00269	CUR	1996
	ENTERITIS/COLITIS	COLITIS	329.008.00187	CUR	1981
	LIVER DISORD	FATTY INFILTRATION OF THE LIVER {CLINICALLY NORMAL}	329.012.00223	PRV	1996
	STOMACH/DUODENUM DISORD	STOMACH PROBLEMS	329.002.00057	CUR	1994
ENDOCR/METAB/IMMUNITY DISORD	HYPOGLYCEMIA	INTERMITTENT GLUCOSE(DECREASED)	329.002.00050	CUR	1995
	OBESITY	MILD OBESITY	329.007.00143	CUR	1994
EXT CAUSES OF INJURY/POISONING	ADVERSE EFF/ANTIBIOTIC	ALLERGY TO CECLOR	329.009.00199	CUR	1995
	ADVERSE EFF/ANTIBIOTIC	DRUG ALLERGY - PENICILLIN	329.009.00239	P&C	1995
	ADVERSE EFF/OTHER DRUG	ALLERGY TO IODINE	329.009.00171	CUR	1994
	ADVERSE EFF/PSYCHOTROPICS	ALLERGIC TO CAFFEINE	329.001.00070	CUR	1992
	RAPE	SEXUAL ASSAULT{STATUS POST,NO POST-TRAUMATIC STRESS DISORDER SYNDROME}	329.009.00171	PRV	1992
	SUICIDE	SUICIDE ATTEMPT{NOT IN CURRENT EPISODE}	329.009.00171	PRV	1994
FAMILY/PERSONAL HISTORY	PREGNANCY	PREGNANCY	329.002.00056	PRV	1994
	PREGNANCY	PREGNANCY	329.009.00171	PRV	1994
GENITOURINARY SYST DIS	GENITAL FEMALE DISORD, OTHER	DYSMENORRHEA	329.003.00249	CUR	1991
	GENITAL FEMALE DISORD, OTHER	DYSMENORRHEA	329.003.00289	CUR	1993

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GENITOURINARY SYST DIS	GENITAL FEMALE DISORD, OTHER	HEAVY CRAMPS DUE TO MENSES	329.002.00244	P&C	1990
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.003.00076	CUR	
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.005.00335	CUR	1997
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.007.00146	CUR	1996
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.009.00134	CUR	1993
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.009.00195	CUR	1994
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.009.00236	CUR	1996
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.009.00325	CUR	1995
	GENITAL FEMALE DISORD, OTHER	OVARIAN CYST	329.006.00040	CUR	1994
	GENITAL FEMALE DISORD, OTHER	QUESTIONABLE OVARIAN CYST	329.005.00007	CUR	1994
	GYNECOMASTIA	GYNECOMASTIA	329.005.00118	CUR	
	KIDNEY DISORD	RIGHT VESICOURETERAL REFLUX	329.002.00050	PRV	1978
	KIDNEY INFECT	PYELONEPHRITIS	329.012.00223	PRV	1995
	URINARY TRACT INFECTION	URINARY TRACT INFECTION	329.005.00255	CUR	1996
	URINARY TRACT INFECTION	URINARY TRACT INFECTION	329.007.00143	PRV	1994
	URINARY TRACT INFECTION	URINARY TRACT INFECTION'S {FREQUENT}	329.012.00223	PRV	1984

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INFECTIOUS/PARASITIC DIS	BACT DIS, OTHER	PSEUDOMONAS INFECTION	329.011.00284	PRV	1988
	INFECTION, BACTERIAL	REPEATED STREP THROAT	329.001.00061	PRV	1978
	INFECTION, BACTERIAL	STREP THROAT	329.007.00270	CUR	1996
	MYCOSES	DERMATOLOGICAL FUNGUS	329.009.00134	CUR	1995
	MYCOSES	RINGWORM	329.007.00270	CUR	1996
	VIRAL DIS/EXANTHEM	CHICKEN POX	329.010.00281	PRV	1987
	VIRUS/CHLAMYD DIS, OTHER	MONONUCLEOSIS	329.009.00239	PRV	1995
	VIRUS/CHLAMYD DIS, OTHER	STATUS POST MONONUCLEOSIS	329.005.00006	PRV	1994
	VIRUS/CHLAMYD DIS, OTHER	VAGINAL WARTS	329.008.00187	CUR	1995
INJURY/POISONING	ALLERGIC REACTION, FOOD	ALLERGIC TO CHOCOLATE	329.001.00070	CUR	1992
	ALLERGIC REACTION, FOOD	ALLERGIES TO MILK	329.009.00194	CUR	1993
	ALLERGIC REACTION, FOOD	FOOD ALLERGIES{MILK PRODUCTS}	329.007.00270	CUR	1985
	ALLERGY, NEC	ALLERGIES	329.006.00040	CUR	1985
	ALLERGY, NEC	ALLERGIES	329.012.00223	CUR	1996
	ALLERGY, NEC	ALLERGIES {ENVIRONMENTAL}	329.011.00209	CUR	1996
	ALLERGY, NEC	ENVIRONMENTAL ALLERGIES	329.005.00003	CUR	1988
	ALLERGY, NEC	ENVIRONMENTAL ALLERGIES	329.005.00255	CUR	
	COMPLIC OF MED CARE	JAUNDICE DUE TO ABO INCOMPATIBILTY {NOS}	329.010.00281	PRV	1983
	CONTUSION	BRUISED FOOT	329.001.00070	PRV	1990
	CONTUSION	BRUISED HAND	329.001.00070	PRV	1993

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INJURY/POISONING	FRACTURE, LOWER LIMB	BROKEN LEFT FEMUR{FELL OUT OF TREE}	329.007.00270	PRV	1994
	FRACTURE, UPPER LIMB	BROKEN LEFT ARM{X2}	329.009.00301	PRV	1988
	FRACTURE, UPPER LIMB	BROKEN RIGHT ARM	329.009.00301	PRV	1989
	FRACTURE, UPPER LIMB	FRACTURED RIGHT ARM	329.007.00139	CUR	1995
	FRACTURE, UPPER LIMB	RADIAL FRACTURE	329.012.00223	PRV	1994
	INJURY, INTRACRANIAL	CONCUSSION	329.002.00057	PRV	1985
	SPRAINS/STRAINS	SPRAINED ANKLE	329.001.00070	PRV	1992
	SPRAINS/STRAINS	SPRAINED ANKLE	329.003.00073	CUR	1995
	SPRAINS/STRAINS	SPRAINED ANKLE	329.003.00076	PRV	1994
	SPRAINS/STRAINS	SPRAINED ARM MUSCLES	329.009.00134	PRV	1995
	SPRAINS/STRAINS	SPRAINED FOOT	329.001.00070	PRV	1990
MENTAL DISORD	CONDUCT DISORD	ATTENTION DEFICIT HYPERACTIVITY DISORDER	329.008.00192	PRV	1996
	DEPRESSION	DEPRESSION	329.002.00100	CUR	1995
	DEPRESSION	STATUS POST HOSPITALIZATION FOR DEPRESSION	329.007.00143	PRV	1994
	PSYCHOGENIC PHYSIOL DYSFUNC	ENCOPRETIC	329.009.00262	CUR	1993
	STRESS REACTION	SEPARATION ANXIETY	329.009.00127	CUR	1995
	TOBACCO USE	CIGARETTE SMOKER	329.003.00249	CUR	
MUSCULOSKEL/CONNECT TISSUE DIS	MYALGIA	MUSCULAR NECK PAIN	329.009.00199	CUR	1995

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MUSCULOSKEL/CONNECT TISSUE DIS	MYALGIA	MYALGIA{UNSPECIFIED}	329.009.00194	CUR	1995
	OSTEOCHONDROPATHIES	SCHEUERMANN'S KYPHOSIS	329.002.00057	CUR	1994
	OSTEOCHONDROPATHIES	SEVER'S DISEASE	329.007.00269	PRV	1994
	PAIN, JOINT	JOINT PAIN{RIGHT WRIST}	329.007.00146	CUR	1995
	SWELLING, LIMB	SWELLING{LEFT CALF}	329.007.00146	CUR	1995
NEOPLASMS	NEOPLASMS BENIGN	MOLE LEFT KNEE-RAISED	329.001.00066	CUR	1994
NERVOUS SYST/SENSE ORGAN DIS	EYE DISORD, OTHER	EYE INFECTION (LEFT AND RIGHT EYE)	329.009.00262	CUR	1997
	EYE DISORD, OTHER	STRABISMUS	329.005.00255	PRV	
	HEARING LOSS	MILD HEARING LOSS	329.005.00117	PRV	1979
	MENINGITIS	SPINAL MENINGITIS	329.007.00308	PRV	1982
	MIGRAINE	CHILDHOOD MIGRAINES	329.002.00057	PRV	1984
	MIGRAINE	MIGRAINE HEADACHES	329.011.00163	CUR	1989
	MIGRAINE	MIGRAINES	329.009.00239	CUR	1991
	OTITIS MEDIA	CHRONIC EAR INFECTIONS	329.009.00262	PRV	1986
	OTITIS MEDIA	EAR INFECTION	329.005.00003	CUR	1994
	OTITIS MEDIA	EAR INFECTIONS	329.001.00070	PRV	1983
	OTITIS MEDIA	EAR INFECTIONS	329.012.00219	PRV	1985
	OTITIS MEDIA	HISTORY OF CHRONIC OTITIS MEDIA	329.005.00117	PRV	1979
	VISUAL DISTURB	GLASSES FOR DISTANCE SINCE GRADE 4	329.003.00076	PRV	1988

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NERVOUS SYST/SENSE ORGAN DIS	VISUAL DISTURB	NEAR-SIGHTED	329.003.00249	CUR	
	VISUAL DISTURB	NEARSIGHTED	329.003.00290	CUR	
OPERATIONS	OPERATION, BONE/JOINT	STATUS POST HIP SURGERY	329.005.00117	PRV	1989
	OPERATION, EAR	BILATERAL TUBE PLACEMENT IN EARS	329.010.00281	PRV	1984
	OPERATION, EAR	TUBES IN EARS	329.002.00057	PRV	1983
	OPERATION, EAR	TUBES IN EARS	329.009.00262	PRV	1986
	OPERATION, EYE	CORRECTIVE SURGERY(BOTH EYES)FOR STRABISMUS	329.011.00163	PRV	1985
	OPERATION, HERNIA REPAIR	BILATERAL HERNIA REPAIR	329.007.00269	PRV	1980
	OPERATION, HERNIA REPAIR	HERNIA OPERATION	329.002.00057	PRV	1985
	OPERATION, HERNIA REPAIR	HERNIA REPAIR	329.001.00122	PRV	1988
	OPERATION, MUSCLE/TENDON	ANKLE PAIN{SECONDARY TO SURGICAL CORRECTION RIGHT FOOT(CLUB)}	329.009.00194	CUR	1984
	OPERATION, NOSE/MOUTH	ADENOIDECTOMY	329.011.00208	PRV	1989
	OPERATION, NOSE/MOUTH	TONSILLECTOMY	329.001.00061	PRV	1989
	OPERATION, NOSE/MOUTH	TONSILLECTOMY	329.002.00057	PRV	1983
	OPERATION, NOSE/MOUTH	TONSILLECTOMY	329.011.00208	PRV	1989
	OPERATION, NOSE/MOUTH	TONSILLECTOMY AND ADENOIDECTOMY	329.003.00290	PRV	1994
	OPERATION, SKIN/SUBCUT	MOLE EXCISED BELOW UMBILICUS/BENIGN	329.001.00066	PRV	1984
	OPERATION, SKIN/SUBCUT	SUTURES IN CHIN	329.001.00066	PRV	1980

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OPERATIONS	OPERATION, SOFT TISSUE	REMOVAL OF BAKER'S CYST FROM RIGHT LEG	329.010.00281	PRV	1989
PERINATAL COND	CONDITIONS, PERINATAL	NECROTIZING ENTEROCOLITIS AT BIRTH-NO COMPLICATIONS	329.008.00161	PRV	1978
	CONDITIONS, PERINATAL	RESPIRATORY DIFFICULTIES AT BIRTH	329.001.00061	PRV	1977
PROCEDURES	THERAPY, REHAB	ACHILLES TENDON CASTED TIMES 6 WEEKS	329.007.00269	PRV	1994
	THERAPY, REHAB	FOOT CASTED	329.001.00061	PRV	1977
RESPIRATORY SYST DIS	ASTHMA	ASTHMA	329.003.00093	CUR	1989
	ASTHMA	ASTHMA	329.003.00317	CUR	
	ASTHMA	ASTHMA	329.005.00110	PRV	1984
	ASTHMA	ASTHMA	329.005.00113	CUR	1985
	ASTHMA	ASTHMA	329.005.00255	CUR	1986
	ASTHMA	ASTHMA	329.009.00203	CUR	1990
	ASTHMA	ASTHMA	329.009.00301	CUR	1983
	ASTHMA	ASTHMA	329.009.00325	CUR	1990
	ASTHMA	ASTHMA	329.011.00286	CUR	1990
	ASTHMA	ASTHMA	329.012.00230	PRV	1993
	ASTHMA	ASTHMA - NO PROBLEMS FOR 2 YRS	329.009.00264	PRV	1991
	ASTHMA	ASTHMA ATTACKS{HOSPITALIZED}	329.009.00301	PRV	1990

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RESPIRATORY SYST DIS	ASTHMA	ASTHMA {AS YOUNG CHILD}	329.003.00289	PRV	1981
	ASTHMA	STRESS INDUCED ASTHMA	329.011.00163	CUR	1994
	INFLUENZA	FLU	329.005.00295	CUR	1996
	LARYNGITIS/TRACH, ACUTE	CROUP	329.011.00284	PRV	1979
	NASOPHARYNGITIS, ACUTE	COLD SYMPTOMS	329.007.00143	CUR	1995
	NASOPHARYNGITIS, ACUTE	COLD SYMPTOMS	329.007.00146	CUR	1996
	NASOPHARYNGITIS, ACUTE	COLD SYMPTOMS	329.009.00326	PRV	1996
	NASOPHARYNGITIS, ACUTE	COLD {COMMON}	329.005.00153	CUR	1996
	NASOPHARYNGITIS, ACUTE	COLD {COMMON}	329.005.00295	CUR	1996
	PHARYNGITIS, ACUTE	PHARYNGITIS	329.003.00314	PRV	1996
	PHARYNGITIS, ACUTE	SORE THROATS {FREQUENT}	329.003.00290	PRV	1994
	RESP DIS, OTHER	BRONCHOSPASM	329.012.00223	CUR	1996
	RHINITIS, ALLERGIC	ALLERGIC RHINITIS	329.003.00317	CUR	
	RHINITIS, ALLERGIC	ALLERGIC TO MOLD	329.001.00070	CUR	1992
	RHINITIS, ALLERGIC	ALLERGIES {TO POLLEN, TREES, DUST}	329.003.00289	CUR	
	RHINITIS, ALLERGIC	HAY FEVER	329.005.00009	PRV	1984
	RHINITIS, ALLERGIC	HISTORY OF ENVIRONMENTAL ALLERGIES-DUST	329.005.00006	PRV	
	RHINITIS, ALLERGIC	HISTORY OF ENVIRONMENTAL ALLERGIES-POLLEN	329.005.00006	PRV	
	RHINITIS, ALLERGIC	RECURRENT SINUSITIS{SEASONAL ALLERGIES}	329.007.00269	CUR	1996

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RESPIRATORY SYST DIS	RHINITIS, ALLERGIC	SEASONAL ALLERGIES	329.007.00146	CUR	1983
	RHINITIS, ALLERGIC	SEASONAL ALLERGIES	329.007.00307	CUR	1993
	RHINITIS, ALLERGIC	SEASONAL ALLERGIES	329.009.00195	CUR	1995
	RHINITIS, ALLERGIC	SEASONAL ALLERGIES	329.009.00203	CUR	1994
	SINUSITIS, OTHER	REPEATED SINUS INFECTIONS ABOUT ONE TIME PER MONTH	329.001.00061	CUR	1989
	SINUSITIS,NOS	SINUS INFECTIONS	329.001.00070	PRV	1991
	SINUSITIS,NOS	SINUSITIS	329.007.00307	PRV	1995
	SINUSITIS,NOS	SINUSITIS	329.011.00286	CUR	
	TONSILLITIS, ACUTE	SORE THROAT-TONSILLITIS	329.002.00243	CUR	1996
	TONSILS/ADENOIDS DIS	HISTORY OF RECURRENT TONSILLITIS	329.005.00006	PRV	
SIGNS,SYMPTOMS,ILL-DEFINED CON	BLOOD PRESSURE, ELEVATED	HISTORY OF HIGH AVERAGE/BORDERLINE HIGH BLOOD PRESSURE	329.012.00223	PRV	1995
	CARDIAC MURMURS	HISTORY FUNCTIONAL HEART MURMUR	329.003.00076	PRV	
	CARDIAC MURMURS	HISTORY OF HEART MURMUR	329.005.00003	PRV	
	CARDIOVAS FUNCTIONS/ECG, ABN	LEFT AXIS DEVIATION	329.009.00203	CUR	1996
	CARDIOVAS FUNCTIONS/ECG, ABN	RIGHTWARD AXIS ON ELECTROCARDIOGRAM	329.006.00041	CUR	1995
	DIARRHEA	DIARRHEA	329.005.00295	CUR	1996
	HEADACHE	HEADACHE	329.005.00009	CUR	1994
	HEADACHE	HEADACHE {OCCASIONAL}	329.009.00325	CUR	1990

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SIGNS,SYMPTOMS,ILL-DEFINED CON	HEADACHE	HEADACHES	329.001.00061	CUR	1993
	HEADACHE	HEADACHES	329.001.00066	CUR	1992
	HEADACHE	HEADACHES	329.001.00070	CUR	1991
	HEADACHE	HEADACHES	329.002.00243	CUR	1994
	HEADACHE	HEADACHES	329.002.00321	CUR	1995
	HEADACHE	HEADACHES	329.003.00093	CUR	1990
	HEADACHE	HEADACHES	329.003.00289	CUR	
	HEADACHE	HEADACHES	329.005.00118	CUR	1995
	HEADACHE	HEADACHES	329.005.00295	CUR	1996
	HEADACHE	HEADACHES	329.008.00272	PRV	1996
	HEADACHE	HEADACHES	329.009.00195	CUR	1991
	HEADACHE	HEADACHES	329.009.00199	CUR	1995
	HEADACHE	HEADACHES	329.009.00236	CUR	1996
	HEADACHE	HEADACHES	329.009.00264	CUR	1994
	HEADACHE	HEADACHES	329.011.00208	CUR	1993
	HEADACHE	HEADACHES	329.011.00209	CUR	1996
	HEADACHE	HEADACHES	329.011.00286	CUR	
	HEADACHE	HEADACHES	329.012.00219	CUR	1996
	HEADACHE	HEADACHES {FREQUENT}	329.012.00223	CUR	1994
	HEADACHE	HEADACHES {MODERATE}	329.012.00221	CUR	1989
	HEADACHE	HEADACHES(DAILY)	329.002.00103	CUR	1995
	HEADACHE	HEADACHES(OCCASIONAL)	329.009.00132	CUR	1990

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SIGNS,SYMPTOMS,ILL-DEFINED CON	HEADACHE	HEADACHES{OCCASIONAL}	329.007.00270	CUR	1993
	HEADACHE	HEADACHES{OCCASIONAL}	329.007.00307	CUR	1992
	HEADACHE	HEADACHES{OCCASIONAL}	329.009.00301	CUR	1995
	HEADACHE	HEADACHE{OCCASIONAL}	329.007.00146	CUR	1994
	HEADACHE	HEADACHE{OCCASIONAL}	329.007.00269	CUR	1995
	HEADACHE	HEADACHE{OCCASIONAL}	329.009.00194	CUR	1995
	HEADACHE	OCCASIONAL HEADACHE	329.009.00172	CUR	1994
	HEADACHE	OCCASIONAL HEADACHES	329.002.00057	CUR	1994
	HEADACHE	OCCASIONAL HEADACHES	329.002.00100	CUR	1995
	HEADACHE	OCCASIONAL HEADACHES	329.009.00262	CUR	1997
	HEADACHE	OCCASIONAL MILD HEADACHES	329.008.00187	CUR	1995
	HEARTBURN	HEARTBURN	329.002.00057	CUR	1994
	HYPERHIDROSIS	HEAVY PERSPIRATION	329.001.00122	CUR	1994
	HYPERHIDROSIS	SWEATING AT BROW	329.002.00100	CUR	1994
	INSOMNIA	INITIAL INSOMNIA	329.009.00127	CUR	1995
	INSOMNIA	INSOMNIA	329.001.00061	CUR	
	INSOMNIA	INSOMNIA	329.007.00307	CUR	1996
	LYMPHADENOPATHY	ENLARGED LYMPH NODES	329.001.00070	CUR	1995
	MALAISE AND FATIGUE	LOW ENERGY	329.004.00215	CUR	1996
	NAUSEA	NAUSEA DUE TO MENSES	329.002.00244	P&C	1990
	NERVOUSNESS	SHAKINESS	329.002.00243	CUR	1994
	PAIN, ABDOMINO-PELVIC	OCCASIONAL STOMACH ACHES	329.009.00134	CUR	1993

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SIGNS,SYMPTOMS,ILL-DEFINED CON	PAIN, ABDOMINO-PELVIC	STOMACH ACHE	329.009.00172	CUR	1995
	PAIN, ABDOMINO-PELVIC	STOMACH ACHES	329.001.00066	CUR	1992
	PAIN, ABDOMINO-PELVIC	STOMACH ACHES	329.009.00236	CUR	1996
	PAIN, ABDOMINO-PELVIC	STOMACH ACHES	329.009.00262	CUR	1997
	PAIN, GENERAL	BODY ACHES	329.005.00295	CUR	1996
	PROTEINURIA	TRACE PROTEIN IN URINE	329.005.00153	CUR	1996
	PROTEINURIA	URINE {1+ PROTEIN}	329.007.00308	CUR	1996
	SWELLING, MASS, LOCALIZED	BENIGN LUMP LEFT FOOT	329.012.00223	CUR	1995
	THYROID FUNCTION, ABN	THYROID-STIMULATING HORMONE DECREASE	329.010.00279	CUR	1996
	TREMOR	HAND TREMOR	329.002.00100	CUR	1994
	WEIGHT LOSS	WEIGHT LOSS{52LBS.-PLANNED}	329.009.00171	PRV	1995
SKIN/SUBCUTANEOUS TISSUE DIS	CELLULITIS/ABSCESS	RIGHT FOOT INFECTION {TOENAILS}	329.001.00122	PRV	1985
	SCARRING	SCARS LEFT AND RIGHT FOREARM	329.003.00249	PRV	
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.001.00122	CUR	1994
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.002.00050	CUR	1991
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.002.00104	CUR	1994
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.004.00013	CUR	1994
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.005.00153	CUR	1995
	SKIN/SUBCUT DISORD, OTHER	MILD ACNE	329.001.00066	CUR	1994

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ANOMALIES	CONG ANOM, MUSCULOSKEL	DISLOCATED RIGHT HIP AT BIRTH	329.005.00010	PRV	1978
	CONGEN ANOM, HEAD/NECK	RUPTURED RIGHT EAR DRUM AT BIRTH	329.005.00010	PRV	1978
BLOOD/BLOOD FORMING ORGAN DIS	ANEMIA, OTHER	ANEMIA	329.003.00252	CUR	
	ANEMIA, OTHER	ANEMIC	329.009.00200	CUR	1996
CIRCULATORY SYST	ANGINA PECTORIS	ANGINA	329.007.00141	CUR	1995
	ARRHYTHMIA	ECG-SINUS ARRHYTHMIA(MILD)	329.006.00042	CUR	1995
	ARRHYTHMIA	SINUS ARRHYTHMIA	329.009.00330	CUR	1996
	BRADYCARDIA	SINUS BRADYCARDIA	329.009.00237	P&C	1996
	BRADYCARDIA	SINUS BRADYCARDIA	329.009.00330	CUR	1996
	CARDIOMEGALY	POSSIBLE VENTRICULAR HYPERTROPHY	329.009.00330	CUR	1996
	EXTRASYSTOLES, ATRIAL	SINUS RHYTHM ALTERNATING WITH ECTOPIC ATRIAL RHYTHM	329.002.00241	CUR	1996
	HYPERTENSION	HYPERTENSION	329.007.00141	PRV	1994
	MITRAL VALVE DISORD	HISTORY OF MITRAL VALVE PROLAPSE-NO FUNCTIONAL IMPAIRMENT	329.002.00059	CUR	1987
COMPLIC OF PREGNANCY/BIRTH	PREGNANCY, COMPLICATIONS	2 VAGINAL DELIVERY BIRTHS	329.005.00293	PRV	1996
DIGESTIVE SYST	APPENDICITIS	APPENDICITIS	329.008.00158	PRV	1989
	APPENDICITIS	STATUS POST ACUTE APPENDICITIS	329.003.00074	PRV	1994

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DIGESTIVE SYST	DENTOFACIAL ANOM	TEMPOROMANDIBULAR JOINT SYNDROME	329.009.00174	CUR	1995
	DYSPEPSIA	EPIGASTRIC DISTRESS	329.002.00107	CUR	1995
	ESOPHAGITIS	GASTRIC REFLUX	329.008.00158	CUR	
	ULCER, GASTRIC	STOMACH ULCER	329.009.00312	CUR	1996
ENDOCR/METAB/IMMUNITY DISORD	CHOLEST/TRIGLYCERIDE, ELEVATED	ELEVATED CHOLESTEROL	329.002.00323	PRV	
	HYPOTHYROIDISM	HYPOTHYROID	329.009.00135	CUR	1992
	HYPOTHYROIDISM	LOW THYROID FUNCTION	329.006.00259	PRV	1996
	OBESITY	MILD OBESITY	329.009.00174	CUR	1995
	OBESITY	OBESE{MILDLY}	329.007.00267	CUR	1995
	OBESITY	OBESITY	329.001.00207	CUR	1995
	OBESITY	OBESITY	329.003.00085	CUR	1988
	OBESITY	OBESITY	329.006.00042	CUR	1990
EXT CAUSES OF INJURY/POISONING	ADVERSE EFF/ANALGESIC	ALLERGY TO CODEINE	329.009.00198	CUR	1995
	ADVERSE EFF/ANTI-INFECT	ALLERGIC TO SULFA DRUGS	329.003.00252	CUR	
	ADVERSE EFF/ANTIBIOTIC	ALLERGIES TO ERYTHROCIN	329.009.00312	CUR	
	ADVERSE EFF/ANTIBIOTIC	ALLERGIES {TO PENICILLIN}	329.002.00241	CUR	1991
FAMILY/PERSONAL HISTORY	ALCOHOL INGESTION, OTHER	{PAST} ALCOHOL USE	329.002.00246	PRV	1994
	PREGNANCY	GRAVIDA 1,PARA 0,ABORTION {PREGNANCY}	329.009.00198	PRV	1993

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GENITOURINARY SYST DIS	GENITAL FEMALE DISORD, OTHER	DYSMENORRHEA{OCCASIONAL}	329.009.00135	CUR	1995
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.001.00123	CUR	1992
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.005.00298	CUR	1996
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.009.00136	CUR	1992
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.009.00202	CUR	1995
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS	329.009.00327	CUR	1994
	GENITAL FEMALE DISORD, OTHER	MENSTRUAL CRAMPS{OCCASIONAL}	329.009.00135	CUR	1995
	GENITAL FEMALE DISORD, OTHER	MISSED MENSES	329.002.00107	CUR	1996
	HEMATURIA	ABNORMAL LAB VALUES URINALYSIS +3 OCCULT BLOOD/RED	329.005.00334	CUR	1997
	HEMATURIA	RBC IN URINE POST PARTUM	329.005.00293	CUR	1997
	URINARY TRACT INFECTION	ABNORMAL LAB VALUES URINALYSIS MODERATE BACTERIA/CLOUDY	329.005.00334	CUR	1997
	VAGINITIS	BACTERIAL VAGINAL RASH	329.001.00123	CUR	1995
INFECTIOUS/PARASITIC DIS	ARTHROPOD-BORNE DIS, OTHER	LYME DISEASE	329.002.00320	PRV	1995
	ARTHROPOD-BORNE DIS, OTHER	LYME DISEASE	329.011.00164	PRV	1993
	INFECT/PARASIT DIS, OTHER	TOXOPLASMOSIS{RIGHT EYE}	329.005.00012	PRV	1994

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INFECTIOUS/PARASITIC DIS	VIRUS/CHLAMYD DIS, OTHER	EPSTEIN BARR VIRUS	329.011.00285	PRV	1993
	VIRUS/CHLAMYD DIS, OTHER	MONONUCLEOSIS	329.010.00263	PRV	1996
	VIRUS/CHLAMYD DIS, OTHER	MONONUCLEOSIS{(2 EPISODES IN ONE YEAR)}	329.012.00217	PRV	1995
INJURY/POISONING	FRACTURE, LOWER LIMB	BROKEN ANKLE	329.001.00123	PRV	1990
	FRACTURE, LOWER LIMB	FRACTURED LEFT FEMUR	329.002.00320	PRV	1990
	FRACTURE, LOWER LIMB	FRACTURED RIGHT TIBIA	329.002.00320	PRV	1990
	FRACTURE, SKULL	FRACTURED SKULL	329.002.00320	PRV	1990
	FRACTURE, UPPER LIMB	BROKEN ARM	329.001.00064	PRV	1994
	FRACTURE, UPPER LIMB	BROKEN ARM	329.005.00334	PRV	1995
	FRACTURE, UPPER LIMB	BROKEN COLLAR BONE	329.009.00129	PRV	1992
	FRACTURE, UPPER LIMB	BROKEN RIGHT WRIST	329.001.00064	PRV	1994
	FRACTURE, UPPER LIMB	BROKEN WRIST	329.001.00123	PRV	1988
	INJURY, INTRACRANIAL	CONCUSSION	329.007.00311	PRV	1994
	INJURY, INTRACRANIAL	SUBDURAL HEMATOMA	329.002.00320	PRV	1990
	INJURY, SUPERFICIAL	INSECT BITES	329.009.00327	CUR	1996
	OPEN WOUND	SKIN CUTS MULTIPLE {SUPERFICIAL ON LEFT FOREARM}	329.003.00094	CUR	1995
	OPEN WOUND	SKIN CUTS MULTIPLE {SUPERFICIAL ON RIGHT THIGH}	329.003.00094	CUR	1995
	SPRAINS/STRAINS	LIGAMENT TEARS{LEFT FOOT,ANKLE}	329.012.00217	PRV	1995

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Listing of Medical/Surgical History and Physical Examination
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TREATMENT GROUP: PLACEBO

DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
INJURY/POISONING	SPRAINS/STRAINS	MUSCLE STRAIN	329.001.00207	PRV	1996
	SPRAINS/STRAINS	SPRAINED LEFT ANKLE	329.009.00136	PRV	1995
	SPRAINS/STRAINS	SPRAINED WRIST	329.002.00320	PRV	1990
	TRAUMA/INJURIES, UNSPEC	INJURY TO LEFT KNEE{PARAGLIDING}	329.012.00217	PRV	1993
MENTAL DISORD	ANXIETY	ANXIETY	329.004.00020	CUR	1995
	ANXIETY	ANXIETY	329.012.00218	CUR	1996
	CONDUCT DISORD	ATTENTION-DEFICIT HYPERACTIVITY DISORDER	329.009.00330	CUR	1996
	DRUG ABUSE	POSITIVE DRUG SCREEN{CANNABINOIDS}	329.007.00267	CUR	1996
	DRUG ABUSE	{PAST} MARIJUANA USE	329.002.00246	PRV	1994
	DRUG DEPEND	POSITIVE URINE DRUG SCREEN FOR CODEINE AND MORPHINE.	329.005.00253	CUR	1996
	NEUROSES	GENERALIZED ANXIETY DISORDER	329.009.00128	CUR	1994
MUSCULOSKEL/CONNECT TISSUE DIS	BACK PAIN	BACK PAIN	329.002.00323	CUR	1996
	BACK PAIN	BACKACHES	329.004.00213	CUR	1996
	BACK PAIN	CHRONIC BACK PAIN	329.002.00320	CUR	1994
	JOINT DISORD, OTHER	FEMORAL EPIPHYSIS RIGHT HIP{JOINT DISORDER}	329.001.00123	PRV	1989
	JOINT DISORD, OTHER	HIP LEFT FEMORAL EPIPHYSIS{JOINT DISORDER}	329.001.00123	PRV	1990
	JOINT DISORD, OTHER	KNEE PROBLEMS{RIGHT}	329.011.00285	CUR	1995

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DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
MUSCULOSKEL/CONNECT TISSUE DIS	PAIN, LIMB	BILATERAL KNEE PAIN	329.002.00320	CUR	1995
	RHEUMATIC DISORD	TENDONITIS	329.009.00302	PRV	1996
NERVOUS SYST/SENSE ORGAN DIS	EAR/MASTOID DISORD	BROKEN EAR DRUM	329.009.00330	CUR	1996
	HEARING LOSS	25% HEARING LOSS RIGHT EAR	329.005.00331	CUR	1982
	MENINGITIS	MENINGITIS	329.010.00282	PRV	1980
	MENINGITIS	MENINGITIS	329.011.00164	PRV	1993
	OTITIS MEDIA	EAR INFECTION	329.001.00064	PRV	1983
	OTITIS MEDIA	OTITIS MEDIA	329.012.00027	CUR	1995
	OTITIS MEDIA	OTITIS MEDIA BILATERAL{PROBABLE}	329.009.00198	CUR	1995
	OTITIS MEDIA	RECURRENT EAR INFECTIONS	329.005.00331	CUR	1982
	OTITIS MEDIA	RIGHT OTITIS MEDIA	329.001.00069	CUR	1995
OPERATIONS	OPERATION, BONE/JOINT	REPAIR OF LEFT FOOT - BONE REALIGNMENT	329.005.00334	CUR	1997
	OPERATION, BONE/JOINT	SURGERY PINNING LEFT HIP	329.001.00123	PRV	1990
	OPERATION, BONE/JOINT	SURGERY REMOVAL OF PINS IN RIGHT,LEFT HIPS	329.001.00123	PRV	1991
	OPERATION, BONE/JOINT	SURGERY-PLACEMENT OF CANNULATED LOG SCREW RIGHT HIP	329.001.00123	PRV	1989
	OPERATION, BREAST	NON MALIGNANT LUMP REMOVED FROM(LEFT)BREAST	329.009.00306	PRV	1996
	OPERATION, EAR	EUSTACHIAN TUBE PLACEMENT	329.007.00141	PRV	1982

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OPERATIONS	OPERATION, EAR	EUSTACHIAN TUBES LEFT EAR {FOR SEVERE, CHRONIC EAR INFECTION}	329.007.00311	PRV	1984
	OPERATION, EAR	EUSTACHIAN TUBES RIGHT EAR {FOR SEVERE, CHRONIC EAR INFECTION}	329.007.00311	PRV	1987
	OPERATION, EAR	MYRINGOTOMY	329.001.00064	PRV	1983
	OPERATION, EAR	MYRINGOTOMY {TUBE PLACEMENT}	329.003.00251	.	
	OPERATION, EAR	PRESSURE EQUALIZATION TUBES IN EARS	329.001.00071	PRV	1983
	OPERATION, EAR	TUBES PLACED IN RIGHT EAR X6	329.005.00331	CUR	1982
	OPERATION, ENDOCR	PARTIAL THYROIDECTOMY	329.009.00135	PRV	1991
	OPERATION, HERNIA REPAIR	BILATERAL HERNIORRHAPHY	329.002.00049	PRV	1980
	OPERATION, HERNIA REPAIR	HERNIA REPAIR AT AGE 7	329.005.00010	PRV	1987
	OPERATION, NOSE/MOUTH	TONSILLECTOMY	329.003.00094	PRV	1989
	OPERATION, NOSE/MOUTH	TONSILLECTOMY	329.007.00267	PRV	1981
	OPERATION, NOSE/MOUTH	TONSILLECTOMY	329.010.00282	PRV	1996
	OPERATION, OTHER ABDOM	ABDOMINAL CYST-SURGERY	329.009.00302	PRV	1990
RESPIRATORY SYST DIS	ASTHMA	ASTHMA	329.001.00123	PRV	1993
	ASTHMA	ASTHMA	329.005.00114	CUR	1993
	ASTHMA	ASTHMA	329.005.00115	CUR	1984
	ASTHMA	ASTHMA	329.012.00027	CUR	1985
	ASTHMA	ASTHMA	329.012.00217	PRV	1995

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DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
RESPIRATORY SYST DIS	ASTHMA	ASTHMA	329.012.00218	PRV	1986
	ASTHMA	ASTHMATIC REACTION{BRIEF}	329.010.00183	PRV	1994
	BRONCHITIS, OTHER	BRONCHITIS	329.005.00253	CUR	1996
	BRONCHITIS, OTHER	BRONCHITIS	329.007.00311	PRV	1996
	BRONCHITIS, OTHER	BRONCHITIS	329.010.00282	CUR	1996
	INFLUENZA	FLU	329.001.00071	PRV	1995
	INFLUENZA	UPPER RESPIRATORY TRACT INFECTION(FLU)	329.009.00198	CUR	1994
	NASOPHARYNGITIS, ACUTE	COLD(HEAD)	329.001.00064	PRV	1994
	NASOPHARYNGITIS, ACUTE	SORE THROAT WITH COLD SYMPTOMS	329.001.00207	PRV	1996
	NASOPHARYNGITIS, ACUTE	{COMMON} COLD	329.009.00200	PRV	1996
	PHARYNGITIS, ACUTE	PHARYNGITIS	329.001.00069	CUR	1995
	PNEUMONIA, OTHER	PNEUMONIA	329.001.00064	PRV	1981
	PNEUMONIA, OTHER	PNEUMONIA	329.001.00069	PRV	1994
	RHINITIS, ALLERGIC	ALLERGIES {CAT AND DOG HAIR, DUST, TREES}	329.005.00331	CUR	1983
	RHINITIS, ALLERGIC	ALLERGIES {SEASONAL}	329.005.00298	CUR	1988
	RHINITIS, ALLERGIC	ALLERGIES {TO POLLEN, POULTRY DUST}	329.002.00241	CUR	1991
	RHINITIS, ALLERGIC	ALLERGIES(SEASONAL)	329.009.00174	CUR	1994
	RHINITIS, ALLERGIC	ALLERGIES-ANIMAL HAIR & POLLENS	329.004.00016	CUR	1988
	RHINITIS, ALLERGIC	SEASONAL ALLERGIES	329.009.00128	CUR	1993

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DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
RESPIRATORY SYST DIS	RHINITIS, ALLERGIC	SEASONAL ALLERGY	329.009.00202	CUR	1995
	RHINITIS, ALLERGIC	SINUS ALLERGIES	329.009.00312	CUR	1996
	RHINITIS, ALLERGIC	SINUS ALLERGIES {CONGESTION}	329.009.00327	CUR	1996
	SINUSITIS,NOS	SINUS INFECTION	329.001.00064	CUR	1994
	SINUSITIS,NOS	SINUS INFECTION	329.005.00331	CUR	1996
	SINUSITIS,NOS	SINUS INFECTIONS	329.001.00069	CUR	1985
	SINUSITIS,NOS	SINUSITIS	329.001.00071	PRV	1995
	UPPER RESP DISORD, OTHER	NASAL CONGESTION	329.002.00241	CUR	1996
	UPPER RESP DISORD, OTHER	RHINORRHEA	329.003.00086	CUR	1993
	UPPER RESP DISORD, OTHER	SINUS CONGESTION	329.009.00136	CUR	1995
	UPPER RESP INFECT, ACUTE	UPPER RESPIRATORY INFECTION	329.002.00097	CUR	1994
	UPPER RESP INFECT, ACUTE	UPPER RESPIRATORY TRACT INFECTION	329.004.00018	CUR	1995
SIGNS,SYMPTOMS,ILL-DEFINED CON	CARDIAC MURMURS	HEART MURMUR	329.002.00323	PRV	1993
	CARDIAC MURMURS	MURMUR {I/VI SYSTOLIC EJECTION MURMUR}	329.003.00252	CUR	
	CARDIOVAS FUNCTIONS/ECG, ABN	EARLY REPOLARIZATION {EKG}	329.009.00276	CUR	1997
	CARDIOVAS FUNCTIONS/ECG, ABN	NORMAL SINUS RHYTHM WITH SHORT PR ON EKG	329.006.00259	CUR	1996
	CONVULSIONS	SEIZURE{UNKNOWN ETIOLOGY 1X}	329.010.00183	PRV	1989
	CREATININE, INCREASED	INCREASED CREATININE	329.010.00183	CUR	1995

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TREATMENT GROUP: PLACEBO

DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
SIGNS,SYMPTOMS,ILL-DEFINED CON	DIZZINESS AND GIDDINESS	DIZZINESS	329.002.00320	CUR	
	DIZZINESS AND GIDDINESS	DIZZINESS	329.003.00251	CUR	1996
	DYSPNEA, OTHER	SHORTNESS OF BREATH	329.003.00251	CUR	1996
	GASTROINTEST PROB, NEC	GASTROINTESTINAL DISTRESS	329.002.00246	CUR	1994
	HEADACHE	HEADACHE	329.001.00069	PRV	1994
	HEADACHE	HEADACHE	329.009.00200	CUR	1994
	HEADACHE	HEADACHE	329.011.00285	CUR	
	HEADACHE	HEADACHE	329.012.00217	CUR	1995
	HEADACHE	HEADACHE {OCCASIONAL}	329.009.00327	CUR	1994
	HEADACHE	HEADACHES	329.001.00062	CUR	1979
	HEADACHE	HEADACHES	329.001.00064	CUR	1990
	HEADACHE	HEADACHES	329.001.00071	CUR	1993
	HEADACHE	HEADACHES	329.002.00246	CUR	1994
	HEADACHE	HEADACHES	329.002.00320	CUR	1990
	HEADACHE	HEADACHES	329.004.00018	CUR	1991
	HEADACHE	HEADACHES	329.004.00213	CUR	1996
	HEADACHE	HEADACHES	329.005.00001	CUR	1992
	HEADACHE	HEADACHES	329.005.00254	CUR	1996
	HEADACHE	HEADACHES	329.009.00174	CUR	1990
	HEADACHE	HEADACHES	329.009.00238	CUR	1995
	HEADACHE	HEADACHES	329.011.00210	CUR	
	HEADACHE	HEADACHES (OCCASIONAL)	329.009.00276	CUR	1996

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DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
SIGNS,SYMPTOMS,ILL-DEFINED CON	HEADACHE	HEADACHES,DAILY 2-3 TIMES	329.002.00097	CUR	1994
	HEADACHE	HEADACHES{FREQUENT}	329.010.00277	CUR	
	HEADACHE	HEADACHES{OCCASIONAL}	329.009.00135	CUR	1995
	HEADACHE	HEADACHES{OCCASIONAL}	329.009.00136	CUR	1993
	HEADACHE	HEADACHES{OCCASIONAL}	329.009.00198	CUR	1995
	HEADACHE	HEADACHES{OCCASIONAL}	329.009.00202	CUR	1995
	HEADACHE	HEADACHE{OCCASIONAL}	329.007.00267	CUR	1995
	HEADACHE	OCCASIONAL HEADACHE	329.009.00312	CUR	1995
	HEADACHE	OCCASIONAL HEADACHES	329.009.00197	CUR	1995
	HEADACHE	OCCASIONAL HEADACHES	329.009.00237	P&C	
	HEADACHE	TENSION HEADACHES	329.012.00027	CUR	1993
	INSOMNIA	INSOMNIA	329.007.00141	CUR	1994
	MALAISE AND FATIGUE	FATIGUE	329.003.00080	CUR	
	MALAISE AND FATIGUE	FATIGUE	329.006.00259	CUR	1995
	MENTAL STATUS, IMPAIRED	ATTENTION DEFICIT DISORDER	329.009.00128	PRV	1994
	PAIN, ABDOMINO-PELVIC	ABDOMINAL PAIN	329.003.00086	CUR	1994
	PAIN, ABDOMINO-PELVIC	STOMACH ACHES	329.001.00062	PRV	1988
	PAIN, ABDOMINO-PELVIC	STOMACH ACHES	329.002.00320	CUR	1994
	PAIN, ABDOMINO-PELVIC	STOMACH ACHES	329.009.00276	CUR	1997
	PAIN, ABDOMINO-PELVIC	STOMACH PAIN	329.009.00197	CUR	1995
	PAIN, ABDOMINO-PELVIC	STOMACHACHE {OCCASIONAL}	329.009.00327	CUR	1995
	PROTEINURIA	PROTEIN IN URINE	329.007.00311	CUR	1996

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DISEASE CLASSIFICATION (LEVEL 1)	PREFERRED TERM	VERBATIM TERM	PATIENT NUMBER	STATUS	DIAGYR
SIGNS,SYMPTOMS,ILL-DEFINED CON	PROTEINURIA	PROTEINURIA	329.010.00277	CUR	1996
	PYREXIA	FEVER	329.001.00069	PRV	1994
	SUDDEN INFANT DEATH SYNDROME	HISTORY OF APNEA AND RESUSCITATION IN FIRST YEAR OF LIFE(SIDS)	329.002.00101	PRV	1979
	SYNCOPE AND COLLAPSE	FAINTING{OCCASIONAL}	329.002.00107	CUR	1995
	TACHYCARDIA, UNSPEC	EKG SHOWS RAPID HEART RATE DUE TO PREVIOUS BLOOD DRAWING-NORMAL	329.003.00085	CUR	1994
	URINARY CASTS/WBC'S	SQUAMOUS CELLS IN URINE POST PARTUM	329.005.00293	CUR	1997
	URINE, ABN, OTHER	INCREASED URINE NITROGEN	329.010.00183	CUR	1995
	WEIGHT GAIN	WEIGHT GAIN	329.002.00246	CUR	1994
SKIN/SUBCUTANEOUS TISSUE DIS	INFLAM SKIN/SUBCUT	ALLERGY TO PENICILLIN {PATIENT GETS A RASH}	329.003.00094	CUR	
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.005.00253	CUR	1996
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.008.00191	CUR	1995
	SKIN/SUBCUT DISORD, OTHER	ACNE	329.009.00237	P&C	
	SKIN/SUBCUT DISORD, OTHER	FACIAL ACNE	329.006.00259	CUR	1994
	SKIN/SUBCUT DISORD, OTHER	FACIAL CYSTIC ACNE	329.003.00252	CUR	
	SKIN/SUBCUT DISORD, OTHER	RASH ON ARMS AND CHEST{FOLLICULITIS}	329.005.00120	CUR	1995

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PAROXETINE - PROTOCOL 329

Appendix B.9

Listing of Concomitant Medications
by WHO ATC Classification and Generic Term
Screening Failures Only

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ANTIINFECTIVES,SYSTEMIC	ANTIBIOTICS	Clarithromycin	Biaxin	329.009.90170	-8	25APR95	06MAY95

* days relative to screening date

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Listing of Concomitant Medications
by WHO ATC Classification and Generic Term
Screening Failures Only

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Chlorphenamine Maleate	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Dextromethorphan Hydrobromide	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Paracetamol	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Pseudoephedrine Hydrochloride	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96

* days relative to screening date

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Listing of Concomitant Medications
by WHO ATC Classification and Generic Term
Screening Failures Only

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
MUSCULO-SKELETAL	ANTIINFLAM/ANTIRHEU PROD	Ibuprofen	Advil	329.005.00296	-16	19MAR96	19MAR96
				329.009.90168	.	.	.

* days relative to screening date

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Listing of Concomitant Medications
by WHO ATC Classification and Generic Term
Screening Failures Only

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	ANTI-ASTHMATICS	Beclometasone Dipropionate	Vancenase	329.009.90170	-3	30APR95	.
	COUGH AND COLD PREP	Chlorphenamine Maleate	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Dextromethorphan Hydrobromide	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Guaifenesin	Guaifed-Pd	329.009.90170	-18	15APR95	.
		Paracetamol	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Pseudoephedrine Hydrochloride	Guaifed-Pd	329.009.90170	-18	15APR95	.
			Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
	NASAL PREP	Beclometasone Dipropionate	Vancenase	329.009.90170	-3	30APR95	.
		Mepyramine Maleate	Poly-Histine D	329.009.90170	-8	25APR95	.
		Pheniramine Maleate	Poly-Histine D	329.009.90170	-8	25APR95	.
		Phenylpropanolamine Hydrochloride	Poly-Histine D	329.009.90170	-8	25APR95	.
		Phenyltoloxamine Citrate	Poly-Histine D	329.009.90170	-8	25APR95	.
	SYSTEMIC ANTIHISTAMINES	Chlorphenamine Maleate	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Dextromethorphan Hydrobromide	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Guaifenesin	Guaifed-Pd	329.009.90170	-18	15APR95	.
		Mepyramine Maleate	Poly-Histine D	329.009.90170	-8	25APR95	.

* days relative to screening date

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Listing of Concomitant Medications
by WHO ATC Classification and Generic Term
Screening Failures Only

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	SYSTEMIC ANTIHISTAMINES	Paracetamol	Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96
		Pheniramine Maleate	Poly-Histine D	329.009.90170	-8	25APR95	.
		Phenylpropanolamine Hydrochloride	Poly-Histine D	329.009.90170	-8	25APR95	.
		Phenyltoloxamine Citrate	Poly-Histine D	329.009.90170	-8	25APR95	.
		Pseudoephedrine Hydrochloride	Guaifed-Pd	329.009.90170	-18	15APR95	.
			Tylenol - Cough And Cold	329.005.00296	-17	18MAR96	22MAR96

* days relative to screening date

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PAROXETINE - PROTOCOL 329

Appendix B.10

Listing of Concomitant Medications
by Patient and WHO ATC Classification
Screening Failures Only

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.005.00296	CENTRAL NERVOUS SYSTEM	Tylenol - Cough And Cold	-17	18MAR96	22MAR96	2 TSP.	COLD/FLU
	MUSCULO-SKELETAL	Advil	-16	19MAR96	19MAR96	2 PILLS	
	RESPIRATORY	Tylenol - Cough And Cold	-17	18MAR96	22MAR96	2 TSP.	COLD/FLU
329.009.90168	MUSCULO-SKELETAL	Advil	.	.	.	500MG PRN	HEADACHE/SINUS
329.009.90170	ANTIINFECTIVES,SYSTEMIC	Biaxin	-8	25APR95	06MAY95	1000MG	BRONCHITIS
	RESPIRATORY	Guaifed-Pd	-18	15APR95	.	60MG	ALLERGIES
		Poly-Histine D	-8	25APR95	.	420MG	ALLERGIES
		Vancenase	-3	30APR95	.	50MG	ALLERGIES

* days relative to screening date

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PAROXETINE - PROTOCOL 329

Appendix B.11

Listing of Adverse Experiences by ADECS Body System and Preferred Term
Screening Failures Only

Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Bundle Branch Block	{BROAD QRS}	329.007.90181	30NOV95	.	Not Stated	CON	MIL	NO	UNR	No	No

* days relative to screening date
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix B.11

Listing of Adverse Experiences by ADECS Body System and Preferred Term
Screening Failures Only

Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dry Mouth	DRY MOUTH	329.003.90112	21JUL95	.	1 Days	1	MIL	NO	UNR	No	No

* days relative to screening date
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix B.11

Listing of Adverse Experiences by ADECS Body System and Preferred Term
Screening Failures Only

Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Drug Dependence	POSITIVE URINE DRUG SCREEN FOR CANNABINOIDS	329.005.90379	27JUN96	.	1 Days	CON	SEV	NO	UNR	No	No
Emotional Lability	SUICIDAL IDEATION	329.010.90272	03DEC95	.	Not Stated	CON	SEV	NO	UNR	No	Yes

* days relative to screening date
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix B.12

Listing of Adverse Experiences by Patient
Screening Failures Only

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.003.90112	Dry Mouth	DRY MOUTH	21JUL95	.	1 Days	1	MIL	NO	UNR	No	No
329.005.90379	Drug Dependence	POSITIVE URINE DRUG SCREEN FOR CANNABINOIDS	27JUN96	.	1 Days	CON	SEV	NO	UNR	No	No
329.007.90181	Bundle Branch Block	{BROAD QRS}	30NOV95	.	Not Stated	CON	MIL	NO	UNR	No	No
329.010.90272	Emotional Lability	SUICIDAL IDEATION	03DEC95	.	Not Stated	CON	SEV	NO	UNR	No	Yes

* days relative to screening date
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix B.13

Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ALIMENTARY TRACT/METAB	ANTACID/ANITFLAT/ANTIPEPTIC	Aluminium Hydroxide	Maalox	329.004.00017	232, 176	08NOV95	08NOV95
			Maalox Liquid	329.009.00170	238, 181	01JUL96	.
		Calcium Carbonate	Tums	329.005.00299	., .	.	.
				329.009.00130	149, 93	13SEP95	.
		Dihydroxyaluminum Sodium Carbonate	Rolaids	329.001.00068	-982, .	01JUN92	08FEB95
				329.009.00196	10, .	27DEC95	.
		Famotidine	Pepcid Ac	329.009.00196	10, .	27DEC95	.
		Magnesium Hydroxide	Maalox	329.004.00017	232, 176	08NOV95	08NOV95
			Maalox Liquid	329.009.00170	238, 181	01JUL96	.
		Ranitidine Hydrochloride	Zantac	329.005.00109	123, 70	01MAY95	08MAY95
				329.007.00309	-44, -96	01JUN96	20JUN96#
	ANTIDIARRHEA/GI ANTIBIOTICS	Bismuth Subsalicylate	Pepto Bismol	329.007.00310	52, -9	16NOV96	17NOV96
				329.009.00133	28, .	10JUL95	.
		Charcoal, Activated	Charcoal	329.005.00011	156, 100	17MAY95	17MAY95
		Loperamide Hydrochloride	Imodium-Ad	329.005.00333	30, .	21FEB97	21FEB97
		Neomycin	Neomycin	329.007.00268	88, 29	27JUN96	29JUN96
		Polymyxin B	Polymyxin	329.007.00268	88, 29	27JUN96	29JUN96
	ANTIOBESITY PREP	Appetite Suppressant	Appetite Suppressant {Nos}	329.007.00294	-58, .	01JAN97	10FEB97#
	GI ANTISPAS/ANTICHOLIN	Atropine Sulfate	Donnatal	329.009.00130	-1568,-1624	01JAN91	18APR95

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ALIMENTARY TRACT/METAB	GI ANTISPAS/ANTICHOLIN	Hyoscine Hydrobromide	Donnatal	329.009.00130	-1568,-1624	01JAN91	18APR95
		Hyoscyamine Sulfate	Donnatal	329.009.00130	-1568,-1624	01JAN91	18APR95
		Phenobarbital	Donnatal	329.009.00130	-1568,-1624	01JAN91	18APR95
	LAXATIVES	Bisacodyl	Dulcolax	329.007.00268	233, 174	19NOV96	19NOV96
					233, 174	19NOV96	19NOV96
		Docusate Sodium	Correctol	329.009.00131	21, -36	22MAY95	22MAY95
		Yellow Phenolphthalein	Correctol	329.009.00131	21, -36	22MAY95	22MAY95
	MINERAL SUPPLEMENTS	Calcium Carbonate	Tums	329.005.00299	., .	.	.
				329.009.00130	149, 93	13SEP95	.
		Sodium Chloride	Normal Saline Solution	329.005.00011	156, 100	17MAY95	19MAY95
	MOUTH PREP	Neomycin	Neomycin	329.007.00268	88, 29	27JUN96	29JUN96
		Triamcinolone	Triamcinolone	329.007.00140	34, -22	18OCT95	22OCT95
	VITAMINS	Ascorbic Acid	Vitamin C	329.004.00015	5, -53	12DEC94	13DEC94
				329.005.00257	3, -54	13MAR96	.
		Calcium Pantothenate	Vitamin B Complex	329.004.00017	48, -9	08MAY95	.
		Minerals Nos	Centrum	329.004.00015	5, -53	12DEC94	13DEC94
		Nicotinamide	Vitamin B Complex	329.004.00017	48, -9	08MAY95	.
		Pyridoxine Hydrochloride	Vitamin B Complex	329.004.00017	48, -9	08MAY95	.
		Riboflavin	Vitamin B Complex	329.004.00017	48, -9	08MAY95	.

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ALIMENTARY TRACT/METAB	VITAMINS	Thiamine Hydrochloride	Vitamin B Complex	329.004.00017	48, -9	08MAY95	.
		Vitamins Nos	Centrum	329.004.00015	5, -53	12DEC94	13DEC94
			Multiple Vitamin	329.001.00068	-69, .	01DEC94	08FEB95
			Prenatal Vitamin	329.005.00109	-395, -448	30NOV93	.

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
ANTIINFECTIVES,SYSTEMIC	ANTIBIOTICS	Amoxicillin	Amoxicillin	329.001.00063	29,	.	06DEC94	16DEC94
				329.002.00058	60,	2	18NOV94	28NOV94
				329.003.00091	211,	157	20OCT95	30OCT95
				329.005.00116	26,	-33	04MAR95	14MAR95
				329.005.00151	41,	-17	16OCT95	02NOV95
				329.005.00257	145,	89	02AUG96	09AUG96
				329.009.00130	140,	84	04SEP95	13SEP95
		Amoxicillin Trihydrate	Amoxil	329.007.00142	-14,	.	04OCT95	13OCT95#
				329.009.00130	8,	-49	25APR95	04MAY95
				329.009.00133	32,	.	14JUL95	20JUL95
				329.012.00222	21,	-43	18JUL96	22JUL96
			Augmentin	329.005.00116	25,	-34	03MAR95	13MAR95
				329.007.00310	85,	25	19DEC96	29DEC96
				329.009.00201	-9,	.	28JAN96	06FEB96
					56,	.	01APR96	.
		Antibiotic Nos	Antibiotic {Nos}	329.008.00275	49,	-7	25JUN96	09JUL96
			Antibiotics Ear Drops {Nos}	329.005.00257	145,	89	02AUG96	09AUG96
		Cefaclor	Ceclor	329.005.00257	15,	-42	25MAR96	05APR96
					43,	-14	22APR96	06MAY96
				329.007.00310	19,	-42	14OCT96	27OCT96
			Ceclor Cd	329.007.00310	173,	113	17MAR97	28MAR97
		Cefalexin	Cephalexin	329.007.00268	82,	23	21JUN96	23JUN96
					87,	28	26JUN96	29JUN96
					92,	33	01JUL96	10JUL96
		Cefalexin Monohydrate	Keflex	329.007.00268	10,	-50	10APR96	14APR96
				329.010.00278	221,	165	16SEP96	19SEP96
		Cefixime	Cefixime	329.009.00196	56,	.	11FEB96	.
		Cefuroxime Axetil	Ceftin	329.005.00116	141,	83	27JUN95	07JUL95

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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ANTIINFECTIVES,SYSTEMIC	ANTIBIOTICS	Clarithromycin	Biaxin	329.008.00271	45, -20	24APR96	30APR96
				329.009.00303	-32, -88	01MAR96	.
		Clavulanic Acid	Augmentin	329.005.00116	25, -34	03MAR95	13MAR95
				329.007.00310	85, 25	19DEC96	29DEC96
				329.009.00201	-9, .	28JAN96	06FEB96
					56, .	01APR96	.
		Doxycycline	Doxycycline	329.008.00160	20, -47	20NOV95	.
		Erythromycin	Erythromycin	329.005.00151	48, -10	23OCT95	07NOV95
				329.007.00309	61, 9	13SEP96	19SEP96
					71, 19	23SEP96	01OCT96
				329.012.00220	113, 53	07OCT96	14OCT96
		Minocycline	Minocycline	329.009.00235	-33, -87	15NOV96	.
		Neomycin	Neomycin	329.007.00268	88, 29	27JUN96	29JUN96
		Penicillin Nos	Penicillin	329.003.00091	182, 128	21SEP95	01OCT95
		Polymyxin B	Polymyxin	329.007.00268	88, 29	27JUN96	29JUN96
		Tetracycline	Tetracycline	329.006.00260	-6, -64	12JUL96	.
		Tetracycline Hydrochloride	Apo-Tetra	329.004.00214	-16, -76	18SEP96	18SEP96#
					10, -51	13OCT96	13OCT96
					14, -47	17OCT96	20OCT96
	ANTIMYCOTICS	Miconazole Nitrate	Micatin	329.012.00231	84, 23	29MAY97	.
			Monistat 7	329.005.00257	242, 186	07NOV96	14NOV96
	CHEMOTHERAPEUTICS	Sulfamethoxazole	Septra Double Strength	329.004.00015	82, 25	27FEB95	05MAR95
		Trimethoprim	Septra Double Strength	329.004.00015	82, 25	27FEB95	05MAR95

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by WHO ATC Classification and Generic Term and by Treatment Group
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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ANTIINFECTIVES,SYSTEMIC	VACCINES	Hepatitis B Vaccine	Hepatitis B Shot {Vaccine}	329.004.00214	60, -1	02DEC96	02DEC96
			Hepatitis B {Vaccine}	329.004.00214	-1, -61	03OCT96	03OCT96#

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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by WHO ATC Classification and Generic Term and by Treatment Group
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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ANTINEOPLASTIC & IMMUNOSUP	ANTINEOPLASTIC,HORMONES	Diethylstilbestrol Dipropionate	Cyclen	329.012.00222	-119, -182	01MAR96	.

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
BLOOD/BLOOD FORM ORGANS	ANTIANAEMIC PREP	Ferrous Sulfate	Ferrous Sulfate	329.005.00109	-133, -186	19AUG94	.
	PLASMA SUBSTIT/PERF SOLUT	I.V. Fluids	Iv Fluids	329.005.00109	129, 76	07MAY95	10MAY95
		Sodium Chloride	Normal Saline Solution	329.005.00011	156, 100	17MAY95	19MAY95
					156, 100	17MAY95	19MAY95

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CARDIOVASCULAR	DIURETICS	Theophylline	Slo-Bid	329.005.00257	54, -3	03MAY96	10MAY96
	VASOPROTECTIVES	Benzocaine	Benzocaine	329.006.00038	-410, .	01JAN94	.
		Betamethasone	Betamethasone	329.012.00231	32, -30	07APR97	.

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix B.13

Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANAESTHETICS	Epinephrine	Xylocaine-Epinephrine	329.007.00309	74,	22	26SEP96	26SEP96
		Fentanyl	Fentanyl	329.007.00309	74,	22	26SEP96	26SEP96
		Lidocaine Hydrochloride	Xylocaine-Epinephrine	329.007.00309	74,	22	26SEP96	26SEP96
		Methohexital Sodium	Brevital	329.007.00309	74,	22	26SEP96	26SEP96
		Midazolam Hydrochloride	Versed	329.007.00309	74,	22	26SEP96	26SEP96
		Nitrous Oxide	Nitrous Oxide	329.007.00309	74,	22	26SEP96	26SEP96
	ANALGESICS	Acetylsalicylic Acid	Aspirin	329.001.00068	-617,	.	01JUN93	08FEB95
				329.002.00105	16,	.	11AUG95	24AUG95
				329.002.00242	-6,	-64	01FEB96	01FEB96#
				329.006.00260	56,	-3	11SEP96	11SEP96
				329.007.00268	29,	-31	29APR96	29APR96
				329.007.00310	218,	158	01MAY97	08MAY97
				329.010.00182	10,	.	28DEC95	28DEC95
				329.010.00278	-39,	-95	01JAN96	.
			Bayer Aspirin Extra Strength	329.005.00011	156,	100	17MAY95	17MAY95
			Excedrin	329.004.00019	7,	.	06JUN95	06JUN95
				329.006.00260	-2390,	-2448	01JAN90	.
					6,	-53	23JUL96	16SEP96
					8,	-51	25JUL96	25JUL96
					20,	-39	06AUG96	06AUG96
					83,	25	08OCT96	08OCT96
				329.008.00271	89,	25	07JUN96	07JUN96
				329.009.00193	-331,	.	01JAN95	.
			Excedrin Extra-Strength	329.005.00336	32,	.	04APR97	09APR97
					38,	.	10APR97	12APR97
					48,	.	20APR97	23APR97
			Extra Strength Excedrin	329.007.00145	111,	55	30APR96	13MAY96

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\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Acetylsalicylic Acid	Fiorinal	329.006.00038	57, .	12APR95	12APR95
			Midol	329.007.00309	34, -19	17AUG96	19AUG96
				329.007.00310	-8, -68	18SEP96	18SEP96#
		Analgesics	Unknown Headache Medicine {Analgesic Nos}	329.007.00294	-4, .	24FEB97	24FEB97#
		Butalbital	Fiorinal	329.006.00038	57, .	12APR95	12APR95
			Phrenilin	329.007.00310	175, 115	19MAR97	23MAR97
					236, 176	19MAY97	23MAY97
		Caffeine	Excedrin	329.004.00019	7, .	06JUN95	06JUN95
				329.006.00260	-2390,-2448	01JAN90	.
					6, -53	23JUL96	16SEP96
					8, -51	25JUL96	25JUL96
					20, -39	06AUG96	06AUG96
					83, 25	08OCT96	08OCT96
				329.008.00271	89, 25	07JUN96	07JUN96
				329.009.00193	-331, .	01JAN95	.
			Excedrin Extra-Strength	329.005.00336	32, .	04APR97	09APR97
					38, .	10APR97	12APR97
					48, .	20APR97	23APR97
			Extra Strength Excedrin	329.007.00145	111, 55	30APR96	13MAY96
			Fiorinal	329.006.00038	57, .	12APR95	12APR95
			Midol	329.007.00309	34, -19	17AUG96	19AUG96
				329.007.00310	-8, -68	18SEP96	18SEP96#
		Chlorphenamine Maleate	Tylenol Cold And Flu	329.001.00205	-27, .	11JAN96	11JAN96#
				329.009.00303	-32, -88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19, -82	01NOV95	.
		Cinnamedrine Hydrochloride	Midol	329.007.00309	34, -19	17AUG96	19AUG96

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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Cinnamedrine Hydrochloride	Midol	329.007.00310	-8, -68	18SEP96	18SEP96#
		Codeine Phosphate	Tylenol #1	329.001.00065	-2115, .	01FEB89	.
			Tylenol Iii	329.007.00309	71, 19	23SEP96	27SEP96
		Dextromethorphan Hydrobromide	Tylenol Cold And Flu	329.001.00205	-27, .	11JAN96	11JAN96#
				329.009.00303	-32, -88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19, -82	01NOV95	.
		Oxycodone Hydrochloride	Percocet	329.010.00278	37, -20	16MAR96	17MAR96
		Oxycodone Terephthalate	Percocet	329.010.00278	37, -20	16MAR96	17MAR96
		Pain Reliever	Premenstrual Syndrome Pain Relief {Nos}	329.009.00133	-893, .	01JAN93	.
		Paracetamol	Acetaminophen	329.010.00280	-10, -65	07MAY96	07MAY96#
			Excedrin	329.004.00019	7, .	06JUN95	06JUN95
				329.006.00260	-2390,-2448	01JAN90	.
					6, -53	23JUL96	16SEP96
					8, -51	25JUL96	25JUL96
					20, -39	06AUG96	06AUG96
					83, 25	08OCT96	08OCT96
				329.008.00271	89, 25	07JUN96	07JUN96
				329.009.00193	-331, .	01JAN95	.
			Excedrin Extra-Strength	329.005.00336	32, .	04APR97	09APR97
					38, .	10APR97	12APR97
					48, .	20APR97	23APR97
			Extra Strength Excedrin	329.007.00145	111, 55	30APR96	13MAY96
			Extra Strength Tylenol	329.005.00151	1, -57	06SEP95	06SEP95

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by WHO ATC Classification and Generic Term and by Treatment Group
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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Extra Strength Tylenol	329.007.00145	125,	69	14MAY96	15MAY96
				329.007.00294	-2,	.	26FEB97	26FEB97#
			Percocet	329.010.00278	37,	-20	16MAR96	17MAR96
			Phrenilin	329.007.00310	175,	115	19MAR97	23MAR97
					236,	176	19MAY97	23MAY97
			Sinutabs	329.004.00212	-215,	.	01NOV95	.
			Tylenol	329.001.00063	-1529,	.	01SEP90	.
				329.001.00068	20,	.	27FEB95	28MAR95
				329.002.00055	123,	68	24OCT94	.
				329.002.00058	122,	64	19JAN95	19JAN95
				329.002.00099	33,	-23	03APR95	03APR95
				329.002.00105	1,	.	27JUL95	03AUG95
				329.002.00242	42,	-17	19MAR96	19MAR96
				329.002.00245	-452,	.	01JAN95	.
				329.003.00075	-7,	-63	18JAN95	.
					16,	-41	09FEB95	14FEB95
				329.003.00081	-193,	.	01JUN95	.
				329.003.00089	8,	.	14MAR95	.
					42,	.	17APR95	18APR95
				329.003.00091	9,	-46	01APR95	01APR95
					36,	-19	28APR95	02MAY95
				329.003.00248	60,	.	29APR96	.
				329.004.00015	13,	-45	20DEC94	20DEC94
					69,	12	14FEB95	14FEB95
					79,	22	24FEB95	24FEB95
				329.004.00017	161,	105	29AUG95	30AUG95
				329.004.00214	36,	-25	08NOV96	09NOV96
					44,	-17	16NOV96	16NOV96
					83,	23	25DEC96	25DEC96
					84,	24	26DEC96	26DEC96
					85,	25	27DEC96	27DEC96
					87,	27	29DEC96	29DEC96
				329.005.00002	-5,	-61	20MAY94	20MAY94#
					54,	-3	17JUL94	20JUL94
				329.005.00004	81,	22	29DEC94	30DEC94
				329.005.00011	8,	-49	20DEC94	03JAN95
				329.005.00109	81,	28	20MAR95	22MAR95
				329.005.00112	-2,	-57	24JAN95	26JAN95

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Tylenol	329.005.00116	25,	-34	03MAR95	04APR95
				329.005.00119	7,	-53	17JUL95	17JUL95
				329.005.00151	-25,	-82	12AUG95	12AUG95#
					40,	-18	15OCT95	17OCT95
					44,	-14	19OCT95	19OCT95
				329.005.00258	21,	.	01APR96	01APR96
					28,	.	08APR96	08APR96
				329.005.00299	138,	78	23OCT96	23OCT96
				329.005.00333	2,	.	24JAN97	24JAN97
				329.005.00336	-12,	.	20FEB97	21FEB97#
				329.006.00038	57,	.	12APR95	12APR95
				329.007.00140	-622,	-677	01JAN94	.
				329.007.00142	-3942,	.	01JAN85	.
				329.007.00265	-3,	.	29JAN96	31JAN96#
				329.007.00294	14,	.	13MAR97	13MAR97
					18,	.	17MAR97	17MAR97
					22,	.	21MAR97	23MAR97
					40,	.	08APR97	08APR97
				329.007.00309	-15,	-67	30JUN96	30JUN96#
					43,	-10	26AUG96	26AUG96
					46,	-7	29AUG96	29AUG96
					107,	55	29OCT96	29OCT96
					237,	185	08MAR97	08MAR97
				329.007.00310	15,	-46	10OCT96	15OCT96
				329.009.00133	-893,	.	01JAN93	.
				329.009.00173	-19,	-82	01NOV95	.
				329.009.00196	-716,	.	01JAN94	.
				329.009.00201	-9,	.	28JAN96	.
				329.009.00204	-808,	-864	01JAN94	.
				329.009.00303	-32,	-88	01MAR96	.
				329.009.00329	-647,	.	01JAN95	.
				329.010.00182	-7,	.	12DEC95	12DEC95#
				329.010.00280	40,	-16	25JUN96	25JUN96
					42,	-14	27JUN96	27JUN96
				329.011.00283	33,	-25	11MAR96	11MAR96
				329.012.00231	49,	-13	24APR97	.
					109,	48	23JUN97	.
			Tylenol #1	329.001.00065	-2115,	.	01FEB89	.

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Listing of Prior and Concomitant Medications
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Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Tylenol (Liquid)	329.009.00235	-11, -65	07DEC96	07DEC96#
			Tylenol Cold And Flu	329.001.00205	-27, .	11JAN96	11JAN96#
				329.009.00303	-32, -88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19, -82	01NOV95	.
			Tylenol Es Gel Caps	329.007.00294	5, .	04MAR97	07MAR97
			Tylenol Extra Strength	329.004.00015	4, -54	11DEC94	11DEC94
					34, -24	10JAN95	10JAN95
					41, -17	17JAN95	17JAN95
					53, -5	29JAN95	29JAN95
					131, 74	17APR95	17APR95
				329.004.00214	-8, -68	26SEP96	26SEP96#
				329.005.00151	., .	.	03SEP95#
				329.008.00271	-5, -69	06MAR96	17MAR96
					28, -37	07APR96	07APR96
					63, -2	12MAY96	12MAY96
					91, 27	09JUN96	09JUN96
				329.009.00324	-88, .	01AUG96	.
			Tylenol Iii	329.007.00309	71, 19	23SEP96	27SEP96
			Tylenol Sinus	329.009.00196	55, .	10FEB96	.
				329.009.00324	-88, .	01AUG96	.
		Phenacetin	Fiorinal	329.006.00038	57, .	12APR95	12APR95
			Sinutabs	329.004.00212	-215, .	01NOV95	.
		Phenylpropanolamine Hydrochloride	Sinutabs	329.004.00212	-215, .	01NOV95	.
		Phenyltoloxamine Citrate	Sinutabs	329.004.00212	-215, .	01NOV95	.
		Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	329.001.00205	-27, .	11JAN96	11JAN96#
				329.009.00303	-32, -88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19, -82	01NOV95	.
			Tylenol Sinus	329.009.00196	55, .	10FEB96	.

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Pseudoephedrine Hydrochloride	Tylenol Sinus	329.009.00324	-88, .	01AUG96	.
		Tramadol Hydrochloride	Ultram	329.010.00278	38, -19	17MAR96	19MAR96
	PSYCHOANALEPTICS	Caffeine	Vivarin	329.005.00333	14, .	05FEB97	05FEB97
		Cannabis	Marijuana	329.010.00182	-1448, .	01JAN92	.
		Fluoxetine	Prozac	329.009.00303	-23, -79	10MAR96	17MAR96#
		Methylphenidate Hydrochloride	Ritalin	329.007.00318	-854, .	01AUG94	11AUG96#
				329.009.00204	-808, -864	01JAN94	01MAR96#
			Ritalin Sr	329.012.00220	-148, -208	21JAN96	15MAY96#
		Nefazodone	Nefazodone	329.009.00130	170, 114	04OCT95	.
		Sertraline Hydrochloride	Zoloft	329.002.00245	-27, .	01MAR96	14MAR96#
	PSYCHOLEPTICS	Methohexital Sodium	Brevital	329.007.00309	74, 22	26SEP96	26SEP96
		Prochlorperazine	Compazine	329.007.00268	218, 159	04NOV96	04NOV96
		Tranquilizer	Tranquilizer {Nos}	329.006.00038	17, .	03MAR95	03MAR95

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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
DERMATOLOGICALS	ANTI-ACNE PREP	Isotretinoin	Accutane	329.005.00257	-121, -177	11NOV95	.
					-121, -177	11NOV95	.
		Sulfur	Clearasil	329.009.00131	29, -28	30MAY95	.
		Triclosan	Clearasil	329.009.00131	29, -28	30MAY95	.
	ANTIBIOTIC&CHEMOTHERAPEUT	Erythromycin	Erythromycin	329.005.00151	48, -10	23OCT95	07NOV95
				329.007.00309	61, 9	13SEP96	19SEP96
					71, 19	23SEP96	01OCT96
				329.012.00220	113, 53	07OCT96	14OCT96
		Neomycin	Neomycin	329.007.00268	88, 29	27JUN96	29JUN96
		Tetracycline	Tetracycline	329.006.00260	-6, -64	12JUL96	.
		Tetracycline Hydrochloride	Apo-Tetra	329.004.00214	-16, -76	18SEP96	18SEP96#
					10, -51	13OCT96	13OCT96
					14, -47	17OCT96	20OCT96
	ANTIFUNGALS	Clotrimazole	Clotrimazole	329.007.00140	39, -17	23OCT95	24OCT95
		Griseofulvin	Gris-Peg	329.007.00140	41, -15	25OCT95	03NOV95
		Miconazole Nitrate	Micatin	329.012.00231	84, 23	29MAY97	.
			Monistat 7	329.005.00257	242, 186	07NOV96	14NOV96
	ANTIPRURITICS	Benzocaine	Benzocaine	329.006.00038	-410, .	01JAN94	.
		Diphenhydramine Hydrochloride	Benadryl	329.001.00063	-4086, .	01SEP83	.
				329.002.00099	34, -22	04APR95	11APR95
				329.002.00105	-329, .	01SEP94	.
				329.003.00250	47, -11	29APR96	29APR96
				329.007.00145	22, -35	01FEB96	01FEB96
				329.008.00275	-738, -793	01MAY94	.
					-1, -56	07MAY96	07MAY96#

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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
DERMATOLOGICALS	ANTIPRURITICS	Diphenhydramine Hydrochloride	Benadryl	329.008.00275	8, -48	15MAY96	.
					56, 1	02JUL96	.
					77, 22	23JUL96	24JUL96
					132, 77	16SEP96	17SEP96
					202, 147	25NOV96	26NOV96
				329.009.00303	23, -34	24APR96	24APR96
				329.010.00280	34, -22	19JUN96	21JUN96
					39, -17	24JUN96	26JUN96
			Benylin	329.004.00017	177, 121	14SEP95	16SEP95
	CORTICOSTEROIDS	Betamethasone	Betamethasone	329.012.00231	32, -30	07APR97	.
		Budesonide	Rhinocort	329.012.00222	-36, -99	23MAY96	.
		Fluticasone Propionate	Flonase	329.005.00257	43, -14	22APR96	28APR96
		Triamcinolone	Triamcinolone	329.007.00140	34, -22	18OCT95	22OCT95

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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
GU SYSTEM/SEX HORMONES	ANTIINFECTIVES/ANTISEPTICS	Clotrimazole	Clotrimazole	329.007.00140	39, -17	23OCT95	24OCT95
		Miconazole Nitrate	Micatin	329.012.00231	84, 23	29MAY97	.
			Monistat 7	329.005.00257	242, 186	07NOV96	14NOV96
	SEX HORMONES/STIMULANTS	Desogestrel	Desogen 28	329.005.00109	14, -40	12JAN95	.
		Diethylstilbestrol Dipropionate	Cyclen	329.012.00222	-119, -182	01MAR96	.
		Ethinylestradiol	Desogen 28	329.005.00109	14, -40	12JAN95	.
			Ortho 777	329.004.00212	-215, .	01NOV95	.
			Ortho Novum 1/35-28	329.009.00235	40, -15	26JAN97	.
			Ortho Tri-Cyclen	329.012.00231	32, -30	07APR97	.
		Norethisterone	Ortho 777	329.004.00212	-215, .	01NOV95	.
			Ortho Novum 1/35-28	329.009.00235	40, -15	26JAN97	.
		Norgestimate	Ortho Tri-Cyclen	329.012.00231	32, -30	07APR97	.
		Oral Contraceptive	Birth Control Pill	329.004.00214	-32, -92	02SEP96	.

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
MUSCULO-SKELETAL	ANTIINFLAM/ANTIRHEU PROD	Etodolac	Lodine	329.009.00133	32,	.	14JUL95	17JUL95
		Ibuprofen	Advil	329.002.00055	123,	68	24OCT94	.
				329.005.00116	65,	7	12APR95	12APR95
					111,	53	28MAY95	30MAY95
				329.005.00119	47,	-13	26AUG95	26AUG95
				329.005.00257	157,	101	14AUG96	21AUG96
				329.005.00299	.,	.	.	.
				329.005.00333	23,	.	14FEB97	16FEB97
					33,	.	24FEB97	24FEB97
				329.006.00038	57,	.	12APR95	12APR95
				329.006.00039	-1134,	-1195	01JAN92	.
				329.006.00260	53,	-6	08SEP96	08SEP96
				329.006.00261	58,	-1	22JAN97	22JAN97
				329.007.00309	29,	-24	12AUG96	13AUG96
					33,	-20	16AUG96	16AUG96
					72,	20	24SEP96	03OCT96
					176,	124	06JAN97	13JAN97
					184,	132	14JAN97	12FEB97
				329.007.00310	14,	-47	09OCT96	09OCT96
					50,	-11	14NOV96	17NOV96
				329.008.00275	-493,	-548	01JAN95	.
					-1,	-56	07MAY96	.
					56,	1	02JUL96	.
				329.009.00240	-13,	.	01JAN97	.
				329.009.00303	-822,	-878	01JAN94	.
				329.009.00304	-464,	-520	01JAN95	.
				329.009.00324	-88,	.	01AUG96	.
			Ibuprofen	329.006.00038	57,	.	12APR95	12APR95
					57,	.	12APR95	12APR95
				329.007.00268	10,	-50	10APR96	10APR96
					57,	-3	27MAY96	30MAY96
				329.007.00294	-1154,	.	01JAN94	.
				329.007.00309	-44,	-96	01JUN96	.
				329.008.00271	21,	-44	31MAR96	31MAR96
				329.009.00193	15,	.	12DEC95	27DEC95
				329.009.00196	-716,	.	01JAN94	.
				329.009.00235	-11,	-65	07DEC96	07DEC96#

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
MUSCULO-SKELETAL	ANTIINFLAM/ANTIRHEU PROD	Ibuprofen	Motrin	329.003.00075	-7,	-63	18JAN95	.
					16,	-41	09FEB95	14FEB95
				329.007.00268	-821,	-880	01JAN94	.
					57,	-3	27MAY96	07JUN96
					98,	39	07JUL96	10JUL96
					102,	43	11JUL96	07NOV96
					184,	125	01OCT96	07NOV96
				329.009.00170	246,	189	09JUL96	.
		Ketoprofen	Orudis Kt	329.007.00310	53,	-8	17NOV96	30NOV96
		Naproxen Sodium	Aleve	329.002.00319	203,	147	18NOV96	18NOV96
				329.007.00294	34,	.	02APR97	02APR97
					39,	.	07APR97	07APR97
				329.007.00309	-44,	-96	01JUN96	.
				329.007.00310	-56,	-116	01AUG96	.
					14,	-47	09OCT96	09OCT96
			Anaprox	329.006.00039	76,	15	24APR95	28APR95
	MUSCLE RELAXANTS	Metaxalone	Skelaxin	329.007.00310	14,	-47	09OCT96	15OCT96
	TOPICAL ANTIRHEU PROD	Eucalyptus Oil	Hall'S Cough Drops	329.009.00193	15,	.	12DEC95	27DEC95
		Menthol	Hall'S Cough Drops	329.009.00193	15,	.	12DEC95	27DEC95
			Vicks Cough Drop	329.008.00271	42,	-23	21APR96	21APR96

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PAROXETINE - PROTOCOL 329

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	ANTI-ASTHMATICS	Acrivastine	Semprex-D	329.005.00257	14, -43	24MAR96	24MAR96
		Budesonide	Rhinocort	329.012.00222	-36, -99	23MAY96	.
		Ephedrine Sulfate	Marax	329.005.00257	202, 146	28SEP96	.
		Hydroxyzine Hydrochloride	Marax	329.005.00257	202, 146	28SEP96	.
		Loratadine	Claritin-D	329.007.00310	85, 25	19DEC96	30DEC96
		Pseudoephedrine	Semprex-D	329.005.00257	14, -43	24MAR96	24MAR96
		Pseudoephedrine Sulfate	Claritin-D	329.007.00310	85, 25	19DEC96	30DEC96
		Salbutamol	Albuterol	329.005.00257	43, -14	22APR96	06MAY96
					43, -14	22APR96	06MAY96
				329.006.00038	-1871, .	01JAN90	.
					-1871, .	01JAN90	.
				329.008.00271	-3722,-3786	01JAN86	.
					-3722,-3786	01JAN86	.
				329.009.00196	-1081, .	01JAN93	.
					-1081, .	01JAN93	.
			Albuterol Inhaler	329.009.00196	-1081, .	01JAN93	.
					-1081, .	01JAN93	.
			Proventil	329.003.00075	., .	.	.
					., .	.	.
				329.006.00261	-4713,-4771	01JAN84	01JAN96#
					-4713,-4771	01JAN84	01JAN96#
			Proventil Inhaler	329.008.00271	-3722,-3786	01JAN86	.
					-3722,-3786	01JAN86	.
			Ventolin Inhaler	329.005.00116	26, -33	04MAR95	14MAR95
					26, -33	04MAR95	14MAR95
				329.008.00160	20, -47	20NOV95	.
					20, -47	20NOV95	.
		Theophylline	Marax	329.005.00257	202, 146	28SEP96	.
			Slo-Bid	329.005.00257	54, -3	03MAY96	10MAY96

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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	CHEST RUBS/INHALANTS	Menthol	Vicks Cough Drop	329.008.00271	42, -23	21APR96	21APR96
	COUGH AND COLD PREP	Carbinoxamine Maleate	Naldecon	329.011.00288	2, .	26JUL96	01AUG96
			Rondec Dm	329.009.00196	56, .	11FEB96	.
		Chlorphenamine Maleate	Contac Cold	329.006.00260	83, 25	08OCT96	08OCT96
			Dristan	329.007.00142	44, .	30NOV95	30NOV95
			Histussin Hc	329.007.00309	47, -6	30AUG96	02SEP96
			Tylenol Cold And Flu	329.001.00205	-27, .	11JAN96	11JAN96#
				329.009.00303	-32, -88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19, -82	01NOV95	.
		Cough Cold Preparations Nos	Ggg-Cold {Cold Preparation Nos}	329.007.00145	224, 168	21AUG96	23AUG96
		Cough Syrup/Med	Smith Brothers Cough Drop	329.005.00116	75, 17	22APR95	07MAY95
			Unknown Cough Drop	329.007.00294	34, .	02APR97	02APR97
		Dextromethorphan Hydrobromide	Contac Cold	329.006.00260	83, 25	08OCT96	08OCT96
			Nyquil	329.002.00099	18, -38	19MAR95	21MAR95
				329.005.00119	79, 20	27SEP95	27SEP95
				329.009.00193	15, .	12DEC95	27DEC95
			Robitussin-Dm	329.011.00288	8, .	01AUG96	.
			Rondec Dm	329.009.00196	56, .	11FEB96	.
			Tylenol Cold And Flu	329.001.00205	-27, .	11JAN96	11JAN96#
				329.009.00303	-32, -88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19, -82	01NOV95	.
		Doxylamine Succinate	Nyquil	329.002.00099	18, -38	19MAR95	21MAR95
				329.005.00119	79, 20	27SEP95	27SEP95
				329.009.00193	15, .	12DEC95	27DEC95
		Ethanol	Robitussin-Dm	329.011.00288	8, .	01AUG96	.

* days relative to start of acute phase, days relative to start of continuation phase
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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	COUGH AND COLD PREP	Eucalyptus Oil	Hall'S Cough Drops	329.009.00193	15, .	12DEC95	27DEC95
		Guaifenesin	Entex	329.009.00196	54, .	09FEB96	09FEB96
			Panmist La	329.007.00310	19, -42	14OCT96	29OCT96
			Robitussin	329.005.00116	75, 17	22APR95	07MAY95
				329.005.00119	80, 21	28SEP95	28SEP95
				329.005.00258	2, .	13MAR96	13MAR96
				329.005.00299	109, 49	24SEP96	02OCT96
					140, 80	25OCT96	25OCT96
			Robitussin-Dm	329.011.00288	8, .	01AUG96	.
		Hydrocodone	Hydrocodone	329.007.00309	74, 22	26SEP96	26SEP96
		Hydrocodone Bitartrate	Codimal Dh	329.009.00201	56, .	01APR96	.
			Histussin Hc	329.007.00309	47, -6	30AUG96	02SEP96
		Menthol	Hall'S Cough Drops	329.009.00193	15, .	12DEC95	27DEC95
		Mepyramine Maleate	Codimal Dh	329.009.00201	56, .	01APR96	.
		Paracetamol	Contac Cold	329.006.00260	83, 25	08OCT96	08OCT96
			Dristan	329.007.00142	44, .	30NOV95	30NOV95
			Nyquil	329.002.00099	18, -38	19MAR95	21MAR95
				329.005.00119	79, 20	27SEP95	27SEP95
				329.009.00193	15, .	12DEC95	27DEC95
			Tylenol Cold And Flu	329.001.00205	-27, .	11JAN96	11JAN96#
				329.009.00303	-32, -88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19, -82	01NOV95	.
		Phenylephrine Hydrochloride	Codimal Dh	329.009.00201	56, .	01APR96	.
			Dristan	329.007.00142	44, .	30NOV95	30NOV95
			Entex	329.009.00196	54, .	09FEB96	09FEB96
			Histussin Hc	329.007.00309	47, -6	30AUG96	02SEP96
			Naldecon	329.011.00288	2, .	26JUL96	01AUG96

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
RESPIRATORY	COUGH AND COLD PREP	Phenylpropanolamine Hydrochloride	Contac Cold	329.006.00260	83,	25	08OCT96	08OCT96
			Entex	329.009.00196	54,	.	09FEB96	09FEB96
			Naldecon	329.011.00288	2,	.	26JUL96	01AUG96
		Phenyltoloxamine Citrate	Naldecon	329.011.00288	2,	.	26JUL96	01AUG96
		Pseudoephedrine	Panmist La	329.007.00310	19,	-42	14OCT96	29OCT96
		Pseudoephedrine Hydrochloride	Nyquil	329.002.00099	18,	-38	19MAR95	21MAR95
				329.005.00119	79,	20	27SEP95	27SEP95
				329.009.00193	15,	.	12DEC95	27DEC95
			Rondec Dm	329.009.00196	56,	.	11FEB96	.
			Tylenol Cold And Flu	329.001.00205	-27,	.	11JAN96	11JAN96#
				329.009.00303	-32,	-88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19,	-82	01NOV95	.
	NASAL PREP	Acrivastine	Semprex-D	329.005.00257	14,	-43	24MAR96	24MAR96
		Aminoacetic Acid	Afrin Spray	329.002.00099	15,	-41	16MAR95	21MAR95
		Benzalkonium Chloride	Afrin Spray	329.002.00099	15,	-41	16MAR95	21MAR95
		Brompheniramine Maleate	Dimetapp	329.005.00336	-18,	.	14FEB97	16FEB97#
		Budesonide	Rhinocort	329.012.00222	-36,	-99	23MAY96	.
		Chlorphenamine Maleate	Contac	329.007.00309	143,	91	04DEC96	04DEC96
					145,	93	06DEC96	06DEC96
					147,	95	08DEC96	08DEC96
			Triaminic Cough Syrup	329.008.00271	-5,	-69	06MAR96	06MAR96#

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Listing of Prior and Concomitant Medications
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Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	NASAL PREP	Chlorphenamine Tannate	Rynatan	329.005.00257	15, -42	25MAR96	27MAR96
		Clemastine Fumarate	Tavist-D	329.010.00280	-2, -57	15MAY96	15MAY96#
		Dexbrompheniramine Maleate	Drixoral	329.007.00309	52, -1	04SEP96	04SEP96
					110, 58	01NOV96	01NOV96
			Drixoral Pills	329.004.00015	5, -53	12DEC94	13DEC94
		Fluticasone Propionate	Flonase	329.005.00257	43, -14	22APR96	28APR96
		Mepyramine Tannate	Rynatan	329.005.00257	15, -42	25MAR96	27MAR96
		Oxymetazoline Hydrochloride	Afrin Spray	329.002.00099	15, -41	16MAR95	21MAR95
		Paracetamol	Tylenol Sinus	329.009.00196	55, .	10FEB96	.
				329.009.00324	-88, .	01AUG96	.
		Phenylephrine Hydrochloride	Dimetapp	329.005.00336	-18, .	14FEB97	16FEB97#
		Phenylephrine Tannate	Rynatan	329.005.00257	15, -42	25MAR96	27MAR96
		Phenylmercuric Acetate	Afrin Spray	329.002.00099	15, -41	16MAR95	21MAR95
		Phenylpropanolamine Hydrochloride	Contac	329.007.00309	143, 91	04DEC96	04DEC96
					145, 93	06DEC96	06DEC96
					147, 95	08DEC96	08DEC96
			Dimetapp	329.005.00336	-18, .	14FEB97	16FEB97#
			Tavist-D	329.010.00280	-2, -57	15MAY96	15MAY96#
			Triaminic Cough Syrup	329.008.00271	-5, -69	06MAR96	06MAR96#

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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	NASAL PREP	Prednisone	Prednisone	329.005.00116	135, 77	21JUN95	28JUN95
					143, 85	29JUN95	02JUL95
					147, 89	03JUL95	07JUL95
					152, 94	08JUL95	12JUL95
				329.009.00196	56, .	11FEB96	.
				329.010.00278	221, 165	16SEP96	17SEP96
					223, 167	18SEP96	19SEP96
					225, 169	20SEP96	21SEP96
					227, 171	22SEP96	23SEP96
					229, 173	24SEP96	25SEP96
		Pseudoephedrine	Semprex-D	329.005.00257	14, -43	24MAR96	24MAR96
		Pseudoephedrine Hydrochloride	Actifed	329.001.00063	-4086, .	01SEP83	.
			Sudafed	329.002.00099	28, -28	29MAR95	29MAR95
				329.004.00212	-215, .	01NOV95	.
				329.009.00324	-88, .	01AUG96	.
			Tylenol Sinus	329.009.00196	55, .	10FEB96	.
				329.009.00324	-88, .	01AUG96	.
		Pseudoephedrine Sulfate	Drixoral	329.007.00309	52, -1	04SEP96	04SEP96
					110, 58	01NOV96	01NOV96
			Drixoral Pills	329.004.00015	5, -53	12DEC94	13DEC94
		Sodium Chloride	Normal Saline Solution	329.005.00011	156, 100	17MAY95	19MAY95
		Sorbitol	Afrin Spray	329.002.00099	15, -41	16MAR95	21MAR95
		Triprolidine Hydrochloride	Actifed	329.001.00063	-4086, .	01SEP83	.
	SYSTEMIC ANTIHISTAMINES	Acrivastine	Semprex-D	329.005.00257	14, -43	24MAR96	24MAR96
		Antihistamine, Nos	Antihistamine {Nos}	329.008.00157	-3893,-3948	01JAN85	.

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
RESPIRATORY	SYSTEMIC ANTIHISTAMINES	Cetirizine Hydrochloride	Reactine	329.012.00025	-115,	.	01JUL95	.
		Chlorphenamine Maleate	Tylenol Cold And Flu	329.001.00205	-27,	.	11JAN96	11JAN96#
				329.009.00303	-32,	-88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19,	-82	01NOV95	.
		Dextromethorphan Hydrobromide	Tylenol Cold And Flu	329.001.00205	-27,	.	11JAN96	11JAN96#
				329.009.00303	-32,	-88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19,	-82	01NOV95	.
		Dimenhydrinate	Dramamine	329.009.00170	238,	181	01JUL96	.
			Gravol	329.004.00214	37,	-24	09NOV96	10NOV96
					44,	-17	16NOV96	17NOV96
		Diphenhydramine Hydrochloride	Benadryl	329.001.00063	-4086,	.	01SEP83	.
				329.002.00099	34,	-22	04APR95	11APR95
				329.002.00105	-329,	.	01SEP94	.
				329.003.00250	47,	-11	29APR96	29APR96
				329.007.00145	22,	-35	01FEB96	01FEB96
				329.008.00275	-738,	-793	01MAY94	.
					-1,	-56	07MAY96	07MAY96#
					8,	-48	15MAY96	.
					56,	1	02JUL96	.
					77,	22	23JUL96	24JUL96
					132,	77	16SEP96	17SEP96
					202,	147	25NOV96	26NOV96
				329.009.00303	23,	-34	24APR96	24APR96
				329.010.00280	34,	-22	19JUN96	21JUN96
					39,	-17	24JUN96	26JUN96
			Benylin	329.004.00017	177,	121	14SEP95	16SEP95
		Fexofenadine Hydrochloride	Allegra	329.005.00333	-236,	.	01JUN96	.

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
RESPIRATORY	SYSTEMIC ANTIHISTAMINES	Loratadine	Claritin	329.004.00212	-215,	.	01NOV95	09JUN96
			Claritin-D	329.007.00310	85,	25	19DEC96	30DEC96
		Paracetamol	Tylenol Cold And Flu	329.001.00205	-27,	.	11JAN96	11JAN96#
				329.009.00303	-32,	-88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19,	-82	01NOV95	.
		Pseudoephedrine	Semprex-D	329.005.00257	14,	-43	24MAR96	24MAR96
		Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	329.001.00205	-27,	.	11JAN96	11JAN96#
				329.009.00303	-32,	-88	01MAR96	.
			Tylenol Cold {Medicine}	329.009.00173	-19,	-82	01NOV95	.
		Pseudoephedrine Sulfate	Claritin-D	329.007.00310	85,	25	19DEC96	30DEC96
	THROAT PREP	Benzocaine	Benzocaine	329.006.00038	-410,	.	01JAN94	.
		Menthol	Vicks Cough Drop	329.008.00271	42,	-23	21APR96	21APR96

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Listing of Prior and Concomitant Medications
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Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
SENSORY ORGANS	OPHTHALMOL/OTOLOGICAL PREP	Erythromycin	Erythromycin	329.005.00151	48, -10	23OCT95	07NOV95
				329.007.00309	61, 9	13SEP96	19SEP96
					71, 19	23SEP96	01OCT96
				329.012.00220	113, 53	07OCT96	14OCT96
		Tetracycline	Tetracycline	329.006.00260	-6, -64	12JUL96	.
		Tetracycline Hydrochloride	Apo-Tetra	329.004.00214	-16, -76	18SEP96	18SEP96#
					10, -51	13OCT96	13OCT96
					14, -47	17OCT96	20OCT96
	OPHTHALMOLOGICALS	Betamethasone	Betamethasone	329.012.00231	32, -30	07APR97	.
		Gramicidin	Polysporin Eye Drops	329.004.00015	-1, -58	07DEC94	18DEC94
					27, -31	03JAN95	14JAN95
		Neomycin	Neomycin	329.007.00268	88, 29	27JUN96	29JUN96
		Polymyxin B Sulfate	Polysporin Eye Drops	329.004.00015	-1, -58	07DEC94	18DEC94
					27, -31	03JAN95	14JAN95
		Polyvidone	Refresh	329.005.00151	156, 99	08FEB96	08MAR96
		Polyvinyl Alcohol	Refresh	329.005.00151	156, 99	08FEB96	08MAR96
		Sodium Chloride	Normal Saline Solution	329.005.00011	156, 100	17MAY95	19MAY95
			Refresh	329.005.00151	156, 99	08FEB96	08MAR96
		Tetracycline	Tetracycline	329.006.00260	-6, -64	12JUL96	.
		Tetracycline Hydrochloride	Apo-Tetra	329.004.00214	-16, -76	18SEP96	18SEP96#
					10, -51	13OCT96	13OCT96
					14, -47	17OCT96	20OCT96
		Triamcinolone	Triamcinolone	329.007.00140	34, -22	18OCT95	22OCT95

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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
SENSORY ORGANS	OTOLOGICALS	Ear Medication, Nos	Ear Drops {Nos}	329.005.00116	25, -34	03MAR95	04APR95

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by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
SYSTEMIC HORMONAL	CORTICOSTEROIDS	Betamethasone	Betamethasone	329.012.00231	32, -30	07APR97	.
		Prednisone	Prednisone	329.005.00116	135, 77	21JUN95	28JUN95
					143, 85	29JUN95	02JUL95
					147, 89	03JUL95	07JUL95
					152, 94	08JUL95	12JUL95
				329.009.00196	56, .	11FEB96	.
				329.010.00278	221, 165	16SEP96	17SEP96
					223, 167	18SEP96	19SEP96
					225, 169	20SEP96	21SEP96
					227, 171	22SEP96	23SEP96
					229, 173	24SEP96	25SEP96
		Triamcinolone	Triamcinolone	329.007.00140	34, -22	18OCT95	22OCT95

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Intent-to-Treat Population

Treatment Group=PAROXETINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
VARIOUS	GENERAL NUTRIENTS	Lysine	Lysine	329.001.00068	-366, .	07FEB94	08FEB95
		Nutritional Supplement Nos	T-Lite {Dietary Supplement}	329.007.00268	154, 95	01SEP96	02OCT96

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
ALIMENTARY TRACT/METAB	ANTACID/ANITFLAT/ANTIPEPTIC	Aluminium Hydroxide	Mylanta	329.003.00090	50,	.	02MAY95	.
				329.003.00092	173,	115	22OCT95	23OCT95
		Calcium Carbonate	Tums	329.005.00006	23,	-38	26NOV94	.
				329.010.00279	193,	137	30SEP96	30SEP96
				329.012.00230	15,	-55	14MAR97	.
					76,	7	14MAY97	26MAY97
		Cimetidine	Cimetidine	329.005.00117	41,	.	27APR95	.
			Tagamet	329.009.00194	28,	-29	01JAN96	.
		Dimeticone, Activated	Mylanta	329.003.00090	50,	.	02MAY95	.
				329.003.00092	173,	115	22OCT95	23OCT95
		Famotidine	Pepcid Ac	329.003.00314	44,	.	04DEC96	06DEC96
				329.007.00269	-101,	.	01JAN96	.
				329.008.00192	-2,	.	03MAR96	.
		Magnesium Hydroxide	Milk Of Magnesia	329.003.00092	173,	115	22OCT95	23OCT95
			Mylanta	329.003.00090	50,	.	02MAY95	.
				329.003.00092	173,	115	22OCT95	23OCT95
		Nizatidine	Axid	329.005.00256	129,	73	11JUL96	.
		Ranitidine Hydrochloride	Zantac	329.009.00325	-604,	-659	01JAN95	.
	ANTIDIARRHEA/GI ANTIBIOTICS	Bismuth Subsalicylate	Pepto Bismol	329.003.00092	39,	-20	10JUN95	10JUN95
				329.007.00146	58,	5	22MAR96	22MAR96
					162,	109	04JUL96	04JUL96
			Pepto-Bismol	329.005.00295	-9,	.	19MAR96	19MAR96#
		Loperamide Hydrochloride	Imodium A-D	329.007.00308	-2,	.	30JUN96	30JUN96#
				329.009.00305	57,	-1	02JUL96	02JUL96

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Listing of Prior and Concomitant Medications
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Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ALIMENTARY TRACT/METAB	ANTIEMETICS & ANTINAUSEANTS	Antiemetics & Antinauseants Nos	Antiemetic {Nos}	329.004.00211	49, .	21MAR96	22MAR96
		Caffeine	Coke Syrup	329.003.00092	173, 115	22OCT95	23OCT95
		Corn Syrup	Coke Syrup	329.003.00092	173, 115	22OCT95	23OCT95
		Natural Flavors	Coke Syrup	329.003.00092	173, 115	22OCT95	23OCT95
	ANTIOBESITY PREP	Caffeine	Dexatrim	329.003.00073	13, .	31JAN95	03FEB95
		Phenylpropanolamine Hydrochloride	Dexatrim	329.003.00073	13, .	31JAN95	03FEB95
	GI ANTISPAS/ANTICHOLIN	Cisapride	Propulsid	329.005.00117	41, .	27APR95	.
		Dicycloverine Hydrochloride	Bentyl	329.003.00073	45, .	04MAR95	06MAR95
		Hyoscyamine Sulfate	Levsinex	329.008.00187	-5445, .	01JAN81	.
	LAXATIVES	Enema, Nos	Enema Nos	329.003.00090	49, .	01MAY95	01MAY95
		Laxatives, Nos	Laxative (Unknown Name)	329.012.00221	112, 49	14OCT96	01NOV96
		Senna Fruit	Senokot	329.003.00090	50, .	02MAY95	.
	MINERAL SUPPLEMENTS	Calcium Carbonate	Tums	329.005.00006	23, -38	26NOV94	.
				329.010.00279	193, 137	30SEP96	30SEP96
				329.012.00230	15, -55	14MAR97	.
					76, 7	14MAY97	26MAY97
	VITAMINS	Ascorbic Acid	Vitamin C	329.004.00014	-5, .	24NOV94	.
				329.004.00211	., .	.	.
				329.005.00295	-24, .	04MAR96	06MAR96#

* days relative to start of acute phase, days relative to start of continuation phase
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Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ALIMENTARY TRACT/METAB	VITAMINS	Calcium Pantothenate	Jamieson B Complex Vitamins	329.004.00211	., .	.	.
		Minerals Nos	Centrum	329.001.00122	-80, -137	01APR95	20JUN95
		Nicotinamide	Jamieson B Complex Vitamins	329.004.00211	., .	.	.
		Pyridoxine Hydrochloride	Jamieson B Complex Vitamins	329.004.00211	., .	.	.
		Riboflavin	Jamieson B Complex Vitamins	329.004.00211	., .	.	.
		Thiamine Hydrochloride	Jamieson B Complex Vitamins	329.004.00211	., .	.	.
		Vitamins Nos	Centrum	329.001.00122	-80, -137	01APR95	20JUN95

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ANTIINFECTIVES,SYSTEMIC	ANTIBIOTICS	Amoxicillin	Amoxicillin	329.001.00070	-8, .	14FEB95	20FEB95#
				329.002.00050	5, .	27MAR95	28MAR95
					6, .	28MAR95	08APR95
				329.002.00104	232, 176	21DEC95	31DEC95
				329.007.00270	-8, .	01MAY96	13MAY96
				329.007.00307	18, .	02JUN96	07JUN96
		Amoxicillin Trihydrate	Amoxil	329.012.00227	42, -28	28JAN97	10FEB97
		Cefaclor	Ceclor	329.005.00006	21, -40	24NOV94	28NOV94
					25, -36	28NOV94	09DEC94
		Clarithromycin	Biaxin	329.012.00230	50, -20	18APR97	24APR97
		Clindamycin Hydrochloride	Cleocin	329.002.00050	-1177, .	01JAN92	.
		Erythromycin	Erycette 2% Cream	329.010.00279	91, 35	20JUN96	.
			Erythromycin	329.005.00003	-19, .	01SEP94	14SEP94#
		Minocycline	Minocin	329.004.00013	-48, -107	01JUN94	01FEB95
			Minocycline	329.002.00050	-1177, .	01JAN92	.
			Monocycline	329.002.00104	-123, -179	01JAN95	.
		Phenoxymethylpenicillin	Pen-Vee-K	329.002.00243	1, .	14MAR96	21MAR96
					1, .	14MAR96	21MAR96
		Phenoxymethylpenicillin Potassium	Pen-Vee-K	329.003.00314	-111, .	03JUL96	13JUL96#
			Penicillin V-K	329.012.00227	21, -49	07JAN97	15JAN97
		Tetracycline	Tetracycline	329.005.00153	-389, -445	01JAN95	.
	ANTIMYCOTICS	Ketoconazole	Nizoral	329.009.00134	-1, .	05JUL95	10JUL95
	CHEMOTHERAPEUTICS	Sulfamethoxazole	Bactrim Ds	329.001.00122	-139, -196	01FEB95	.

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Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ANTIINFECTIVES,SYSTEMIC	CHEMOTHERAPEUTICS	Sulfamethoxazole	Sulfamethoxazole/Trimethoprim Ds	329.005.00255	36, .	08APR96	15APR96
		Trimethoprim	Bactrim Ds	329.001.00122	-139, -196	01FEB95	.
			Sulfamethoxazole/Trimethoprim Ds	329.005.00255	36, .	08APR96	15APR96
	VACCINES	Hepatitis B Vaccine	Hepatitis B Vaccine	329.011.00284	29, -28	19APR96	19APR96

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
BLOOD/BLOOD FORM ORGANS	ANTIANAEMIC PREP	Cyanocobalamin	Vitamin B12	329.006.00041	-63, -127	01FEB95	05APR95
	PLASMA SUBSTIT/PERF SOLUT	I.V. Fluids	Intravenous Fluids	329.004.00211	49, .	21MAR96	22MAR96

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Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CARDIOVASCULAR	DIURETICS	Theophylline	Theo-Dur	329.009.00301	-443, -499	01JAN95	.

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Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Acetylsalicylic Acid	Actron	329.009.00239	-263, -320	01MAR96	.
			Alka-Seltzer	329.001.00066	-731, .	21NOV92	.
			Aspirin	329.002.00050	4, .	26MAR95	26MAR95
				329.009.00134	38, .	12AUG95	.
				329.009.00264	-732, .	31OCT94	.
				329.012.00221	78, 15	10SEP96	10SEP96
			Bayer Aspirin	329.002.00057	83, 26	29NOV94	29NOV94
			Bc Powder	329.007.00139	-9, .	29APR95	01MAY95#
			Excedrin	329.008.00187	-332, .	01JAN95	.
					36, .	03JAN96	04JAN96
				329.009.00239	92, 35	18FEB97	17MAR97
			Excedrin Extra Strength	329.008.00187	44, .	11JAN96	12JAN96
					58, .	25JAN96	26JAN96
			Midol	329.003.00076	., .	.	.
				329.005.00153	7, -50	31JAN96	31JAN96
				329.009.00134	-916, .	01JAN93	.
				329.009.00236	-168, .	15JUL96	.
		Analgesics	Analgesic {Nos}	329.004.00211	49, .	21MAR96	22MAR96
			Pain Medication {Nos}	329.003.00073	-11, .	08JAN95	.
		Caffeine	Actron	329.009.00239	-263, -320	01MAR96	.
			Bc Powder	329.007.00139	-9, .	29APR95	01MAY95#
			Excedrin	329.008.00187	-332, .	01JAN95	.
					36, .	03JAN96	04JAN96
				329.009.00239	92, 35	18FEB97	17MAR97
			Excedrin Extra Strength	329.008.00187	44, .	11JAN96	12JAN96
					58, .	25JAN96	26JAN96
			Midol	329.003.00076	., .	.	.
				329.005.00153	7, -50	31JAN96	31JAN96
				329.009.00134	-916, .	01JAN93	.
				329.009.00236	-168, .	15JUL96	.
		Chlorphenamine Maleate	Tylenol Cold And Flu	329.005.00153	-9, -65	16JAN96	27JAN96

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Cinnamedrine Hydrochloride	Midol	329.003.00076	.,	.	.	.
				329.005.00153	7,	-50	31JAN96	31JAN96
				329.009.00134	-916,	.	01JAN93	.
				329.009.00236	-168,	.	15JUL96	.
		Citric Acid	Actron	329.009.00239	-263,	-320	01MAR96	.
			Alka-Seltzer	329.001.00066	-731,	.	21NOV92	.
		Codeine Phosphate	Tylenol #2	329.008.00187	19,	.	17DEC95	.
			Tylenol Number 3	329.009.00195	-14,	.	01DEC95	02DEC95#
			Tylenol With Codeine	329.012.00230	50,	-20	18APR97	20APR97
					53,	-17	21APR97	21APR97
		Dextromethorphan Hydrobromide	Tylenol Cold And Flu	329.005.00153	-9,	-65	16JAN96	27JAN96
		Diphenhydramine Citrate	Excedrin Pm	329.001.00061	-28,	.	01JUL94	28JUL94#
		Mepyramine Maleate	Pamprin	329.003.00289	.,	.	.	.
		Oxycodone Hydrochloride	Percocet	329.005.00117	52,	.	08MAY95	15MAY95
		Oxycodone Terephthalate	Percocet	329.005.00117	52,	.	08MAY95	15MAY95
		Pamabrom	Pamprin	329.003.00289	.,	.	.	.
		Paracetamol	Acetaminophen	329.002.00057	-38,	-95	01AUG94	.
				329.005.00003	-5,	.	15SEP94	15SEP94#
			Actron	329.009.00239	-263,	-320	01MAR96	.
			Excedrin	329.008.00187	-332,	.	01JAN95	.
					36,	.	03JAN96	04JAN96
				329.009.00239	92,	35	18FEB97	17MAR97
			Excedrin Extra Strength	329.008.00187	44,	.	11JAN96	12JAN96
					58,	.	25JAN96	26JAN96

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Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Excedrin Pm	329.001.00061	-28,	.	01JUL94	28JUL94#
			Pamprin	329.003.00289	.,	.	.	.
			Percocet	329.005.00117	52,	.	08MAY95	15MAY95
			Tylenol	329.001.00066	-731,	.	21NOV92	.
				329.001.00070	-2,	.	20FEB95	20FEB95#
				329.002.00100	-34,	-92	01FEB95	01MAR95#
					41,	-18	16APR95	30MAY95
				329.002.00103	4,	-53	23APR95	23APR95
					7,	-50	26APR95	26APR95
				329.002.00243	22,	.	04APR96	04APR96
				329.003.00090	.,	.	.	.
					50,	.	02MAY95	02MAY95
				329.003.00289	.,	.	.	.
				329.003.00314	60,	.	20DEC96	20DEC96
				329.003.00317	1,	.	19DEC96	04FEB97
					34,	.	21JAN97	21JAN97
				329.004.00211	38,	.	10MAR96	.
				329.005.00007	81,	18	28JAN95	.
					180,	117	07MAY95	07MAY95
				329.005.00009	-11,	.	01DEC94	07DEC94#
					5,	.	16DEC94	19DEC94
					11,	.	22DEC94	27DEC94
					21,	.	01JAN95	01JAN95
				329.005.00113	2,	.	31JAN95	31JAN95
				329.005.00118	4,	.	20MAY95	23MAY95
				329.005.00153	.,	.	.	17APR96
					28,	-29	21FEB96	21FEB96
					38,	-19	02MAR96	02MAR96
					57,	1	21MAR96	17APR96
					84,	28	17APR96	15MAY96
					112,	56	15MAY96	12JUN96
					140,	84	12JUN96	10JUL96
					168,	112	10JUL96	05AUG96
				329.005.00256	1,	-56	05MAR96	07MAR96
					13,	-44	17MAR96	20MAR96
					16,	-41	20MAR96	21MAR96
				329.005.00295	-9,	.	19MAR96	19MAR96#
				329.005.00297	-5,	.	14APR96	16APR96#

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Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Tylenol	329.005.00297	22,	.	10MAY96	11MAY96
				329.005.00335	-21,	.	07FEB97	08FEB97#
					-1,	.	27FEB97	27FEB97#
					43,	.	11APR97	11APR97
					54,	.	22APR97	22APR97
				329.007.00139	-9,	.	29APR95	01MAY95#
				329.007.00143	-1,	.	08NOV95	09NOV95
				329.007.00146	-15,	-68	10JAN96	10JAN96#
					-8,	-61	17JAN96	17JAN96#
				329.007.00269	.,	.	.	.
					11,	.	21APR96	21APR96
				329.007.00270	-494,	.	01JAN95	.
				329.007.00307	-1,	.	15MAY96	15MAY96#
				329.008.00159	.,	.	.	.
				329.008.00272	-37,	-93	26FEB96	19MAR96#
					8,	-49	10APR96	10APR96
				329.008.00273	-37,	-100	10APR96	.
				329.009.00172	-681,	-738	01JAN94	.
				329.009.00194	-703,	-759	01JAN94	.
				329.009.00195	-1809,	.	01JAN91	.
				329.009.00236	-45,	.	15NOV96	.
				329.009.00262	40,	.	28MAR97	28MAR97
				329.009.00301	-443,	-499	01JAN95	.
				329.010.00279	11,	-46	01APR96	01APR96
					139,	83	07AUG96	07AUG96
				329.010.00281	40,	-22	03SEP96	03SEP96
					146,	85	18DEC96	19DEC96
				329.011.00163	-2519,	.	01JAN89	.
					-693,	.	01JAN94	.
					-2,	.	23NOV95	.
					4,	.	28NOV95	.
				329.011.00208	-1344,	-1403	01JAN93	.
				329.011.00209	-254,	-316	01JAN96	.
				329.011.00284	-21,	-77	01MAR96	.
					31,	-26	21APR96	21APR96
				329.011.00286	-2348,	-2416	01JAN90	.
				329.012.00221	-906,	-969	01JAN94	.
				329.012.00223	-972,	.	01JAN94	.

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Tylenol	329.012.00230	32, -38	31MAR97	31MAR97
			Tylenol #2	329.008.00187	19, .	17DEC95	.
			Tylenol Cold And Flu	329.005.00153	-9, -65	16JAN96	27JAN96
			Tylenol Extra Strength	329.005.00153	-2, -58	23JAN96	23JAN96#
					17, -40	10FEB96	10FEB96
				329.005.00256	28, -29	01APR96	01APR96
				329.009.00325	-604, -659	01JAN95	.
			Tylenol Gelcaps	329.005.00153	-9, -65	16JAN96	27JAN96
				329.007.00146	-754, -807	01JAN94	.
					172, 119	14JUL96	14JUL96
			Tylenol Number 3	329.009.00195	-14, .	01DEC95	02DEC95#
			Tylenol Sinus	329.009.00194	29, -28	02JAN96	16JAN96
			Tylenol With Codeine	329.012.00230	50, -20	18APR97	20APR97
					53, -17	21APR97	21APR97
		Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	329.005.00153	-9, -65	16JAN96	27JAN96
			Tylenol Sinus	329.009.00194	29, -28	02JAN96	16JAN96
		Salicylamide	Bc Powder	329.007.00139	-9, .	29APR95	01MAY95#
		Sodium Bicarbonate	Actron	329.009.00239	-263, -320	01MAR96	.
			Alka-Seltzer	329.001.00066	-731, .	21NOV92	.
	PSYCHOANALEPTICS	Cannabis	Cannabis	329.002.00057	., .	.	.
					53, -5	30OCT94	30OCT94
			Marijuana	329.012.00227	32, -38	18JAN97	18JAN97
		Cyclobenzaprine	Cyclobenzaprine	329.007.00146	7, -47	31JAN96	31JAN96
					238, 185	18SEP96	18SEP96
		Methylphenidate Hydrochloride	Ritalin	329.008.00192	-643, .	01JUN94	01FEB96#
	PSYCHOLEPTICS	Butalbital	Butalbital	329.003.00093	-171, -234	01JAN95	.
		Chloral Hydrate	Chloral Hydrate	329.012.00221	56, -8	19AUG96	22SEP96

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	PSYCHOLEPTICS	Lorazepam	Lorazepam	329.012.00221	132, 69	03NOV96	03NOV96
		Prochlorperazine	Compazine	329.005.00007	195, 132	22MAY95	22MAY95
			Compazine Suppositories	329.005.00007	196, 133	23MAY95	24MAY95
		Sleeping Pill	Sleep Aid {Nos}	329.008.00159	21, -42	03OCT95	10OCT95

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
DERMATOLOGICALS	ANTI-ACNE PREP	Benzoyl Peroxide	Vanoxide-Hc Lotion	329.010.00279	91, 35	20JUN96	.
		Edetic Acid	Vanoxide-Hc Lotion	329.010.00279	91, 35	20JUN96	.
		Hydrocortisone Acetate	Vanoxide-Hc Lotion	329.010.00279	91, 35	20JUN96	.
		Isotretinoin	Accutane	329.004.00013	59, -1	15SEP94	16SEP94
		Parabens	Vanoxide-Hc Lotion	329.010.00279	91, 35	20JUN96	.
		Paraffin, Liquid	Vanoxide-Hc Lotion	329.010.00279	91, 35	20JUN96	.
		Propylene Glycol	Vanoxide-Hc Lotion	329.010.00279	91, 35	20JUN96	.
	ANTIBIOTIC&CHEMOTHERAPEUT	Erythromycin	Erycette 2% Cream	329.010.00279	91, 35	20JUN96	.
			Erythromycin	329.005.00003	-19, .	01SEP94	14SEP94#
		Tetracycline	Tetracycline	329.005.00153	-389, -445	01JAN95	.
	ANTIFUNGALS	Butoconazole Nitrate	Femstat	329.005.00255	38, .	10APR96	15APR96
		Clotrimazole	Lotrimin Cream	329.007.00270	-10, .	29APR96	19MAY96
		Ketoconazole	Nizoral	329.009.00134	-1, .	05JUL95	10JUL95
		Terconazole	Terazol-7	329.005.00255	47, .	19APR96	21APR96
		Topical Antifungal Nos	Antifungal Cream {Nos}	329.007.00270	26, .	03JUN96	15JUN96
	ANTIPRURITICS	Bentonite	Calamine Lotion	329.007.00270	9, .	17MAY96	19MAY96
		Calamine	Caladryl	329.002.00243	4, .	17MAR96	24MAR96
			Caladryl Lotion	329.005.00007	2, -62	10NOV94	14NOV94
			Calamine Lotion	329.007.00270	9, .	17MAY96	19MAY96
		Camphor	Caladryl	329.002.00243	4, .	17MAR96	24MAR96

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by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
DERMATOLOGICALS	ANTIPRURITICS	Camphor	Caladryl Clear	329.010.00279	110, 54	09JUL96	12JUL96
					157, 101	25AUG96	29AUG96
					168, 112	05SEP96	05OCT96
			Caladryl Lotion	329.005.00007	2, -62	10NOV94	14NOV94
		Chlorophyllin Sodium	Caladryl Clear	329.010.00279	110, 54	09JUL96	12JUL96
					157, 101	25AUG96	29AUG96
					168, 112	05SEP96	05OCT96
		Diphenhydramine Citrate	Excedrin Pm	329.001.00061	-28, .	01JUL94	28JUL94#
		Diphenhydramine Hydrochloride	Benadryl	329.002.00243	4, .	17MAR96	24MAR96
				329.003.00079	15, .	17MAY95	17MAY95
				329.003.00317	27, .	14JAN97	14JAN97
				329.005.00007	197, 134	24MAY95	24MAY95
				329.007.00146	-24, -77	01JAN96	.
				329.007.00270	9, .	17MAY96	19MAY96
				329.007.00307	-45, .	01APR96	01APR96#
					32, .	16JUN96	21JUN96
				329.009.00262	27, .	15MAR97	15MAR97
				329.009.00325	45, -11	10OCT96	.
				329.010.00279	162, 106	30AUG96	05SEP96
				329.011.00163	-4, .	21NOV95	21NOV95#
					-4, .	21NOV95	21NOV95#
			Caladryl	329.002.00243	4, .	17MAR96	24MAR96
			Caladryl Clear	329.010.00279	110, 54	09JUL96	12JUL96
					157, 101	25AUG96	29AUG96
					168, 112	05SEP96	05OCT96
			Caladryl Lotion	329.005.00007	2, -62	10NOV94	14NOV94
		Ethanol	Caladryl Clear	329.010.00279	110, 54	09JUL96	12JUL96
					157, 101	25AUG96	29AUG96
					168, 112	05SEP96	05OCT96
		Glycerol	Caladryl	329.002.00243	4, .	17MAR96	24MAR96
			Caladryl Clear	329.010.00279	110, 54	09JUL96	12JUL96
					157, 101	25AUG96	29AUG96

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
DERMATOLOGICALS	ANTIPRURITICS	Glycerol	Caladryl Clear	329.010.00279	168, 112	05SEP96	05OCT96
			Caladryl Lotion	329.005.00007	2, -62	10NOV94	14NOV94
			Calamine Lotion	329.007.00270	9, .	17MAY96	19MAY96
		Isopropanol	Ivy Dry	329.010.00279	161, 105	29AUG96	04SEP96
		Parabens	Caladryl Clear	329.010.00279	110, 54	09JUL96	12JUL96
					157, 101	25AUG96	29AUG96
					168, 112	05SEP96	05OCT96
		Paracetamol	Excedrin Pm	329.001.00061	-28, .	01JUL94	28JUL94#
		Phenol, Liquefied	Calamine Lotion	329.007.00270	9, .	17MAY96	19MAY96
		Promethazine Hydrochloride	Phenergan	329.009.00239	41, -17	29DEC96	29DEC96
		Sodium Citrate	Calamine Lotion	329.007.00270	9, .	17MAY96	19MAY96
		Tannic Acid	Ivy Dry	329.010.00279	161, 105	29AUG96	04SEP96
		Zinc Oxide	Caladryl Clear	329.010.00279	110, 54	09JUL96	12JUL96
					157, 101	25AUG96	29AUG96
					168, 112	05SEP96	05OCT96
			Calamine Lotion	329.007.00270	9, .	17MAY96	19MAY96
	ANTISEPTICS & DISINFECTANTS	Dofamium Chloride	Desogen	329.009.00325	27, -29	22SEP96	.
		Phenol	Chloraseptic	329.003.00247	34, -21	05MAR96	.
	CORTICOSTEROIDS	Clobetasol Propionate	Temovate Emollient Cream	329.009.00239	119, 62	17MAR97	.
		Fluticasone Propionate	Flonase	329.012.00223	-107, .	15MAY96	.
		Methylprednisolone Sodium Succinate	Solu-Medrol	329.012.00230	50, -20	18APR97	18APR97

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
GU SYSTEM/SEX HORMONES	ANTIINFECTIVES/ANTISEPTICS	Butoconazole Nitrate	Femstat	329.005.00255	38, .	10APR96	15APR96
		Clotrimazole	Lotrimin Cream	329.007.00270	-10, .	29APR96	19MAY96
	SEX HORMONES/STIMULANTS	Desogestrel	Desogen-28	329.003.00082	-344, .	01JAN95	.
		Ethinylestradiol	Desogen-28	329.003.00082	-344, .	01JAN95	.
			Levlen 28	329.008.00187	9, .	07DEC95	.
					9, .	07DEC95	.
			Loestrin	329.006.00040	-63, .	15DEC94	.
					-63, .	15DEC94	.
			Ovcon	329.008.00187	-332, .	01JAN95	.
			Triphasil	329.009.00134	-1282, .	01JAN92	.
					-1282, .	01JAN92	.
				329.009.00171	1, .	07NOV95	.
					1, .	07NOV95	.
		Levonorgestrel	Levlen 28	329.008.00187	9, .	07DEC95	.
					9, .	07DEC95	.
			Triphasil	329.009.00134	-1282, .	01JAN92	.
					-1282, .	01JAN92	.
				329.009.00171	1, .	07NOV95	.
					1, .	07NOV95	.
		Norethisterone	Ovcon	329.008.00187	-332, .	01JAN95	.
		Norethisterone Acetate	Loestrin	329.006.00040	-63, .	15DEC94	.
					-63, .	15DEC94	.
		Oral Contraceptive	Birth Control Pills	329.005.00007	-219, -282	04APR94	.

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

Appendix B.13

Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
MUSCULO-SKELETAL	ANTIINFLAM/ANTIRHEU PROD	Flurbiprofen	Ansaid	329.008.00273	-58, -121	20MAR96	10APR96#
		Ibuprofen	Advil	329.002.00100	-34, -92	01FEB95	01MAR95#
				329.003.00090	3, .	16MAR95	.
				329.003.00249	-1892, .	01JAN91	.
					3, .	09MAR96	09MAR96
					38, .	13APR96	15APR96
				329.003.00314	25, .	15NOV96	17NOV96
				329.005.00295	-7, .	21MAR96	21MAR96#
				329.006.00041	12, -53	16APR95	18APR95
				329.007.00139	-9, .	29APR95	01MAY95#
				329.007.00307	2, .	17MAY96	17MAY96
					14, .	29MAY96	29MAY96
					19, .	03JUN96	04JUN96
				329.009.00195	-1809, .	01JAN91	.
				329.009.00203	-63, .	01JAN96	.
				329.012.00230	53, -17	21APR97	23APR97
			Coadvil	329.009.00264	-732, .	31OCT94	.
			Ibuprofen	329.001.00061	-15, .	14JUL94	14JUL94#
				329.002.00321	-508, .	01JAN95	.
				329.005.00118	-20, .	27APR95	27APR95#
				329.005.00153	., .	.	.
					84, 28	17APR96	15MAY96
				329.005.00255	-3, .	01MAR96	03MAR96#
					8, .	11MAR96	11MAR96
				329.005.00335	-20, .	08FEB97	09FEB97#
				329.007.00307	-1597, .	01JAN92	.
			Motrin	329.002.00057	22, -36	29SEP94	29SEP94
				329.008.00187	4, .	02DEC95	05DEC95
			Nuprin	329.006.00041	141, 77	23AUG95	23AUG95
		Ketoprofen	Orudis Kt	329.009.00325	-2430,-2485	01JAN90	.
		Naproxen	Naproxen	329.009.00134	-34, .	02JUN95	09JUN95#
		Naproxen Sodium	Aleve	329.002.00050	5, .	27MAR95	28MAR95
				329.011.00208	-249, -308	01JAN96	.
			Anaprox	329.009.00134	-916, .	01JAN93	.

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\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
MUSCULO-SKELETAL	ANTIINFLAM/ANTIRHEU PROD	Naproxen Sodium	Anaprox	329.009.00195	-713, .	01JAN94	.
		Pseudoephedrine Hydrochloride	Coadvil	329.009.00264	-732, .	31OCT94	.
	MUSCLE RELAXANTS	Baclofen	Baclofen	329.006.00040	-3698, .	01JAN85	.
		Cyclobenzaprine	Cyclobenzaprine	329.007.00146	7, -47 238, 185	31JAN96 18SEP96	31JAN96 18SEP96

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Listing of Prior and Concomitant Medications
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Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	ANTI-ASTHMATICS	Antiasthmatic, Nos	Over The Counter {Asthma Nos}	329.003.00317	., .	.	.
		Beclometasone Dipropionate	Vancenase	329.006.00040	-3698, .	01JAN85	.
		Cromoglicate Sodium	Sodium (Cromoglycate)	329.012.00223	-107, .	15MAY96	.
		Orciprenaline Sulfate	Alupent	329.009.00301	-808, -864	01JAN94	.
		Pseudoephedrine	Pseudoephed	329.007.00269	-101, .	01JAN96	.
		Salbutamol	Albuterol	329.003.00093	-1997,-2060	01JAN90	.
					-1997,-2060	01JAN90	.
			Proventil	329.009.00195	-348, .	01JAN95	.
					-348, .	01JAN95	.
				329.011.00286	-2348,-2416	01JAN90	.
					-2348,-2416	01JAN90	.
			Ventolin	329.005.00113	-3591, .	01APR85	.
					-3591, .	01APR85	.
				329.006.00040	-3698, .	01JAN85	.
					-3698, .	01JAN85	.
				329.011.00163	-603, .	01APR94	.
					-603, .	01APR94	.
			Ventolin Inhaler	329.009.00325	-2430,-2485	01JAN90	.
					-2430,-2485	01JAN90	.
		Theophylline	Theo-Dur	329.009.00301	-443, -499	01JAN95	.
	COUGH AND COLD PREP	Carbinoxamine Maleate	Naldecon	329.005.00003	., .	.	.
		Chlorphenamine Maleate	Comtrex	329.003.00249	48, .	23APR96	23APR96
			Dristan	329.012.00227	142, 73	08MAY97	09MAY97
			Tylenol Cold And Flu	329.005.00153	-9, -65	16JAN96	27JAN96

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
RESPIRATORY	COUGH AND COLD PREP	Codeine Phosphate	Tussi-Organidin	329.005.00003	.,	.	.	.
		Cough Cold Preparations Nos	Flu Relief {Nos}	329.007.00146	12,	-42	05FEB96	06FEB96
			Osco Brand Cold And Flu Medication {Nos}	329.006.00041	12,	-53	16APR95	18APR95
		Cough Syrup/Med	Cough Syrup {Nos}	329.009.00194	29,	-28	02JAN96	16JAN96
		Dextromethorphan Hydrobromide	Comtrex	329.003.00249	48,	.	23APR96	23APR96
			Dayquil	329.006.00041	140,	76	22AUG95	22AUG95
				329.011.00284	9,	-48	30MAR96	30MAR96
			Nyquil	329.003.00247	34,	-21	05MAR96	.
				329.009.00326	-24,	-77	12AUG96	15AUG96#
			Tylenol Cold And Flu	329.005.00153	-9,	-65	16JAN96	27JAN96
		Doxylamine Succinate	Nyquil	329.003.00247	34,	-21	05MAR96	.
				329.009.00326	-24,	-77	12AUG96	15AUG96#
		Guaifenesin	Dayquil	329.006.00041	140,	76	22AUG95	22AUG95
				329.011.00284	9,	-48	30MAR96	30MAR96
			Robitussin	329.005.00118	3,	.	19MAY95	.
				329.005.00297	-5,	.	14APR96	16APR96#
				329.011.00163	6,	.	30NOV95	01DEC95
		Hydrocodone Bitartrate	Codimal Dh	329.009.00203	-63,	.	01JAN96	.
		Iodinated Glycerol	Tussi-Organidin	329.005.00003	.,	.	.	.
		Mepyramine Maleate	Codimal Dh	329.009.00203	-63,	.	01JAN96	.
		Paracetamol	Comtrex	329.003.00249	48,	.	23APR96	23APR96
			Dayquil	329.006.00041	140,	76	22AUG95	22AUG95
				329.011.00284	9,	-48	30MAR96	30MAR96
			Dristan	329.012.00227	142,	73	08MAY97	09MAY97
			Nyquil	329.003.00247	34,	-21	05MAR96	.
				329.009.00326	-24,	-77	12AUG96	15AUG96#

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Appendix B.13

Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	COUGH AND COLD PREP	Paracetamol	Tylenol Cold And Flu	329.005.00153	-9, -65	16JAN96	27JAN96
		Phenylephrine Hydrochloride	Codimal Dh	329.009.00203	-63, .	01JAN96	.
			Dristan	329.012.00227	142, 73	08MAY97	09MAY97
			Naldecon	329.005.00003	., .	.	.
		Phenylpropanolamine Hydrochloride	Comtrex	329.003.00249	48, .	23APR96	23APR96
			Naldecon	329.005.00003	., .	.	.
		Phenyltoloxamine Citrate	Naldecon	329.005.00003	., .	.	.
		Pseudoephedrine Hydrochloride	Dayquil	329.006.00041	140, 76	22AUG95	22AUG95
				329.011.00284	9, -48	30MAR96	30MAR96
			Nyquil	329.003.00247	34, -21	05MAR96	.
				329.009.00326	-24, -77	12AUG96	15AUG96#
			Tylenol Cold And Flu	329.005.00153	-9, -65	16JAN96	27JAN96
	NASAL PREP	Beclometasone Dipropionate	Vancenase	329.006.00040	-3698, .	01JAN85	.
		Brompheniramine Maleate	Dimetapp	329.007.00146	220, 167	31AUG96	01SEP96
		Cromoglicate Sodium	Sodium (Cromoglycate)	329.012.00223	-107, .	15MAY96	.
		Dexbrompheniramine Maleate	Drixoral	329.007.00146	-16, -69	09JAN96	09JAN96#
				329.009.00239	92, 35	18FEB97	17MAR97
		Fluticasone Propionate	Flonase	329.012.00223	-107, .	15MAY96	.
		Ibuprofen	Coadvil	329.009.00264	-732, .	31OCT94	.

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	NASAL PREP	Mepyramine Maleate	Triaminic	329.012.00227	142, 73	08MAY97	09MAY97
		Paracetamol	Tylenol Sinus	329.009.00194	29, -28	02JAN96	16JAN96
		Pheniramine Maleate	Triaminic	329.012.00227	142, 73	08MAY97	09MAY97
		Phenylephrine Hydrochloride	Dimetapp	329.007.00146	220, 167	31AUG96	01SEP96
		Phenylpropanolamine Hydrochloride	Dimetapp	329.007.00146	220, 167	31AUG96	01SEP96
			Triaminic	329.012.00227	142, 73	08MAY97	09MAY97
		Pseudoephedrine	Pseudoephed	329.007.00269	-101, .	01JAN96	.
		Pseudoephedrine Hydrochloride	Actifed	329.007.00307	31, .	15JUN96	16JUN96
			Coadvil	329.009.00264	-732, .	31OCT94	.
			Efidac	329.007.00146	222, 169	02SEP96	06SEP96
			Efidac/24	329.007.00146	178, 125	20JUL96	22JUL96
			Sudafed	329.005.00255	32, .	04APR96	04APR96
					45, .	17APR96	18APR96
				329.005.00256	1, -56	05MAR96	07MAR96
				329.011.00209	20, -43	30SEP96	03OCT96
				329.011.00286	-2348,-2416	01JAN90	.
			Tylenol Sinus	329.009.00194	29, -28	02JAN96	16JAN96
		Pseudoephedrine Sulfate	Drixoral	329.007.00146	-16, -69	09JAN96	09JAN96#
				329.009.00239	92, 35	18FEB97	17MAR97
		Triprolidine Hydrochloride	Actifed	329.007.00307	31, .	15JUN96	16JUN96
	SYSTEMIC ANTIHISTAMINES	Chlorphenamine Maleate	Tylenol Cold And Flu	329.005.00153	-9, -65	16JAN96	27JAN96
		Dextromethorphan Hydrobromide	Tylenol Cold And Flu	329.005.00153	-9, -65	16JAN96	27JAN96

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
RESPIRATORY	SYSTEMIC ANTIHISTAMINES	Dimenhydrinate	Gravol	329.012.00230	69,	-1	07MAY97	07MAY97
		Diphenhydramine Citrate	Excedrin Pm	329.001.00061	-28,	.	01JUL94	28JUL94#
		Diphenhydramine Hydrochloride	Benadryl	329.002.00243	4,	.	17MAR96	24MAR96
				329.003.00079	15,	.	17MAY95	17MAY95
				329.003.00317	27,	.	14JAN97	14JAN97
				329.005.00007	197,	134	24MAY95	24MAY95
				329.007.00146	-24,	-77	01JAN96	.
				329.007.00270	9,	.	17MAY96	19MAY96
				329.007.00307	-45,	.	01APR96	01APR96#
					32,	.	16JUN96	21JUN96
				329.009.00262	27,	.	15MAR97	15MAR97
				329.009.00325	45,	-11	10OCT96	.
				329.010.00279	162,	106	30AUG96	05SEP96
				329.011.00163	-4,	.	21NOV95	21NOV95#
					-4,	.	21NOV95	21NOV95#
		Loratadine	Claritin	329.011.00209	-72,	-134	01JUL96	.
		Paracetamol	Excedrin Pm	329.001.00061	-28,	.	01JUL94	28JUL94#
			Tylenol Cold And Flu	329.005.00153	-9,	-65	16JAN96	27JAN96
		Promethazine Hydrochloride	Phenergan	329.009.00239	41,	-17	29DEC96	29DEC96
		Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	329.005.00153	-9,	-65	16JAN96	27JAN96

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

Appendix B.13

Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
SENSORY ORGANS	OPHTALMOL/OTOLOGICAL PREP	Erythromycin	Erycette 2% Cream	329.010.00279	91, 35	20JUN96	.
			Erythromycin	329.005.00003	-19, .	01SEP94	14SEP94#
		Tetracycline	Tetracycline	329.005.00153	-389, -445	01JAN95	.
	OPHTHALMOLOGICALS	Cromoglicate Sodium	Sodium (Cromoglycate)	329.012.00223	-107, .	15MAY96	.
		Methylprednisolone Sodium Succinate	Solu-Medrol	329.012.00230	50, -20	18APR97	18APR97
		Sulfacetamide Sodium	Sulfacetamide Sodium	329.009.00262	-7, .	10FEB97	07APR97
		Tetracycline	Tetracycline	329.005.00153	-389, -445	01JAN95	.

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
SYSTEMIC HORMONAL	CORTICOSTEROIDS	Methylprednisolone Sodium Succinate	Solu-Medrol	329.012.00230	50, -20	18APR97	18APR97
	OTHER	Melatonin	Melatonin	329.009.00239	42, -16	30DEC96	.

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
VARIOUS	ALL OTHER THERAP PROD	Herbal Medication	Unknown Chinese Herbal Med	329.004.00215	-139, .	01NOV96	11MAR97#
		Homeopathic Preparations	Yinchia0 Tablet (Chiehtupien) {Homeopathic}	329.004.00215	7, .	26MAR97	26MAR97
	ALLERGENS	Allergenic Extract, Nos	Allergy Shots	329.009.00203	-793, .	01JAN94	.
			Homeopathic Allergy Medicine	329.007.00146	222, 169	02SEP96	07SEP96
			Over The Counter {Allergenic Extract Nos}	329.003.00317	., .	.	.
	GENERAL NUTRIENTS	Nutritional Supplement Nos	Met-Rx {Nutritional Supplement}	329.006.00041	134, 70	16AUG95	23AUG95

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ALIMENTARY TRACT/METAB	ANTACID/ANITFLAT/ANTIPEPTIC	Aluminium Hydroxide	Mylanta	329.001.00062	-2240, .	01SEP88	01SEP93#
			Mylanta Double Strength	329.009.00327	-624, .	01JAN95	.
		Dimeticone, Activated	Mylanta	329.001.00062	-2240, .	01SEP88	01SEP93#
			Mylanta Double Strength	329.009.00327	-624, .	01JAN95	.
		Famotidine	Pepcid	329.002.00246	-838, .	01JAN94	.
				329.009.00197	-58, -112	01NOV95	.
		Magnesium Hydroxide	Mylanta	329.001.00062	-2240, .	01SEP88	01SEP93#
			Mylanta Double Strength	329.009.00327	-624, .	01JAN95	.
		Omeprazole	Prilosec	329.003.00094	32, .	24NOV95	.
		Ranitidine Hydrochloride	Zantac	329.009.00312	-308, .	01JAN96	.
				329.009.00327	-624, .	01JAN95	.
	ANTIDIARRHEA/GI ANTIBIOTICS	Bismuth Subsalicylate	Pepto Bismol	329.006.00042	32, -26	07JAN96	07JAN96
				329.007.00311	113, 53	23JAN97	24JAN97
				329.009.00174	13, -45	03DEC95	07DEC95
				329.012.00217	29, .	18JUN96	19JUN96
		Loperamide Hydrochloride	Imodium	329.009.00276	70, .	31MAR97	31MAR97
	GI ANTISPAS/ANTICHOLIN	Dicycloverine	Dicyclomine	329.009.00327	-624, .	01JAN95	.
		Hyoscine Butylbromide	Buscopan	329.004.00016	16, .	28MAR95	30MAR95
	LAXATIVES	Bisacodyl	Dulcolax	329.007.00311	7, -54	09OCT96	09OCT96

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ALIMENTARY TRACT/METAB	LAXATIVES	Bisacodyl	Dulcolax	329.007.00311	7, -54	09OCT96	09OCT96

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
ANTIINFECTIVES,SYSTEMIC	ANTIBIOTICS	Amoxicillin	Amoxicillin	329.001.00069	-51,	.	27DEC94	27JAN95#
				329.001.00071	-20,	.	03FEB95	13FEB95#
				329.002.00107	236,	180	16SEP96	26SEP96
				329.002.00323	151,	93	11APR97	18APR97
				329.005.00111	37,	-20	16FEB95	20FEB95
				329.005.00114	7,	-51	06FEB95	16FEB95
				329.005.00115	19,	-53	24FEB95	15MAR95
				329.005.00253	-10,	.	29JAN96	31JAN96#
					-10,	.	29JAN96	31JAN96#
				329.005.00334	7,	.	06FEB97	16FEB97
				329.010.00282	-17,	.	09JUL96	14JUL96#
		Amoxicillin Trihydrate	Amoxil	329.012.00224	87,	21	11DEC96	18DEC96
			Augmentin	329.002.00320	117,	56	09SEP96	19SEP96
				329.005.00111	97,	41	17APR95	27APR95
				329.005.00331	27,	.	17DEC96	27DEC96
				329.009.00197	174,	120	19JUN96	23JUN96
				329.009.00330	-20,	.	01OCT96	.
		Antibiotic Nos	Antibiotic {Nos}	329.008.00162	29,	-37	29NOV95	09DEC95
					37,	-29	07DEC95	17DEC95
		Azithromycin	Zithromax	329.001.00123	10,	.	13JAN96	18JAN96
				329.005.00331	-22,	.	30OCT96	06NOV96#
		Cefalexin Monohydrate	Keflex	329.007.00266	52,	.	27APR96	10MAY96
		Clarithromycin	Biaxin	329.001.00207	56,	.	23APR96	02MAY96
		Clavulanic Acid	Augmentin	329.002.00320	117,	56	09SEP96	19SEP96
				329.005.00111	97,	41	17APR95	27APR95
				329.005.00331	27,	.	17DEC96	27DEC96
				329.009.00197	174,	120	19JUN96	23JUN96
				329.009.00330	-20,	.	01OCT96	.
		Doxycycline	Doxycycline	329.005.00253	26,	.	04MAR96	12MAR96

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
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Intent-to-Treat Population

Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ANTIINFECTIVES,SYSTEMIC	ANTIBIOTICS	Doxycycline	Doxycycline	329.006.00037	10, .	06FEB95	13FEB95
		Erythromycin	Erythromycin	329.004.00018	-9, .	24APR95	02MAY95#
				329.012.00027	-8, .	28NOV95	08DEC95
		Erythromycin Ethylsuccinate	Pediazole	329.012.00225	124, 60	29MAR97	07APR97
		Metacycline	Metacycline	329.009.00202	-415, .	01JAN95	.
		Minocycline	Minocin	329.006.00259	-540, .	01DEC94	.
		Sulfafurazole Acetyl	Pediazole	329.012.00225	124, 60	29MAR97	07APR97
		Tetracycline	Tetracycline	329.008.00191	-51, -112	12DEC95	.
	CHEMOTHERAPEUTICS	Erythromycin Ethylsuccinate	Pediazole	329.012.00225	124, 60	29MAR97	07APR97
		Sulfafurazole Acetyl	Pediazole	329.012.00225	124, 60	29MAR97	07APR97
		Sulfamethoxazole	Bactrim	329.007.00311	-27, -87	06SEP96	20SEP96#
					21, -40	23OCT96	24OCT96
					28, -33	30OCT96	02NOV96
			Septra Double Strength	329.001.00069	1, .	16FEB95	24FEB95
			Sulfatrim	329.007.00311	166, 106	17MAR97	31MAR97
		Trimethoprim	Bactrim	329.007.00311	-27, -87	06SEP96	20SEP96#
					21, -40	23OCT96	24OCT96
					28, -33	30OCT96	02NOV96
			Septra Double Strength	329.001.00069	1, .	16FEB95	24FEB95
			Sulfatrim	329.007.00311	166, 106	17MAR97	31MAR97
	VACCINES	Tetanus Toxoid	Tetanus {Toxoid}	329.009.00198	48, .	18FEB96	18FEB96

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\# stop date earlier than start of study medication

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
ANTINEOPLASTIC & IMMUNOSUP	ANTINEOPLASTIC,HORMONES	Diethylstilbestrol Dipropionate	Cyclen	329.004.00018	-1583, .	01JAN91	24MAY95
		Medroxyprogesterone Acetate	Depo-Provera	329.005.00293	21, .	01APR97	01APR97

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\# stop date earlier than start of study medication

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Intent-to-Treat Population

Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
BLOOD/BLOOD FORM ORGANS	ANTIANAEMIC PREP	Ferrous Sulfate	Feosol Liquid	329.009.00306	44, .	24JUL96	.

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\# stop date earlier than start of study medication

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Acetylsalicylic Acid	222	329.004.00213	65, 11	05OCT96	05OCT96
			Aspirin	329.001.00123	12, .	15JAN96	.
				329.002.00049	19, .	27MAR95	27MAR95
				329.003.00094	49, .	11DEC95	11DEC95
				329.005.00253	-6, .	02FEB96	14FEB96
				329.010.00277	., .	.	.
			Bayer Aspirin	329.005.00254	104, 49	28MAY96	28MAY96
			Bufferin	329.004.00213	3, -52	04AUG96	04AUG96
			Entrophen	329.012.00027	19, .	24DEC95	.
			Excedrin	329.009.00174	-689, -746	01JAN94	.
					13, -45	03DEC95	07DEC95
			Midol	329.003.00252	39, .	18MAY96	18MAY96
				329.009.00136	-1005, .	01JAN93	.
				329.009.00202	-50, .	01JAN96	.
			Midol (Teen)	329.005.00298	231, 175	07JAN97	09JAN97
		Aluminium Glycinate	Bufferin	329.004.00213	3, -52	04AUG96	04AUG96
		Analgesics	Unknown {Analgesic Nos}	329.002.00323	-1, -59	11NOV96	01DEC96
			Unknown {Analgesic}	329.002.00323	49, -10	30DEC96	.
		Caffeine	Excedrin	329.009.00174	-689, -746	01JAN94	.
					13, -45	03DEC95	07DEC95
			Midol	329.003.00252	39, .	18MAY96	18MAY96
				329.009.00136	-1005, .	01JAN93	.
				329.009.00202	-50, .	01JAN96	.
			Midol (Teen)	329.005.00298	231, 175	07JAN97	09JAN97
		Caffeine Citrate	222	329.004.00213	65, 11	05OCT96	05OCT96
		Chlorphenamine Maleate	Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
		Cinnamedrine Hydrochloride	Midol	329.003.00252	39, .	18MAY96	18MAY96
				329.009.00136	-1005, .	01JAN93	.

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Cinnamedrine Hydrochloride	Midol	329.009.00202	-50, .	01JAN96	.
			Midol (Teen)	329.005.00298	231, 175	07JAN97	09JAN97
		Codeine Phosphate	222	329.004.00213	65, 11	05OCT96	05OCT96
			Tylenol#3	329.005.00111	96, 40	16APR95	17APR95
		Dextromethorphan	Sudafed Cold And Cough	329.005.00298	204, 148	11DEC96	12DEC96
		Dextromethorphan Hydrobromide	Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
		Diphenhydramine Hydrochloride	Benadryl Cold	329.009.00200	-22, .	01JAN96	05JAN96#
		Hydrocodone Bitartrate	Vicodin	329.005.00115	19, -53	24FEB95	10MAR95
		Magnesium Carbonate	Bufferin	329.004.00213	3, -52	04AUG96	04AUG96
		Mepyramine Maleate	Pamprin	329.001.00123	-20, .	15DEC95	17DEC95#
				329.005.00298	-7, -63	15MAY96	15MAY96#
					46, -11	06JUL96	07JUL96
					167, 111	04NOV96	04NOV96
					200, 144	07DEC96	09DEC96
		Pamabrom	Pamprin	329.001.00123	-20, .	15DEC95	17DEC95#
				329.005.00298	-7, -63	15MAY96	15MAY96#
					46, -11	06JUL96	07JUL96
					167, 111	04NOV96	04NOV96
					200, 144	07DEC96	09DEC96
		Paracetamol	Acetaminophen	329.004.00213	65, 11	05OCT96	05OCT96
					110, 56	19NOV96	19NOV96
					122, 68	01DEC96	01DEC96
					150, 96	29DEC96	29DEC96
					224, 170	13MAR97	13MAR97

* days relative to start of acute phase, days relative to start of continuation phase
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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Acetaminophen	329.006.00042	140, 83	24APR96	24APR96
			Benadryl Cold	329.009.00200	-22, .	01JAN96	05JAN96#
			Excedrin	329.009.00174	-689, -746	01JAN94	.
					13, -45	03DEC95	07DEC95
			Pamprin	329.001.00123	-20, .	15DEC95	17DEC95#
				329.005.00298	-7, -63	15MAY96	15MAY96#
					46, -11	06JUL96	07JUL96
					167, 111	04NOV96	04NOV96
					200, 144	07DEC96	09DEC96
			Sinutab	329.003.00315	7, .	18NOV96	20NOV96
				329.004.00213	11, -44	12AUG96	12AUG96
					134, 80	13DEC96	13DEC96
				329.012.00217	16, .	05JUN96	05JUN96
			Sudafed Cold And Cough	329.005.00298	204, 148	11DEC96	12DEC96
			Sudafed Sinus	329.005.00298	202, 146	09DEC96	10DEC96
			Tylenol	329.001.00062	-5437, .	01DEC79	.
				329.001.00064	-4013,-4067	15NOV83	.
				329.001.00069	-51, .	27DEC94	27JAN95#
				329.001.00071	-17, .	06FEB95	12FEB95#
				329.001.00123	49, .	21FEB96	.
				329.001.00207	53, .	20APR96	25APR96
				329.002.00097	-15, -73	19DEC94	26DEC94#
					14, -45	16JAN95	17JAN95
					29, -30	31JAN95	07FEB95
					87, 29	30MAR95	.
				329.003.00086	-58, -115	01OCT94	08OCT94#
					36, -22	02JAN95	03JAN95
				329.003.00252	., .	.	.
				329.004.00018	-1583, .	01JAN91	03MAY95
					22, .	24MAY95	.
				329.005.00010	122, 65	13APR95	15APR95
				329.005.00012	37, -23	24JAN95	24JAN95
				329.005.00111	-4, -60	07JAN95	14FEB95
					36, -21	15FEB95	20FEB95
					65, 9	16MAR95	17MAR95
					94, 38	14APR95	15APR95
					96, 40	16APR95	17APR95

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
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Intent-to-Treat Population

Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Tylenol	329.005.00114	5,	-53	04FEB95	08FEB95
				329.005.00253	19,	.	26FEB96	26FEB96
				329.005.00254	-13,	-68	02FEB96	06FEB96#
					-4,	-59	11FEB96	11FEB96#
					23,	-33	08MAR96	08MAR96
					53,	-3	07APR96	07APR96
					201,	146	02SEP96	02SEP96
					202,	147	03SEP96	03SEP96
				329.005.00293	-23,	.	17FEB97	18FEB97#
					26,	.	06APR97	06APR97
					39,	.	19APR97	19APR97
				329.005.00331	1,	.	21NOV96	21NOV96
					36,	.	26DEC96	26DEC96
				329.005.00334	-50,	.	12DEC96	19DEC96#
					32,	.	03MAR97	03MAR97
					41,	.	12MAR97	12MAR97
					48,	.	19MAR97	20MAR97
				329.007.00144	39,	-18	14JAN96	15JAN96
				329.009.00198	-366,	.	01JAN95	.
				329.009.00200	-752,	.	01JAN94	.
				329.009.00202	-415,	.	01JAN95	.
				329.009.00238	-681,	.	01JAN95	.
					50,	.	31DEC96	.
				329.009.00276	-386,	.	01JAN96	.
					-314,	.	13MAR96	.
				329.009.00327	-989,	.	01JAN94	.
				329.010.00263	6,	.	14AUG96	14AUG96
					9,	.	17AUG96	17AUG96
				329.010.00282	21,	.	15AUG96	15AUG96
					39,	.	02SEP96	02SEP96
				329.011.00210	.,	.	.	.
				329.011.00285	-503,	.	01JAN95	.
				329.012.00027	-1069,	.	01JAN93	.
					-15,	.	21NOV95	07DEC95
				329.012.00217	-81,	.	01MAR96	.
				329.012.00218	-8,	-66	08JUN96	08JUN96#
					26,	-33	11JUL96	11JUL96
				329.012.00224	16,	-51	01OCT96	01OCT96

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	ANALGESICS	Paracetamol	Tylenol	329.012.00224	25, -42	10OCT96	.
			Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
			Tylenol Gelcaps	329.007.00267	10, .	16MAR96	16MAR96
					31, .	06APR96	06APR96
			Tylenol Sinus	329.005.00298	12, -45	02JUN96	05JUN96
			Tylenol#3	329.005.00111	96, 40	16APR95	17APR95
			Vicodin	329.005.00115	19, -53	24FEB95	10MAR95
		Phenacetin	Sinutab	329.003.00315	7, .	18NOV96	20NOV96
				329.004.00213	11, -44	12AUG96	12AUG96
					134, 80	13DEC96	13DEC96
				329.012.00217	16, .	05JUN96	05JUN96
		Phenylpropanolamine Hydrochloride	Sinutab	329.003.00315	7, .	18NOV96	20NOV96
				329.004.00213	11, -44	12AUG96	12AUG96
					134, 80	13DEC96	13DEC96
				329.012.00217	16, .	05JUN96	05JUN96
		Phenyltoloxamine Citrate	Sinutab	329.003.00315	7, .	18NOV96	20NOV96
				329.004.00213	11, -44	12AUG96	12AUG96
					134, 80	13DEC96	13DEC96
				329.012.00217	16, .	05JUN96	05JUN96
		Pseudoephedrine	Sudafed Cold And Cough	329.005.00298	204, 148	11DEC96	12DEC96
		Pseudoephedrine Hydrochloride	Benadryl Cold	329.009.00200	-22, .	01JAN96	05JAN96#
			Sudafed Sinus	329.005.00298	202, 146	09DEC96	10DEC96
			Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
			Tylenol Sinus	329.005.00298	12, -45	02JUN96	05JUN96
	ANTIEPILEPTICS	Clonazepam	Clonazepam	329.012.00218	-34, -92	13MAY96	16MAY96#

* days relative to start of acute phase, days relative to start of continuation phase
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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
Intent-to-Treat Population

Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
CENTRAL NERVOUS SYSTEM	PSYCHOANALEPTICS	Amitriptyline Hydrochloride	Elavil	329.009.00135	-9, .	23SEP95	24SEP95#
		Fluoxetine	Prozac	329.002.00241	108, 52	23MAY96	.
		Pemoline Magnesium	Cylert	329.009.00330	-13, .	08OCT96	08OCT96#
		Sertraline Hydrochloride	Zoloft	329.012.00217	30, .	19JUN96	.
		Venlafaxine Hydrochloride	Effexor	329.007.00311	-155, -215	01MAY96	27SEP96#
	PSYCHOLEPTICS	Diazepam	Valium	329.004.00018	26, .	28MAY95	28MAY95
				329.004.00020	-21, .	19OCT95	19OCT95#
		Lorazepam	Lorazepam	329.012.00027	16, .	21DEC95	26DEC95
		Paroxetine	Paxil	329.009.00135	36, .	06NOV95	.

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
DERMATOLOGICALS	ANTI-ACNE PREP	Isotretinoin	Accutane	329.009.00237	., .	.	.
		Tretinoin	Retin-A	329.003.00252	., .	.	.
	ANTIBIOTIC&CHEMOTHERAPEUT	Erythromycin	Erythromycin	329.004.00018	-9, .	24APR95	02MAY95#
				329.012.00027	-8, .	28NOV95	08DEC95
		Tetracycline	Tetracycline	329.008.00191	-51, -112	12DEC95	.
	ANTIPRURITICS	Calamine	Caladryl Lotion	329.003.00086	78, 21	13FEB95	25APR95
		Camphor	Caladryl Lotion	329.003.00086	78, 21	13FEB95	25APR95
		Diphenhydramine Hydrochloride	Benadryl	329.002.00097	-15, -73	19DEC94	26DEC94#
				329.005.00010	81, 24	03MAR95	05MAR95
				329.007.00141	-23, .	29AUG95	30AUG95#
				329.009.00327	-259, .	01JAN96	.
			Caladryl Lotion	329.003.00086	78, 21	13FEB95	25APR95
		Glycerol	Caladryl Lotion	329.003.00086	78, 21	13FEB95	25APR95
	CORTICOSTEROIDS	Budesonide	Pulmicort	329.012.00217	29, .	18JUN96	19JUN96
		Fluticasone Propionate	Flonase	329.007.00311	21, -40	23OCT96	23NOV96
		Methylprednisolone	Methylprednisolone	329.001.00123	10, .	13JAN96	18JAN96
	OTHER	Dermatologicals Nos	Topical Cream {Dermatological Nos}	329.005.00120	., .	.	.
		Permethrin	Elimite	329.009.00169	36, -30	05DEC95	05DEC95

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
GU SYSTEM/SEX HORMONES	SEX HORMONES/STIMULANTS	Desogestrel	Ortho-Cept 28	329.001.00123	18, .	21JAN96	.
		Diethylstilbestrol Dipropionate	Cyclen	329.004.00018	-1583, .	01JAN91	24MAY95
		Ethinylestradiol	Ortho Tri-Cyclen	329.004.00018	30, .	01JUN95	.
			Ortho-Cept 28	329.001.00123	18, .	21JAN96	.
			Ovcon 35	329.006.00037	-119, .	01OCT94	.
			Tri-Levlen	329.009.00312	-1038, .	01JAN94	.
					-1038, .	01JAN94	.
			Triphasil	329.009.00198	-1096, .	01JAN93	.
					-1096, .	01JAN93	.
		Injectable Contraceptive, Nos	Injectable Contraceptive {Nos}	329.003.00080	-51, .	07OCT95	.
		Levonorgestrel	Tri-Levlen	329.009.00312	-1038, .	01JAN94	.
					-1038, .	01JAN94	.
			Triphasil	329.009.00198	-1096, .	01JAN93	.
					-1096, .	01JAN93	.
		Medroxyprogesterone Acetate	Depo-Provera	329.005.00293	21, .	01APR97	01APR97
		Mestranol	Ortho Novum	329.009.00202	-50, .	01JAN96	.
					-50, .	01JAN96	.
		Norethisterone	Ortho Novum	329.009.00202	-50, .	01JAN96	.
					-50, .	01JAN96	.
			Ovcon 35	329.006.00037	-119, .	01OCT94	.
		Norgestimate	Ortho Tri-Cyclen	329.004.00018	30, .	01JUN95	.
		Oral Contraceptive	Birth Control Pills	329.005.00115	-31, -102	06JAN95	.

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
MUSCULO-SKELETAL	ANTIINFLAM/ANTIRHEU PROD	Ibuprofen	Advil	329.002.00246	48,	.	04JUN96	04JUN96
				329.005.00253	20,	.	27FEB96	27FEB96
				329.005.00298	26,	-31	16JUN96	16JUN96
					33,	-24	23JUN96	23JUN96
					56,	-1	16JUL96	16JUL96
					133,	77	01OCT96	04OCT96
				329.005.00331	3,	.	23NOV96	23NOV96
				329.005.00334	48,	.	19MAR97	20MAR97
				329.007.00267	26,	.	01APR96	01APR96
				329.009.00136	-275,	.	01JAN95	.
				329.009.00197	-362,	-416	01JAN95	.
				329.009.00302	-86,	.	01JAN96	20MAR96#
				329.011.00164	19,	.	09JAN96	.
			Advil Cold And Sinus	329.005.00298	-22,	-78	30APR96	30APR96#
			Ibuprofen	329.002.00320	32,	-30	16JUN96	22JUN96
				329.005.00254	24,	-32	09MAR96	09MAR96
				329.005.00298	149,	93	17OCT96	17OCT96
				329.006.00042	108,	51	23MAR96	23MAR96
					209,	152	02JUL96	02JUL96
					210,	153	03JUL96	03JUL96
					211,	154	04JUL96	04JUL96
					212,	155	05JUL96	05JUL96
					213,	156	06JUL96	06JUL96
					216,	159	09JUL96	09JUL96
					218,	161	11JUL96	11JUL96
					220,	163	13JUL96	13JUL96
				329.009.00312	-673,	.	01JAN95	.
				329.010.00263	33,	.	10SEP96	10SEP96
				329.012.00225	237,	173	20JUL97	23JUL97
			Midol Ib	329.009.00327	-989,	.	01JAN94	.
			Motrin	329.010.00282	56,	.	19SEP96	19SEP96
				329.011.00285	18,	.	04JUN96	.
		Naproxen	Naprosyn	329.007.00311	47,	-14	18NOV96	22NOV96
		Naproxen Sodium	Aleve	329.001.00207	-7,	.	21FEB96	28FEB96
				329.005.00253	45,	.	23MAR96	23MAR96
				329.006.00042	211,	154	04JUL96	04JUL96

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
MUSCULO-SKELETAL	ANTIINFLAM/ANTIRHEU PROD	Naproxen Sodium	Aleve	329.009.00135	-274,	.	01JAN95	.
				329.009.00276	53,	.	14MAR97	14MAR97
				329.010.00277	159,	103	06AUG96	06AUG96
			Anaprox	329.012.00027	-25,	.	11NOV95	17NOV95#
		Oxaprozin	Daypro	329.009.00174	-13,	-70	08NOV95	.
		Pseudoephedrine Hydrochloride	Advil Cold And Sinus	329.005.00298	-22,	-78	30APR96	30APR96#

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Listing of Prior and Concomitant Medications
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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *		Start Date	Stop Date
RESPIRATORY	ANTI-ASTHMATICS	Beclometasone Dipropionate	Becloforte	329.012.00027	-127,	.	01AUG95	20NOV95#
			Beconase Nasal Spray .042%	329.005.00111	85,	29	05APR95	.
			Vancenase	329.005.00111	37,	-20	16FEB95	.
		Budesonide	Pulmicort	329.012.00217	29,	.	18JUN96	19JUN96
		Chlorphenamine Maleate	Codimal La	329.009.00327	-259,	.	01JAN96	.
		Cromoglicate Sodium	Intal	329.012.00027	-96,	.	01SEP95	.
			Nasalcrom	329.005.00111	37,	-20	16FEB95	.
		Dextromethorphan	Sudafed Cold And Cough	329.005.00298	204,	148	11DEC96	12DEC96
		Paracetamol	Sudafed Cold And Cough	329.005.00298	204,	148	11DEC96	12DEC96
		Pseudoephedrine	Sudafed Cold And Cough	329.005.00298	204,	148	11DEC96	12DEC96
		Pseudoephedrine Hydrochloride	Codimal La	329.009.00327	-259,	.	01JAN96	.
		Salbutamol	Albuterol	329.007.00311	166,	106	17MAR97	24MAR97
					166,	106	17MAR97	24MAR97
			Proventil	329.005.00111	85,	29	05APR95	07APR95
					85,	29	05APR95	07APR95
				329.007.00311	-27,	-87	06SEP96	13SEP96#
					-27,	-87	06SEP96	13SEP96#
			Proventil Inhaler	329.005.00253	-10,	.	29JAN96	08FEB96
					-10,	.	29JAN96	08FEB96
			Ventolin	329.012.00027	-461,	.	01SEP94	17NOV95#
					-461,	.	01SEP94	17NOV95#
					10,	.	15DEC95	.
					10,	.	15DEC95	.
				329.012.00225	130,	66	04APR97	04APR97

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	ANTI-ASTHMATICS	Salbutamol	Ventolin	329.012.00225	130, 66	04APR97	04APR97
			Ventolin Inhaler	329.005.00114	-565, -622	15JUL93	18OCT94#
					-565, -622	15JUL93	18OCT94#
				329.005.00115	-27, -98	10JAN95	10JAN95#
					-27, -98	10JAN95	10JAN95#
		Salbutamol Sulfate	Ventodisk	329.004.00016	-2628, .	01JAN88	.
					-2628, .	01JAN88	.
		Terbutaline Sulfate	Bricanyl Inhaler	329.012.00225	130, 66	04APR97	08APR97
	CHEST RUBS/INHALANTS	Decongestant Nos	Unknown Decongestant {Nos}	329.005.00331	-14, .	07NOV96	17NOV96#
	COUGH AND COLD PREP	Brompheniramine Maleate	Dimetapp-C	329.004.00018	-12, .	21APR95	28APR95#
		Chlorphenamine Maleate	Dristan	329.002.00241	-36, -92	01JAN96	25JAN96#
			Tylenol Allergy And Sinus	329.005.00298	-26, -82	26APR96	26APR96#
			Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
		Codeine	Promethazine With Codeine	329.005.00253	-10, .	29JAN96	31JAN96#
					-10, .	29JAN96	31JAN96#
		Codeine Phosphate	Dimetapp-C	329.004.00018	-12, .	21APR95	28APR95#
		Cough Syrup/Med	Cough Medicine	329.002.00241	64, 8	09APR96	30APR96
			Unknown Cough Syrup	329.007.00311	166, 106	17MAR97	24MAR97
		Dextromethorphan	Sudafed Cold And Cough	329.005.00298	204, 148	11DEC96	12DEC96
		Dextromethorphan Hydrobromide	Nyquil	329.001.00071	-17, .	06FEB95	10FEB95#
			Robitussin Cf	329.001.00071	-21, .	02FEB95	08FEB95#

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	COUGH AND COLD PREP	Dextromethorphan Hydrobromide	Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
		Doxylamine Succinate	Nyquil	329.001.00071	-17, .	06FEB95	10FEB95#
		Guaifenesin	Entex	329.009.00312	-308, .	01JAN96	.
				329.010.00263	45, .	22SEP96	23SEP96
			Entex La	329.007.00311	21, -40	23OCT96	24OCT96
					28, -33	30OCT96	02NOV96
			Humibid	329.005.00293	7, .	18MAR97	18MAR97
			Robitussin	329.005.00120	19, .	17SEP95	19SEP95
					55, .	23OCT95	23OCT95
				329.005.00331	23, .	13DEC96	17DEC96
				329.009.00198	-366, .	01JAN95	.
				329.009.00276	51, .	12MAR97	18MAR97
				329.012.00217	21, .	10JUN96	12JUN96
			Robitussin Cf	329.001.00071	-21, .	02FEB95	08FEB95#
		Hydrocodone Bitartrate	Vicodin	329.005.00115	19, -53	24FEB95	10MAR95
		Paracetamol	Dristan	329.002.00241	-36, -92	01JAN96	25JAN96#
			Neo Citran	329.004.00018	-12, .	21APR95	21APR95#
			Neo-Citran	329.012.00027	10, .	15DEC95	17DEC95
			Nyquil	329.001.00071	-17, .	06FEB95	10FEB95#
			Sudafed Cold And Cough	329.005.00298	204, 148	11DEC96	12DEC96
			Tylenol Allergy And Sinus	329.005.00298	-26, -82	26APR96	26APR96#
			Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
			Vicodin	329.005.00115	19, -53	24FEB95	10MAR95
		Pheniramine Maleate	Neo Citran	329.004.00018	-12, .	21APR95	21APR95#
			Neo-Citran	329.012.00027	10, .	15DEC95	17DEC95
		Phenylephrine Hydrochloride	Dimetapp-C	329.004.00018	-12, .	21APR95	28APR95#

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	COUGH AND COLD PREP	Phenylephrine Hydrochloride	Dristan	329.002.00241	-36, -92	01JAN96	25JAN96#
			Entex	329.009.00312	-308, .	01JAN96	.
				329.010.00263	45, .	22SEP96	23SEP96
			Neo Citran	329.004.00018	-12, .	21APR95	21APR95#
			Neo-Citran	329.012.00027	10, .	15DEC95	17DEC95
		Phenylpropanolamine Hydrochloride	Dimetapp-C	329.004.00018	-12, .	21APR95	28APR95#
			Entex	329.009.00312	-308, .	01JAN96	.
				329.010.00263	45, .	22SEP96	23SEP96
			Entex La	329.007.00311	21, -40	23OCT96	24OCT96
					28, -33	30OCT96	02NOV96
			Robitussin Cf	329.001.00071	-21, .	02FEB95	08FEB95#
		Promethazine Hydrochloride	Promethazine With Codeine	329.005.00253	-10, .	29JAN96	31JAN96#
					-10, .	29JAN96	31JAN96#
		Pseudoephedrine	Sudafed Cold And Cough	329.005.00298	204, 148	11DEC96	12DEC96
		Pseudoephedrine Hydrochloride	Nyquil	329.001.00071	-17, .	06FEB95	10FEB95#
			Tylenol Allergy And Sinus	329.005.00298	-26, -82	26APR96	26APR96#
			Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
	NASAL PREP	Aminoacetic Acid	Afrin	329.003.00086	-423, -480	01OCT93	09NOV94#
		Beclometasone Dipropionate	Becloforte	329.012.00027	-127, .	01AUG95	20NOV95#
			Beconase Nasal Spray .042%	329.005.00111	85, 29	05APR95	.
			Vancenase	329.005.00111	37, -20	16FEB95	.
		Benzalkonium Chloride	Afrin	329.003.00086	-423, -480	01OCT93	09NOV94#

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RESPIRATORY	NASAL PREP	Brompheniramine Maleate	Dimetapp	329.004.00018	-12,	.	21APR95	21APR95#
				329.009.00128	-830,	.	01JAN93	.
		Budesonide	Pulmicort	329.012.00217	29,	.	18JUN96	19JUN96
		Clemastine Fumarate	Tavist D	329.003.00086	15,	-43	12DEC94	14DEC94
			Tavist-D	329.003.00086	169,	112	15MAY95	19MAY95
		Cromoglicate Sodium	Intal	329.012.00027	-96,	.	01SEP95	.
			Nasalcrom	329.005.00111	37,	-20	16FEB95	.
		Decongestant Nos	Unknown Decongestant {Nos}	329.005.00331	-14,	.	07NOV96	17NOV96#
		Dexbrompheniramine Maleate	Drixoral	329.009.00136	-275,	.	01JAN95	.
				329.009.00174	-385,	-442	01NOV94	.
		Diphenhydramine Hydrochloride	Benadryl Cold	329.009.00200	-22,	.	01JAN96	05JAN96#
		Fluticasone Propionate	Flonase	329.007.00311	21,	-40	23OCT96	23NOV96
		Ibuprofen	Advil Cold And Sinus	329.005.00298	-22,	-78	30APR96	30APR96#
		Oxymetazoline Hydrochloride	Afrin	329.003.00086	-423,	-480	01OCT93	09NOV94#
		Paracetamol	Benadryl Cold	329.009.00200	-22,	.	01JAN96	05JAN96#
			Sudafed Sinus	329.005.00298	202,	146	09DEC96	10DEC96
			Tylenol Sinus	329.005.00298	12,	-45	02JUN96	05JUN96
		Phenylephrine Hydrochloride	Dimetapp	329.004.00018	-12,	.	21APR95	21APR95#
				329.009.00128	-830,	.	01JAN93	.

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ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	NASAL PREP	Phenylmercuric Acetate	Afrin	329.003.00086	-423, -480	01OCT93	09NOV94#
		Phenylpropanolamine Hydrochloride	Dimetapp	329.004.00018	-12, .	21APR95	21APR95#
				329.009.00128	-830, .	01JAN93	.
			Tavist D	329.003.00086	15, -43	12DEC94	14DEC94
			Tavist-D	329.003.00086	169, 112	15MAY95	19MAY95
		Prednisone	Prednisone	329.012.00225	130, 66	04APR97	09APR97
		Pseudoephedrine Hydrochloride	Actifed	329.005.00120	15, .	13SEP95	14SEP95
			Advil Cold And Sinus	329.005.00298	-22, -78	30APR96	30APR96#
			Benadryl Cold	329.009.00200	-22, .	01JAN96	05JAN96#
			Sudafed	329.001.00207	-21, .	07FEB96	28FEB96
				329.007.00311	85, 25	26DEC96	26DEC96
				329.009.00238	38, .	19DEC96	31DEC96
				329.012.00027	10, .	15DEC95	17DEC95
			Sudafed Sinus	329.005.00298	202, 146	09DEC96	10DEC96
			Tylenol Sinus	329.005.00298	12, -45	02JUN96	05JUN96
		Pseudoephedrine Sulfate	Drixoral	329.009.00136	-275, .	01JAN95	.
				329.009.00174	-385, -442	01NOV94	.
		Sorbitol	Afrin	329.003.00086	-423, -480	01OCT93	09NOV94#
		Triprolidine Hydrochloride	Actifed	329.005.00120	15, .	13SEP95	14SEP95
	SYSTEMIC ANTIHISTAMINES	Cetirizine Hydrochloride	Reactine	329.004.00016	13, .	25MAR95	.
		Chlorphenamine Maleate	Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#

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Listing of Prior and Concomitant Medications
by WHO ATC Classification and Generic Term and by Treatment Group
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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
RESPIRATORY	SYSTEMIC ANTIHISTAMINES	Codeine	Promethazine With Codeine	329.005.00253	-10, .	29JAN96	31JAN96#
					-10, .	29JAN96	31JAN96#
		Dextromethorphan Hydrobromide	Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
		Dimenhydrinate	Gravol	329.012.00224	108, 42	01JAN97	01JAN97
		Diphenhydramine Hydrochloride	Benadryl	329.002.00097	-15, -73	19DEC94	26DEC94#
				329.005.00010	81, 24	03MAR95	05MAR95
				329.007.00141	-23, .	29AUG95	30AUG95#
				329.009.00327	-259, .	01JAN96	.
			Benadryl Cold	329.009.00200	-22, .	01JAN96	05JAN96#
		Loratadine	Claritin	329.004.00018	13, .	15MAY95	18MAY95
				329.005.00298	40, -17	30JUN96	01JUL96
				329.009.00312	-308, .	01JAN96	.
		Paracetamol	Benadryl Cold	329.009.00200	-22, .	01JAN96	05JAN96#
			Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#
		Promethazine Hydrochloride	Promethazine With Codeine	329.005.00253	-10, .	29JAN96	31JAN96#
					-10, .	29JAN96	31JAN96#
		Pseudoephedrine Hydrochloride	Benadryl Cold	329.009.00200	-22, .	01JAN96	05JAN96#
			Tylenol Cold	329.005.00298	39, -18	29JUN96	29JUN96
			Tylenol Cold Tablets	329.001.00071	-17, .	06FEB95	12FEB95#

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
SENSORY ORGANS	OPHTALMOL/OTOLOGICAL PREP	Betamethasone Sodium Phosphate	Garasone	329.012.00027	-9, .	27NOV95	08DEC95
		Erythromycin	Erythromycin	329.004.00018	-9, .	24APR95	02MAY95#
				329.012.00027	-8, .	28NOV95	08DEC95
		Gentamicin Sulfate	Garasone	329.012.00027	-9, .	27NOV95	08DEC95
		Tetracycline	Tetracycline	329.008.00191	-51, -112	12DEC95	.
	OPHTHALMOLOGICALS	Cromoglicate Sodium	Intal	329.012.00027	-96, .	01SEP95	.
			Nasalcrom	329.005.00111	37, -20	16FEB95	.
		Methylprednisolone	Methylprednisolone	329.001.00123	10, .	13JAN96	18JAN96
		Steroid Eye Drops, Nos	Steroid Eye Drops {Nos}	329.005.00012	165, 106	01JUN95	.
		Tetracycline	Tetracycline	329.008.00191	-51, -112	12DEC95	.

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Treatment Group=PLACEBO

ATC Level I	ATC Level II	Generic Term	Drug Name	Patient ID	Relative Days *	Start Date	Stop Date
SYSTEMIC HORMONAL	CORTICOSTEROIDS	Corticosteroids	Steroidal Nasal Preps. {Nos}	329.005.00111	97, 41	17APR95	.
		Methylprednisolone	Methylprednisolone	329.001.00123	10, .	13JAN96	18JAN96
		Prednisone	Prednisone	329.012.00225	130, 66	04APR97	09APR97
	THYROID THERAPY	Levothyroxine Sodium	Synthroid	329.009.00135	-1370, .	01JAN92	.

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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.001.00063	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	29,	.	06DEC94	16DEC94	750MG	EAR ACHE SORE THROAT
	CENTRAL NERVOUS SYSTEM	Tylenol	-1529,	.	01SEP90	.	500MG PRN	HEADACHE
	DERMATOLOGICALS	Benadryl	-4086,	.	01SEP83	.	25MG PRN	ALLERGY
	RESPIRATORY	Actifed	-4086,	.	01SEP83	.	1TAB PRN	ALLERGY
		Benadryl	-4086,	.	01SEP83	.	25MG PRN	ALLERGY
329.001.00065	CENTRAL NERVOUS SYSTEM	Tylenol #1	-2115,	.	01FEB89	.	1000MG	HEADACHE
329.001.00068	ALIMENTARY TRACT/METAB	Multiple Vitamin	-69,	.	01DEC94	08FEB95	1TABLET	DIETARY SUPPLEMENT
		Rolaids	-982,	.	01JUN92	08FEB95	2TABLET	UPSET STOMACH
	CENTRAL NERVOUS SYSTEM	Aspirin	-617,	.	01JUN93	08FEB95	2TABS PRN	HEADACHE
		Tylenol	20,	.	27FEB95	28MAR95	1300MG	VIRAL SORE THROAT UPPER RESPIRATORY INFE
	VARIOUS	Lysine	-366,	.	07FEB94	08FEB95	1TABLET	FEVER BLISTER
329.001.00205	CENTRAL NERVOUS SYSTEM	Tylenol Cold And Flu	-27,	.	11JAN96	11JAN96#	5TSP.	SINUS
	RESPIRATORY	Tylenol Cold And Flu	-27,	.	11JAN96	11JAN96#	5TSP.	SINUS
329.002.00055	CENTRAL NERVOUS SYSTEM	Tylenol	123,	68	24OCT94	.	ESTIMATE 650MG PM	HEADACHE
	MUSCULO-SKELETAL	Advil	123,	68	24OCT94	.	800-1200MG PRN	HEADACHE
329.002.00058	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	60,	2	18NOV94	28NOV94	500MG	STREP THROAT
	CENTRAL NERVOUS SYSTEM	Tylenol	122,	64	19JAN95	19JAN95	26,650MG	INTENTIONAL OVERDOSE
329.002.00099	CENTRAL NERVOUS SYSTEM	Tylenol	33,	-23	03APR95	03APR95	325MG	HEADACHE
	DERMATOLOGICALS	Benadryl	34,	-22	04APR95	11APR95	100 MG	SEASONAL ALLERGIES
	RESPIRATORY	Afrin Spray	15,	-41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
		Benadryl	34,	-22	04APR95	11APR95	100 MG	SEASONAL ALLERGIES
		Nyquil	18,	-38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
		Sudafed	28,	-28	29MAR95	29MAR95	60MG	STUFFY NOSE
329.002.00105	CENTRAL NERVOUS SYSTEM	Aspirin	16,	.	11AUG95	24AUG95	650 MG	HEADACHE
		Tylenol	1,	.	27JUL95	03AUG95	1950 MG	HEADACHE
	DERMATOLOGICALS	Benadryl	-329,	.	01SEP94	.	2 TBSP PRN	ALLERGIES
	RESPIRATORY	Benadryl	-329,	.	01SEP94	.	2 TBSP PRN	ALLERGIES

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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.002.00242	CENTRAL NERVOUS SYSTEM	Aspirin	-6,	-64	01FEB96	01FEB96#	650 MG	HEADACHE
		Tylenol	42,	-17	19MAR96	19MAR96	650 MG	HEADACHE
329.002.00245	CENTRAL NERVOUS SYSTEM	Tylenol	-452,	.	01JAN95	.	PRN	HEADACHE
		Zoloft	-27,	.	01MAR96	14MAR96#	25 MG	DEPRESSION
329.002.00319	MUSCULO-SKELETAL	Aleve	203,	147	18NOV96	18NOV96	1 TABLET	HEADACHE
329.003.00075	CENTRAL NERVOUS SYSTEM	Tylenol	-7,	-63	18JAN95	.	PRN	HEADACHE
			16,	-41	09FEB95	14FEB95	PRN	HEADACHES
	MUSCULO-SKELETAL	Motrin	-7,	-63	18JAN95	.	PRN	HEADACHE
			16,	-41	09FEB95	14FEB95	PRN 200-400	HEADACHE
	RESPIRATORY	Proventil	.,	.	.	.	PRN	ASTHMA
329.003.00081	CENTRAL NERVOUS SYSTEM	Tylenol	-193,	.	01JUN95	.	500MGS	HEADACHE
329.003.00089	CENTRAL NERVOUS SYSTEM	Tylenol	8,	.	14MAR95	.	500MG	HEADACHE
			42,	.	17APR95	18APR95	650MG	HEADACHE
329.003.00091	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	211,	157	20OCT95	30OCT95	1000 MG	COLD AND SORE THROAT
		Penicillin	182,	128	21SEP95	01OCT95	1000 MG	SORE THROAT
	CENTRAL NERVOUS SYSTEM	Tylenol	9,	-46	01APR95	01APR95	650MG	HEADACHE
			36,	-19	28APR95	02MAY95	650MG	COLD
329.003.00248	CENTRAL NERVOUS SYSTEM	Tylenol	60,	.	29APR96	.		HEADACHE
329.003.00250	DERMATOLOGICALS	Benadryl	47,	-11	29APR96	29APR96	25 MG	ALLERGY
	RESPIRATORY	Benadryl	47,	-11	29APR96	29APR96	25 MG	ALLERGY
329.004.00015	ALIMENTARY TRACT/METAB	Centrum	5,	-53	12DEC94	13DEC94	1	COLD-NASAL CONGESTION
		Vitamin C	5,	-53	12DEC94	13DEC94	1	COLD,NASAL CONGESTION
	ANTIINFECTIVES,SYSTEMIC	Septra Double Strength	82,	25	27FEB95	05MAR95	2TABS	COLD
	CENTRAL NERVOUS SYSTEM	Tylenol	13,	-45	20DEC94	20DEC94	500MG	HEADACHE
			69,	12	14FEB95	14FEB95	2TAB	HEADACHE
			79,	22	24FEB95	24FEB95	2TAB	HEADACHE
		Tylenol Extra Strength	4,	-54	11DEC94	11DEC94	2000MG	HEADACHE
			34,	-24	10JAN95	10JAN95	500MG	HEADACHE

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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.004.00015	CENTRAL NERVOUS SYSTEM	Tylenol Extra Strength	41,	-17	17JAN95	17JAN95	2000MG	HEADACHE
			53,	-5	29JAN95	29JAN95	2000MG	MENSTRUAL CRAMPS
			131,	74	17APR95	17APR95	2TAB	MENSTRUAL CRAMPS
	RESPIRATORY	Drixoral Pills	5,	-53	12DEC94	13DEC94	1	COLD NASAL CONGESTION
	SENSORY ORGANS	Polysporin Eye Drops	-1,	-58	07DEC94	18DEC94	6DROPS	BILATERAL EYE INFECTION
			27,	-31	03JAN95	14JAN95	4DROPS	BILATERAL EYE INFECTION
329.004.00017	ALIMENTARY TRACT/METAB	Maalox	232,	176	08NOV95	08NOV95	5CC	NAUSEA
		Vitamin B Complex	48,	-9	08MAY95	.	ONE TAB	SHIVERING(>
	CENTRAL NERVOUS SYSTEM	Tylenol	161,	105	29AUG95	30AUG95	650MG	FEVER
	DERMATOLOGICALS	Benylin	177,	121	14SEP95	16SEP95	1TSP	COLD
	RESPIRATORY	Benylin	177,	121	14SEP95	16SEP95	1TSP	COLD
329.004.00019	CENTRAL NERVOUS SYSTEM	Excedrin	7,	.	06JUN95	06JUN95	3TABS	HEADACHE
329.004.00212	CENTRAL NERVOUS SYSTEM	Sinutabs	-215,	.	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
	GU SYSTEM/SEX HORMONES	Ortho 777	-215,	.	01NOV95	.	1 TABLET	BIRTH CONTROL
	RESPIRATORY	Claritin	-215,	.	01NOV95	09JUN96	0-2 TABS	ENVIRONMENTAL ALLERGIES
		Sudafed	-215,	.	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
329.004.00214	ANTIINFECTIVES,SYSTEMIC	Apo-Tetra	-16,	-76	18SEP96	18SEP96#		COLD
			10,	-51	13OCT96	13OCT96	500 MG	COLD
			14,	-47	17OCT96	20OCT96	500 MG	COLD
		Hepatitis B Shot {Vaccine}	60,	-1	02DEC96	02DEC96		PROPHYLAXIS
		Hepatitis B {Vaccine}	-1,	-61	03OCT96	03OCT96#		PROPHYLAXIS
	CENTRAL NERVOUS SYSTEM	Tylenol	36,	-25	08NOV96	09NOV96	700 MG	HEADACHE
			44,	-17	16NOV96	16NOV96	700 MG	HEADACHE
			83,	23	25DEC96	25DEC96	1000 MG	DIZZINESS
			84,	24	26DEC96	26DEC96	1000 MG	DIZZINESS
			85,	25	27DEC96	27DEC96	1000 MG	DIZZINESS
			87,	27	29DEC96	29DEC96	1000 MG	DIZZINESS

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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.004.00214	CENTRAL NERVOUS SYSTEM	Tylenol Extra Strength	-8, -68	26SEP96	26SEP96#	700 MG	KNEE PAIN
	DERMATOLOGICALS	Apo-Tetra	-16, -76	18SEP96	18SEP96#		COLD
			10, -51	13OCT96	13OCT96	500 MG	COLD
			14, -47	17OCT96	20OCT96	500 MG	COLD
	GU SYSTEM/SEX HORMONES	Birth Control Pill	-32, -92	02SEP96	.	1	TO REGULATE PERIODS
	RESPIRATORY	Gravol	37, -24	09NOV96	10NOV96	100 MG	UPSET STOMACH
			44, -17	16NOV96	17NOV96	50 MG	NAUSEA
	SENSORY ORGANS	Apo-Tetra	-16, -76	18SEP96	18SEP96#		COLD
			10, -51	13OCT96	13OCT96	500 MG	COLD
			14, -47	17OCT96	20OCT96	500 MG	COLD
329.005.00002	CENTRAL NERVOUS SYSTEM	Tylenol	-5, -61	20MAY94	20MAY94#	500MG	HEADACHE
			54, -3	17JUL94	20JUL94	500MG	HEADACHE
329.005.00004	CENTRAL NERVOUS SYSTEM	Tylenol	81, 22	29DEC94	30DEC94	500MG	SORE THROAT
329.005.00011	ALIMENTARY TRACT/METAB	Charcoal	156, 100	17MAY95	17MAY95	UNKNOWN	OVERDOSE WITH BAYER EXTRA STRENGTH
		Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
	BLOOD/BLOOD FORM ORGANS	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
	CENTRAL NERVOUS SYSTEM	Bayer Aspirin Extra Strength	156, 100	17MAY95	17MAY95	UNKNOWN	OVERDOSE
		Tylenol	8, -49	20DEC94	03JAN95	500MG	HEADACHE
	RESPIRATORY	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
	SENSORY ORGANS	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
329.005.00109	ALIMENTARY TRACT/METAB	Prenatal Vitamin	-395, -448	30NOV93	.	1 4X DAILY	PREGNANCY/LACTATION
		Zantac	123, 70	01MAY95	08MAY95		QUESTIONABLE BLEEDING ULCER
	BLOOD/BLOOD FORM ORGANS	Ferrous Sulfate	-133, -186	19AUG94	.	320 MG	LOW IRON
		Iv Fluids	129, 76	07MAY95	10MAY95		QUESTIONABLE BLEEDING ULCER
	CENTRAL NERVOUS SYSTEM	Tylenol	81, 28	20MAR95	22MAR95	1 GM	HEADACHE
	GU SYSTEM/SEX HORMONES	Desogen 28	14, -40	12JAN95	.	1 4X DAILY	BIRTH CONTROL

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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.005.00112	CENTRAL NERVOUS SYSTEM	Tylenol	-2, -57	24JAN95	26JAN95	1000MG	HEADACHE,FEVER
329.005.00116	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	26, -33	04MAR95	14MAR95	750MG	BRONCHITIS
		Augmentin	25, -34	03MAR95	13MAR95	UNKNOWN,THRE E TIMES DAILY	EAR INFECTION
		Ceftin	141, 83	27JUN95	07JUL95	UNKNOWN MG(2PILLS)	TONSILLITIS
	CENTRAL NERVOUS SYSTEM	Tylenol	25, -34	03MAR95	04APR95	500MG	EARACHE
	MUSCULO-SKELETAL	Advil	65, 7	12APR95	12APR95	UNKNOWN	HEADACHE
			111, 53	28MAY95	30MAY95	UNKNOWN PRN	MENSTRUAL CRAMPS
	RESPIRATORY	Prednisone	135, 77	21JUN95	28JUN95	30MG	POISON IVY
			143, 85	29JUN95	02JUL95	20MG	POISON IVY
			147, 89	03JUL95	07JUL95	10MG	POISON IVY
			152, 94	08JUL95	12JUL95	10MG EVERY OTHER DAY	POISON IVY
		Robitussin	75, 17	22APR95	07MAY95	2TSP	COUGH
		Smith Brothers Cough Drop	75, 17	22APR95	07MAY95	1DAILY	COUGH
		Ventolin Inhaler	26, -33	04MAR95	14MAR95	2PUFFS 4TIME A DAY	BRONCHITIS
	SENSORY ORGANS	Ear Drops {Nos}	25, -34	03MAR95	04APR95	THREE TIMES DAILY	EARACHE
	SYSTEMIC HORMONAL	Prednisone	135, 77	21JUN95	28JUN95	30MG	POISON IVY
			143, 85	29JUN95	02JUL95	20MG	POISON IVY
			147, 89	03JUL95	07JUL95	10MG	POISON IVY
			152, 94	08JUL95	12JUL95	10MG EVERY OTHER DAY	POISON IVY
329.005.00119	CENTRAL NERVOUS SYSTEM	Tylenol	7, -53	17JUL95	17JUL95	650MG	HEADACHE
	MUSCULO-SKELETAL	Advil	47, -13	26AUG95	26AUG95	1TAB DAILY	ORTHODONTIC DISCOMFORT
	RESPIRATORY	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS
		Robitussin	80, 21	28SEP95	28SEP95	1 DOSE	COLD SYMPTOMS
329.005.00151	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	41, -17	16OCT95	02NOV95	750MG	EAR INFECTION STREP THROAT
		Erythromycin	48, -10	23OCT95	07NOV95		URI

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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.005.00151	CENTRAL NERVOUS SYSTEM	Extra Strength Tylenol	1,	-57	06SEP95	06SEP95	2TABS A DAY	BACK PAIN
		Tylenol	-25,	-82	12AUG95	12AUG95#	650MG	HEADACHE
			40,	-18	15OCT95	17OCT95	2GM	SORE THROAT/STREP
			44,	-14	19OCT95	19OCT95	1GM	BACK PAIN
		Tylenol Extra Strength	.,	.	.	03SEP95#	650MG	BACK PAIN
	DERMATOLOGICALS	Erythromycin	48,	-10	23OCT95	07NOV95		URI
	SENSORY ORGANS	Erythromycin	48,	-10	23OCT95	07NOV95		URI
		Refresh	156,	99	08FEB96	08MAR96		FOREIGN OBJECT IN EYE
329.005.00257	ALIMENTARY TRACT/METAB	Vitamin C	3,	-54	13MAR96	.		"A COLD"
	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	145,	89	02AUG96	09AUG96		SWIMMER'S EAR
		Antibiotics Ear Drops {Nos}	145,	89	02AUG96	09AUG96		SWIMMER'S EAR
		Ceclor	15,	-42	25MAR96	05APR96		SINUS INFECTION
			43,	-14	22APR96	06MAY96		SINUS INFECTION
		Monistat 7	242,	186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
	CARDIOVASCULAR	Slo-Bid	54,	-3	03MAY96	10MAY96	150 MG BID	UPPER RESPIRATORY INFECTION AND SINUS IN
	DERMATOLOGICALS	Accutane	-121,	-177	11NOV95	.		ACNE
			-121,	-177	11NOV95	.		ACNE
		Flonase	43,	-14	22APR96	28APR96	2 SQUIRTS	SINUS INFECTION
		Monistat 7	242,	186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
	GU SYSTEM/SEX HORMONES	Monistat 7	242,	186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
	MUSCULO-SKELETAL	Advil	157,	101	14AUG96	21AUG96		HEADACHE
	RESPIRATORY	Albuterol	43,	-14	22APR96	06MAY96	2 PUFF X 4	SINUS INFECTION
		Flonase	43,	-14	22APR96	28APR96	2 SQUIRTS	SINUS INFECTION
		Marax	202,	146	28SEP96	.		EXERCISE INDUCED ASTHMA
		Rynatan	15,	-42	25MAR96	27MAR96		SINUS INFECTION
		Semprex-D	14,	-43	24MAR96	24MAR96		"A COLD"
		Slo-Bid	54,	-3	03MAY96	10MAY96	150 MG BID	UPPER RESPIRATORY INFECTION AND SINUS IN
329.005.00258	CENTRAL NERVOUS SYSTEM	Tylenol	21,	.	01APR96	01APR96	2 TABS	ORTHODONTIC DISCOMFORT

* days relative to start of acute phase, days relative to start of continuation phase
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PAROXETINE - PROTOCOL 329

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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.005.00258	CENTRAL NERVOUS SYSTEM	Tylenol	28,	.	08APR96	08APR96	2 TABS	ORTHODONTIC DISCOMFORT
	RESPIRATORY	Robitussin	2,	.	13MAR96	13MAR96		COUGH
329.005.00299	ALIMENTARY TRACT/METAB	Tums	.,	.	.	.		STOMACH
	CENTRAL NERVOUS SYSTEM	Tylenol	138,	78	23OCT96	23OCT96	2 TABS	HEADACHE
	MUSCULO-SKELETAL	Advil	.,	.	.	.		HEADACHE
	RESPIRATORY	Robitussin	109,	49	24SEP96	02OCT96	2 TSP	"COLD"
			140,	80	25OCT96	25OCT96	2 TSP	COLD SYMPTOMS
329.005.00333	ALIMENTARY TRACT/METAB	Imodium-Ad	30,	.	21FEB97	21FEB97	1 TBSP	DIARRHEA
	CENTRAL NERVOUS SYSTEM	Tylenol	2,	.	24JAN97	24JAN97	500 MG	HEADACHE
		Vivarin	14,	.	05FEB97	05FEB97	1 TAB	SLEEPINESS
	MUSCULO-SKELETAL	Advil	23,	.	14FEB97	16FEB97	800 MG	HEADACHE
			33,	.	24FEB97	24FEB97	400 MG	HEADACHE
	RESPIRATORY	Allegra	-236,	.	01JUN96	.		ENVIRONMENTAL
329.005.00336	CENTRAL NERVOUS SYSTEM	Excedrin Extra-Strength	32,	.	04APR97	09APR97	2 GM	SORE THROAT WITH COUGH
			38,	.	10APR97	12APR97	2 GM	STUFFY NOSE, COUGH
			48,	.	20APR97	23APR97	2 GM	BACKACHE
		Tylenol	-12,	.	20FEB97	21FEB97#	500 MG	BACKACHE
	RESPIRATORY	Dimetapp	-18,	.	14FEB97	16FEB97#	2	COLD SX
329.006.00038	CARDIOVASCULAR	Benzocaine	-410,	.	01JAN94	.	9 TABLETS	DIETING
	CENTRAL NERVOUS SYSTEM	Fiorinal	57,	.	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
		Tranquilizer {Nos}	17,	.	03MAR95	03MAR95	UNKNOWN	DENTAL PROCEDURE
		Tylenol	57,	.	12APR95	12APR95	1300MG	ATTEMPTED SUICIDE
	DERMATOLOGICALS	Benzocaine	-410,	.	01JAN94	.	9 TABLETS	DIETING
	MUSCULO-SKELETAL	Advil	57,	.	12APR95	12APR95	4600MG	ATTEMPTED SUICIDE
		Ibuprofen	57,	.	12APR95	12APR95	4800MG	ATTEMPTED SUICIDE
			57,	.	12APR95	12APR95	13800MG	ATTEMPTED SUICIDE
	RESPIRATORY	Albuterol	-1871,	.	01JAN90	.	1PUFF	ASTHMA
		Benzocaine	-410,	.	01JAN94	.	9 TABLETS	DIETING
329.006.00039	MUSCULO-SKELETAL	Advil	-1134,	-1195	01JAN92	.	PRN-600MG	HEADACHES
		Anaprox	76,	15	24APR95	28APR95	275MG	HEADACHE
329.006.00260	ANTIINFECTIVES,SYSTEMIC	Tetracycline	-6,	-64	12JUL96	.	1000MG	ACNE

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Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.006.00260	CENTRAL NERVOUS SYSTEM	Aspirin	56, -3	11SEP96	11SEP96	2 TABS	HEADACHE
		Excedrin	-2390,-2448	01JAN90	.	2 TABS	OCCASIONAL HEADACHES
			6, -53	23JUL96	16SEP96	2 TABS: PRN	HEADACHE
			8, -51	25JUL96	25JUL96	4 TABS	TOOTHACHE PAIN
			20, -39	06AUG96	06AUG96	2 TABS	TOOTHACHE
			83, 25	08OCT96	08OCT96	2 TAB	HEADACHE
	DERMATOLOGICALS	Tetracycline	-6, -64	12JUL96	.	1000MG	ACNE
	MUSCULO-SKELETAL	Advil	53, -6	08SEP96	08SEP96	2 TABS	HEADACHE
	RESPIRATORY	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
	SENSORY ORGANS	Tetracycline	-6, -64	12JUL96	.	1000MG	ACNE
329.006.00261	MUSCULO-SKELETAL	Advil	58, -1	22JAN97	22JAN97	2 TABS	HEADACHE
	RESPIRATORY	Proventil	-4713,-4771	01JAN84	01JAN96#	PRN	ASTHMA
329.007.00140	ALIMENTARY TRACT/METAB	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
	CENTRAL NERVOUS SYSTEM	Tylenol	-622, -677	01JAN94	.	325MG PRN	HEADACHE
	DERMATOLOGICALS	Clotrimazole	39, -17	23OCT95	24OCT95	ONCE DAILY	RINGWORM
		Gris-Peg	41, -15	25OCT95	03NOV95	250MG	RINGWORM
		Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
	GU SYSTEM/SEX HORMONES	Clotrimazole	39, -17	23OCT95	24OCT95	ONCE DAILY	RINGWORM
	SENSORY ORGANS	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
	SYSTEMIC HORMONAL	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
329.007.00142	ANTIINFECTIVES,SYSTEMIC	Amoxil	-14, .	04OCT95	13OCT95#	500MG	SORE THROAT
	CENTRAL NERVOUS SYSTEM	Tylenol	-3942, .	01JAN85	.	500MG PRN	HEADACHE
	RESPIRATORY	Dristan	44, .	30NOV95	30NOV95	2TABS	NASAL CONGESTION
329.007.00145	CENTRAL NERVOUS SYSTEM	Extra Strength Excedrin	111, 55	30APR96	13MAY96	1 TAB	HEADACHE
		Extra Strength Tylenol	125, 69	14MAY96	15MAY96	1,000 MG	HEADACHE
	DERMATOLOGICALS	Benadryl	22, -35	01FEB96	01FEB96	1TSP.	NASAL CONGESTION
	RESPIRATORY	Benadryl	22, -35	01FEB96	01FEB96	1TSP.	NASAL CONGESTION
		Ggg-Cold {Cold Preparation Nos}	224, 168	21AUG96	23AUG96	6 TSP	COLD SYMPTOMS
329.007.00265	CENTRAL NERVOUS SYSTEM	Tylenol	-3, .	29JAN96	31JAN96#	1,000MG	HEADACHE
329.007.00268	ALIMENTARY TRACT/METAB	Dulcolax	233, 174	19NOV96	19NOV96	2 TABS	CONSTIPATION

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Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.007.00268	ALIMENTARY TRACT/METAB	Neomycin	88,	29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
		Polymyxin	88,	29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
	ANTIINFECTIVES,SYSTEMIC	Cephalexin	82,	23	21JUN96	23JUN96	1000 MG	LEFT EAR INFECTION
			87,	28	26JUN96	29JUN96	1000 MG	LEFT EAR INFECTION
			92,	33	01JUL96	10JUL96	250 MG	LEFT INNER EAR INFECTION
		Keflex	10,	-50	10APR96	14APR96	750MG	EAR INFECTION
		Neomycin	88,	29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
		Polymyxin	88,	29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
	CENTRAL NERVOUS SYSTEM	Aspirin	29,	-31	29APR96	29APR96	4TABS	NAUSEA{FROM RIDE}
		Compazine	218,	159	04NOV96	04NOV96	5 MG	NAUSEA
	DERMATOLOGICALS	Neomycin	88,	29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
	MUSCULO-SKELETAL	Ibuprofen	10,	-50	10APR96	10APR96	800MG	HEADACHE
			57,	-3	27MAY96	30MAY96	1600MG	PAIN{DUE TO ACCIDENT}
		Motrin	-821,	-880	01JAN94	.	800MG PRN	HEADACHES
			57,	-3	27MAY96	07JUN96	1600 MG	NECK PAIN DUE TO ACCIDENT
			98,	39	07JUL96	10JUL96	1 - 2 TABS	MUSCLE ACHES DUE TO CAR ACCIDENT
			102,	43	11JUL96	07NOV96	800 MG PRN	MUSCLE ACHES DUE TO CAR ACCIDENT
			184,	125	01OCT96	07NOV96	400 MG PRN	HEADACHES
	SENSORY ORGANS	Neomycin	88,	29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
	VARIOUS	T-Lite {Dietary Supplement}	154,	95	01SEP96	02OCT96	4 TABS	WEIGHT GAIN
329.007.00294	ALIMENTARY TRACT/METAB	Appetite Suppressant {Nos}	-58,	.	01JAN97	10FEB97#	3 TABS	WEIGHT GAIN
	CENTRAL NERVOUS SYSTEM	Extra Strength Tylenol	-2,	.	26FEB97	26FEB97#	3 TABS	HEADACHE
		Tylenol	14,	.	13MAR97	13MAR97	1,000 MG	HEADACHE
			18,	.	17MAR97	17MAR97	1,000 MG	HEADACHE
			22,	.	21MAR97	23MAR97	4 TABS	BACKACHE
			40,	.	08APR97	08APR97	2 TABS	HEADACHE
		Tylenol Es Gel Caps	5,	.	04MAR97	07MAR97	1,000 MG	HEADACHE
		Unknown Headache Medicine {Analgesic Nos}	-4,	.	24FEB97	24FEB97#	3 TABS	HEADACHE

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# stop date earlier than start of study medication
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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.007.00294	MUSCULO-SKELETAL	Aleve	34,	.	02APR97	02APR97	2 TABS	HEADACHE
			39,	.	07APR97	07APR97	2 TABS	HEADACHE & CRAMPS
		Ibuprofen	-1154,	.	01JAN94	.	2 TABS PRN	HEADACHE
	RESPIRATORY	Unknown Cough Drop	34,	.	02APR97	02APR97	1 TAB	URI
329.007.00309	ALIMENTARY TRACT/METAB	Zantac	-44,	-96	01JUN96	20JUN96#	300 MG	ULCER-LIKE SYMPTOMS
	ANTIINFECTIVES,SYSTEMIC	Erythromycin	61,	9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71,	19	23SEP96	01OCT96	2000 MG	TOOTHACHE
	CENTRAL NERVOUS SYSTEM	Brevital	74,	22	26SEP96	26SEP96	70 MG	ABSCESSED TOOTH
		Fentanyl	74,	22	26SEP96	26SEP96	1 CC	ABSCESSED TOOTH
		Midol	34,	-19	17AUG96	19AUG96	2 TABS	MENSTRUAL CRAMP
		Nitrous Oxide	74,	22	26SEP96	26SEP96	3.0 L/M	ABSCESSED TOOTH
		Tylenol	-15,	-67	30JUN96	30JUN96#	1 TAB	HEADACHE
			43,	-10	26AUG96	26AUG96	500 MG	TOOTHACHE
			46,	-7	29AUG96	29AUG96	500 MG	TOOTHACHE
			107,	55	29OCT96	29OCT96	1 TAB	HEADACHE
			237,	185	08MAR97	08MAR97	500 MG	HEADACHE
		Tylenol Iii	71,	19	23SEP96	27SEP96	3 TABS	TOOTHPAIN
		Versed	74,	22	26SEP96	26SEP96	5 MG	ABSCESSED TOOTH
		Xylocaine-Epinephrin e	74,	22	26SEP96	26SEP96	4 CC	ABSCESSED TOOTH
	DERMATOLOGICALS	Erythromycin	61,	9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71,	19	23SEP96	01OCT96	2000 MG	TOOTHACHE
	MUSCULO-SKELETAL	Advil	29,	-24	12AUG96	13AUG96	400 MG	HEADACHE
			33,	-20	16AUG96	16AUG96	5 TABS	MENSTRUAL CRAMP
			72,	20	24SEP96	03OCT96	1 TAB	HEADACHES
			176,	124	06JAN97	13JAN97	2 TABS	EARACHE
			184,	132	14JAN97	12FEB97	400 MG PRN	HEADACHES
		Aleve	-44,	-96	01JUN96	.	1-2 TABS	HEADACHE
		Ibuprofen	-44,	-96	01JUN96	.	1 TAB	HEADACHE
	RESPIRATORY	Contac	143,	91	04DEC96	04DEC96	1 TAB	FEVER & CONGESTION
			145,	93	06DEC96	06DEC96	1 TAB	FEVER & CONGESTION
			147,	95	08DEC96	08DEC96	1 TAB	CONGESTION
		Drixoral	52,	-1	04SEP96	04SEP96	2 CAPS	URI
			110,	58	01NOV96	01NOV96	1 TAB	ALLERGIES
		Histussin Hc	47,	-6	30AUG96	02SEP96	2 TSP	URI
		Hydrocodone	74,	22	26SEP96	26SEP96	1 TAB	ABSCESSED TOOTH
	SENSORY ORGANS	Erythromycin	61,	9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71,	19	23SEP96	01OCT96	2000 MG	TOOTHACHE

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Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.007.00310	ALIMENTARY TRACT/METAB	Pepto Bismol	52, -9	16NOV96	17NOV96	2 TABS	FOOD POISONING
	ANTIINFECTIVES,SYSTEMIC	Augmentin	85, 25	19DEC96	29DEC96	1,000 MG	SORE THROAT
		Ceclor	19, -42	14OCT96	27OCT96	750 MG	SORE THROAT, EARACHE
		Ceclor Cd	173, 113	17MAR97	28MAR97	1,000 MG	POSSIBLE STREP THROAT
	CENTRAL NERVOUS SYSTEM	Aspirin	218, 158	01MAY97	08MAY97	1 TAB	SUNBURN
		Midol	-8, -68	18SEP96	18SEP96#	2 TABS	MENSTRUAL CRAMPS
		Phrenilin	175, 115	19MAR97	23MAR97	1 TAB	STIFF NECK
			236, 176	19MAY97	23MAY97	1 TAB	HEADACHE
		Tylenol	15, -46	10OCT96	15OCT96	4000 MG	FEVER, HEADACHE
	MUSCULO-SKELETAL	Advil	14, -47	09OCT96	09OCT96	500 MG	PAIN IN NECK MUSCLES
			50, -11	14NOV96	17NOV96	1,200 MG	LEFT KNEE PAIN
		Aleve	-56, -116	01AUG96	.	2 TABS	HEADACHE
			14, -47	09OCT96	09OCT96	1 TAB	PAIN IN NECK MUSCLES
		Orudis Kt	53, -8	17NOV96	30NOV96	1-2 TABS	LEFT KNEE PAIN
		Skelaxin	14, -47	09OCT96	15OCT96	400 MG PRN	PAIN IN NECK MUSCLES
	RESPIRATORY	Claritin-D	85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION
		Panmist La	19, -42	14OCT96	29OCT96	2 TABS PRN	CONGESTION
329.007.00318	CENTRAL NERVOUS SYSTEM	Ritalin	-854, .	01AUG94	11AUG96#	10 MG	ADHD
329.008.00157	RESPIRATORY	Antihistamine {Nos}	-3893,-3948	01JAN85	.		HAY FEVER
329.008.00160	ANTIINFECTIVES,SYSTEMIC	Doxycycline	20, -47	20NOV95	.	50 MG	ACNE
	RESPIRATORY	Ventolin Inhaler	20, -47	20NOV95	.		EXERCISE INDUCED SHORTNESS OF BREATH
329.008.00271	ANTIINFECTIVES,SYSTEMIC	Biaxin	45, -20	24APR96	30APR96	500 MG	RESPIRATORY INFECTION
	CENTRAL NERVOUS SYSTEM	Excedrin	89, 25	07JUN96	07JUN96	X2 TABS	HEADACHE
		Tylenol Extra Strength	-5, -69	06MAR96	17MAR96	2 TABS	UPPER RESPIRATORY TRACT INFECTION
			28, -37	07APR96	07APR96	2 TABS	HEADACHE
			63, -2	12MAY96	12MAY96	2 TABS	HEADACHE
			91, 27	09JUN96	09JUN96	X2 TABS	HEADACHE
	MUSCULO-SKELETAL	Ibuprofen	21, -44	31MAR96	31MAR96	200 MG	NECK PAIN
		Vicks Cough Drop	42, -23	21APR96	21APR96		PHARYNGITIS
	RESPIRATORY	Albuterol	-3722,-3786	01JAN86	.	1TAB DAY	ASTHMA
		Proventil Inhaler	-3722,-3786	01JAN86	.	4PUFFSX1-PRN	ASTHMA
		Triaminic Cough Syrup	-5, -69	06MAR96	06MAR96#	X1	RESPIRATORY INFECTION

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329.008.00271	RESPIRATORY	Vicks Cough Drop	42, -23	21APR96	21APR96		PHARYNGITIS
329.008.00275	ANTIINFECTIVES,SYSTEMIC	Antibiotic {Nos}	49, -7	25JUN96	09JUL96		FOOT INFECTION
	DERMATOLOGICALS	Benadryl	-738, -793	01MAY94	.	PRN	ALLERGIES, INSOMNIA
			-1, -56	07MAY96	07MAY96#	50 MG	ALLERGY
			8, -48	15MAY96	.	50 MG	ALLERGY
			56, 1	02JUL96	.		ITCHINESS
			77, 22	23JUL96	24JUL96	50 MG	ALLERGIES
			132, 77	16SEP96	17SEP96	50 MG	ALLERGIES
			202, 147	25NOV96	26NOV96	50 MG	ALLERGIES
	MUSCULO-SKELETAL	Advil	-493, -548	01JAN95	.	PRN	HEADACHES
			-1, -56	07MAY96	.		HEADACHES
			56, 1	02JUL96	.		ANKLE SPRAIN
	RESPIRATORY	Benadryl	-738, -793	01MAY94	.	PRN	ALLERGIES, INSOMNIA
			-1, -56	07MAY96	07MAY96#	50 MG	ALLERGY
			8, -48	15MAY96	.	50 MG	ALLERGY
			56, 1	02JUL96	.		ITCHINESS
			77, 22	23JUL96	24JUL96	50 MG	ALLERGIES
			132, 77	16SEP96	17SEP96	50 MG	ALLERGIES
			202, 147	25NOV96	26NOV96	50 MG	ALLERGIES
329.009.00130	ALIMENTARY TRACT/METAB	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
		Tums	149, 93	13SEP95	.	1TAB PRN	STOMACH ACHE
	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	140, 84	04SEP95	13SEP95	1500MG	SINUS INFECTION
		Amoxil	8, -49	25APR95	04MAY95	1500MG	SINUSITIS
	CENTRAL NERVOUS SYSTEM	Nefazodone	170, 114	04OCT95	.	100MG	DEPRESSION
329.009.00131	ALIMENTARY TRACT/METAB	Correctol	21, -36	22MAY95	22MAY95	2TABLETS	CONSTIPATION
	DERMATOLOGICALS	Clearasil	29, -28	30MAY95	.	1GRAM	ACNE
329.009.00133	ALIMENTARY TRACT/METAB	Pepto Bismol	28, .	10JUL95	.	2TBSP.PRN	LOOSE STOOLS
	ANTIINFECTIVES,SYSTEMIC	Amoxil	32, .	14JUL95	20JUL95	500MG	EXTRACTED WISDOM TOOTH
	CENTRAL NERVOUS SYSTEM	Premenstrual Syndrome Pain Relief {Nos}	-893, .	01JAN93	.	500MG PRN	PREMENSTRUAL TENSION
		Tylenol	-893, .	01JAN93	.	500MG PRN	HEADACHE

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329.009.00133	MUSCULO-SKELETAL	Lodine	32,	.	14JUL95	17JUL95	200MG	EXTRACTED WIDSOM TEETH
329.009.00170	ALIMENTARY TRACT/METAB	Maalox Liquid	238,	181	01JUL96	.	8-16 TSP	NAUSEA
	MUSCULO-SKELETAL	Motrin	246,	189	09JUL96	.	400 MG	DYSMENORRHEA
	RESPIRATORY	Dramamine	238,	181	01JUL96	.	100 MG	NAUSEA
329.009.00173	CENTRAL NERVOUS SYSTEM	Tylenol	-19,	-82	01NOV95	.	650MG PRN	UPPER RESP. TRACT INFECTION
		Tylenol Cold {Medicine}	-19,	-82	01NOV95	.	2TABS PRN	URI
	RESPIRATORY	Tylenol Cold {Medicine}	-19,	-82	01NOV95	.	2TABS PRN	URI
329.009.00193	CENTRAL NERVOUS SYSTEM	Excedrin	-331,	.	01JAN95	.	500PRN	HEADACHE
	MUSCULO-SKELETAL	Hall'S Cough Drops	15,	.	12DEC95	27DEC95	1PRN	URI
		Ibuprofen	15,	.	12DEC95	27DEC95	200MG PRN	URI
	RESPIRATORY	Hall'S Cough Drops	15,	.	12DEC95	27DEC95	1PRN	URI
		Nyquil	15,	.	12DEC95	27DEC95	1TBS PRN	URI
329.009.00196	ALIMENTARY TRACT/METAB	Pepcid Ac	10,	.	27DEC95	.	75MG	HEARTBURN
		Rolaids	10,	.	27DEC95	.	2TABS PRN	HEARTBURN
	ANTIINFECTIVES,SYSTEMIC	Cefixime	56,	.	11FEB96	.	400MG	SINUS INFECTION
	CENTRAL NERVOUS SYSTEM	Tylenol	-716,	.	01JAN94	.	975MG	HEADACHES
		Tylenol Sinus	55,	.	10FEB96	.	975MG	SINUS INFECTION
	MUSCULO-SKELETAL	Ibuprofen	-716,	.	01JAN94	.	800MG PRN	HEADACHES
	RESPIRATORY	Albuterol	-1081,	.	01JAN93	.	2TSP PRN	ASTHMA
		Albuterol Inhaler	-1081,	.	01JAN93	.	2PUFFS PRN	ASTHMA
		Entex	54,	.	09FEB96	09FEB96	4TABS	SINUS INFECTION
		Prednisone	56,	.	11FEB96	.	5MG QD	ASTHMA
		Rondec Dm	56,	.	11FEB96	.	4TABS	SINUS INFECTION
		Tylenol Sinus	55,	.	10FEB96	.	975MG	SINUS INFECTION
	SYSTEMIC HORMONAL	Prednisone	56,	.	11FEB96	.	5MG QD	ASTHMA
329.009.00201	ANTIINFECTIVES,SYSTEMIC	Augmentin	-9,	.	28JAN96	06FEB96	750MG	STREP THROAT
			56,	.	01APR96	.	750 MG	TONSILLITIS
	CENTRAL NERVOUS SYSTEM	Tylenol	-9,	.	28JAN96	.	650 PRN	FEVER
	RESPIRATORY	Codimal Dh	56,	.	01APR96	.	2 TSP. PRN	TONSILLITIS

* days relative to start of acute phase, days relative to start of continuation phase
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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.009.00204	CENTRAL NERVOUS SYSTEM	Ritalin	-808, -864	01JAN94	01MAR96#	20MG SR	ATTENTION DEFICIT HYPERACTIVITY DISORDER
		Tylenol	-808, -864	01JAN94	.	675MG PRN	OCCASIONAL HEADACHE
329.009.00235	ANTIINFECTIVES,SYSTEMIC	Minocycline	-33, -87	15NOV96	.	100MG	ACNE
	CENTRAL NERVOUS SYSTEM	Tylenol (Liquid)	-11, -65	07DEC96	07DEC96#	2 TEASPOONS	FLU SYMPTOMS
	GU SYSTEM/SEX HORMONES	Ortho Novum 1/35-28	40, -15	26JAN97	.	1 PILL	BIRTH CONTROL
	MUSCULO-SKELETAL	Ibuprofen	-11, -65	07DEC96	07DEC96#	200 MG PRN	FLU SYMPTOMS
329.009.00240	MUSCULO-SKELETAL	Advil	-13, .	01JAN97	.	400 MG PRN	HEADACHES
329.009.00303	ANTIINFECTIVES,SYSTEMIC	Biaxin	-32, -88	01MAR96	.	500MG	SINUS INFECTION
	CENTRAL NERVOUS SYSTEM	Prozac	-23, -79	10MAR96	17MAR96#	10MG	DEPRESSION
		Tylenol	-32, -88	01MAR96	.	650 PRN	SINUS INFECTION
		Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	DERMATOLOGICALS	Benadryl	23, -34	24APR96	24APR96	20MG	NASAL CONGESTION
	MUSCULO-SKELETAL	Advil	-822, -878	01JAN94	.	200MG	OCCASIONAL HEADACHE
	RESPIRATORY	Benadryl	23, -34	24APR96	24APR96	20MG	NASAL CONGESTION
		Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
329.009.00304	MUSCULO-SKELETAL	Advil	-464, -520	01JAN95	.	400MG	OCCASIONAL HEADACHE
329.009.00324	CENTRAL NERVOUS SYSTEM	Tylenol Extra Strength	-88, .	01AUG96	.	500 MG PRN	OCCASIONAL HEADACHES
		Tylenol Sinus	-88, .	01AUG96	.	1 TAB PRN	SINUS CONGESTION
	MUSCULO-SKELETAL	Advil	-88, .	01AUG96	.	200 MG PRN	OCCASSIONAL HEADACHES
	RESPIRATORY	Sudafed	-88, .	01AUG96	.	120 MG PRN	SINUS CONGESTION
		Tylenol Sinus	-88, .	01AUG96	.	1 TAB PRN	SINUS CONGESTION
329.009.00329	CENTRAL NERVOUS SYSTEM	Tylenol	-647, .	01JAN95	.	500 MG PRN	HEADACHE OCCASIONAL
329.010.00182	CENTRAL NERVOUS SYSTEM	Aspirin	10, .	28DEC95	28DEC95	325	HEADACHE
		Marijuana	-1448, .	01JAN92	.		ILLICIT USE
		Tylenol	-7, .	12DEC95	12DEC95#	650MG	HEADACHE
329.010.00278	ANTIINFECTIVES,SYSTEMIC	Keflex	221, 165	16SEP96	19SEP96	4000 MG	MONONUCLEOSIS
	CENTRAL NERVOUS SYSTEM	Aspirin	-39, -95	01JAN96	.	325	ABDOMINAL PAIN
		Percocet	37, -20	16MAR96	17MAR96	PRN	ABDOMINAL PAIN

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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.010.00278	CENTRAL NERVOUS SYSTEM	Ultram	38, -19	17MAR96	19MAR96	PRN	ABDOMINAL PAIN
	RESPIRATORY	Prednisone	221, 165	16SEP96	17SEP96	80 MG	MONONUCLEOSIS
			223, 167	18SEP96	19SEP96	60 MG	MONONUCLEOSIS
			225, 169	20SEP96	21SEP96	40 MG	MONONUCLEOSIS
			227, 171	22SEP96	23SEP96	20 MG	MONONUCLEOSIS
			229, 173	24SEP96	25SEP96	10 MG	MONONUCLEOSIS
	SYSTEMIC HORMONAL	Prednisone	221, 165	16SEP96	17SEP96	80 MG	MONONUCLEOSIS
			223, 167	18SEP96	19SEP96	60 MG	MONONUCLEOSIS
			225, 169	20SEP96	21SEP96	40 MG	MONONUCLEOSIS
			227, 171	22SEP96	23SEP96	20 MG	MONONUCLEOSIS
			229, 173	24SEP96	25SEP96	10 MG	MONONUCLEOSIS
329.010.00280	CENTRAL NERVOUS SYSTEM	Acetaminophen	-10, -65	07MAY96	07MAY96#	650 MG	HEADACHE
		Tylenol	40, -16	25JUN96	25JUN96	1,000 MG	HEADACHE
			42, -14	27JUN96	27JUN96	1,000 MG	HEADACHE
	DERMATOLOGICALS	Benadryl	34, -22	19JUN96	21JUN96	25 MG	ALLERGIES
			39, -17	24JUN96	26JUN96	25 MG + QHS	ALLERGIES
	RESPIRATORY	Benadryl	34, -22	19JUN96	21JUN96	25 MG	ALLERGIES
			39, -17	24JUN96	26JUN96	25 MG + QHS	ALLERGIES
		Tavist-D	-2, -57	15MAY96	15MAY96#	1X PILL DAY	CONGESTION
329.011.00283	CENTRAL NERVOUS SYSTEM	Tylenol	33, -25	11MAR96	11MAR96	650MG	HEADACHE
329.011.00288	RESPIRATORY	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH
		Robitussin-Dm	8, .	01AUG96	.		COUGH
329.012.00025	RESPIRATORY	Reactine	-115, .	01JUL95	.	10MG	SKIN ALLERGIES
329.012.00220	ANTIINFECTIVES,SYSTEMIC	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS
	CENTRAL NERVOUS SYSTEM	Ritalin Sr	-148, -208	21JAN96	15MAY96#	20 MG	ADHD
	DERMATOLOGICALS	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS
	SENSORY ORGANS	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS
329.012.00222	ANTIINFECTIVES,SYSTEMIC	Amoxil	21, -43	18JUL96	22JUL96	1500 MG	BLADDER INFECTION
	ANTINEOPLASTIC & IMMUNOSUP	Cyclen	-119, -182	01MAR96	.	1TAB	CONTRACEPTION
	DERMATOLOGICALS	Rhinocort	-36, -99	23MAY96	.	PRN 2SPRAYS OD	HAY FEVER
	GU SYSTEM/SEX HORMONES	Cyclen	-119, -182	01MAR96	.	1TAB	CONTRACEPTION

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Listing of Prior and Concomitant Medications
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Treatment Group=PAROXETINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.012.00222	RESPIRATORY	Rhinocort	-36, -99	23MAY96	.	PRN 2SPRAYS OD	HAY FEVER
329.012.00231	ANTIINFECTIVES,SYSTEMIC	Micatin	84, 23	29MAY97	.		ECZEMA
	CARDIOVASCULAR	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
	CENTRAL NERVOUS SYSTEM	Tylenol	49, -13	24APR97	.	650 MG PRN	HEADACHE
			109, 48	23JUN97	.	500 MG PRN	MOD HEADACHES
	DERMATOLOGICALS	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
		Micatin	84, 23	29MAY97	.		ECZEMA
	GU SYSTEM/SEX HORMONES	Micatin	84, 23	29MAY97	.		ECZEMA
		Ortho Tri-Cyclen	32, -30	07APR97	.	1 TAB	CONTRACEPTIVE
	SENSORY ORGANS	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
	SYSTEMIC HORMONAL	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA

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Listing of Prior and Concomitant Medications
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Treatment Group=IMIPRAMINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.001.00061	CENTRAL NERVOUS SYSTEM	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
	DERMATOLOGICALS	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
	MUSCULO-SKELETAL	Ibuprofen	-15, .	14JUL94	14JUL94#	200MG	HEADACHE
	RESPIRATORY	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
329.001.00066	CENTRAL NERVOUS SYSTEM	Alka-Seltzer	-731, .	21NOV92	.	2	STOMACH ACHE
		Tylenol	-731, .	21NOV92	.	650MG	HEADACHE
329.001.00070	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	-8, .	14FEB95	20FEB95#		ENLARGED LYMPH NODES
	CENTRAL NERVOUS SYSTEM	Tylenol	-2, .	20FEB95	20FEB95#	325MG	HEADACHE
329.001.00122	ALIMENTARY TRACT/METAB	Centrum	-80, -137	01APR95	20JUN95	ONE DAILY	HEALTH MAINTENANCE
	ANTIINFECTIVES,SYSTEMIC	Bactrim Ds	-139, -196	01FEB95	.	2TWICE DAILY	ACNE
329.002.00050	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	5, .	27MAR95	28MAR95	250MG	SORE THROAT
			6, .	28MAR95	08APR95	1500MG	SORE THROAT
		Cleocin	-1177, .	01JAN92	.	1%LOTION	ACNE
		Minocycline	-1177, .	01JAN92	.	100MG	ACNE
	CENTRAL NERVOUS SYSTEM	Aspirin	4, .	26MAR95	26MAR95	650MG	FEVER
	MUSCULO-SKELETAL	Aleve	5, .	27MAR95	28MAR95	1-2TABS	FEVER/SORE THROAT
329.002.00057	CENTRAL NERVOUS SYSTEM	Acetaminophen	-38, -95	01AUG94	.	650MG PRN	HEADACHE
		Bayer Aspirin	83, 26	29NOV94	29NOV94	1500MG	HEADACHE
		Cannabis	., .	.	.	UNKNOWN	
			53, -5	30OCT94	30OCT94	UNKNOWN	
	MUSCULO-SKELETAL	Motrin	22, -36	29SEP94	29SEP94	800MG	HEADACHE
329.002.00100	CENTRAL NERVOUS SYSTEM	Tylenol	-34, -92	01FEB95	01MAR95#	PRN 650MG	HEADACHE
			41, -18	16APR95	30MAY95	325MG	HEADACHE
	MUSCULO-SKELETAL	Advil	-34, -92	01FEB95	01MAR95#	400MG	HEADACHE
329.002.00103	CENTRAL NERVOUS SYSTEM	Tylenol	4, -53	23APR95	23APR95	200MG	HEADACHE
			7, -50	26APR95	26APR95	200MG	HEADACHE
329.002.00104	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	232, 176	21DEC95	31DEC95	1500 MG	STREP THROAT
		Monocycline	-123, -179	01JAN95	.	150 MGS	ACNE
329.002.00243	ANTIINFECTIVES,SYSTEMIC	Pen-Vee-K	1, .	14MAR96	21MAR96	250 4XDAY	TONSILLITIS
			1, .	14MAR96	21MAR96	1000 MG	PROBABLE STREP THROAT

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Treatment Group=IMIPRAMINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.002.00243	CENTRAL NERVOUS SYSTEM	Tylenol	22, .	04APR96	04APR96	650 MG PRN	HEADACHES
	DERMATOLOGICALS	Benadryl	4, .	17MAR96	24MAR96	25 MG	RASH
		Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
	RESPIRATORY	Benadryl	4, .	17MAR96	24MAR96	25 MG	RASH
329.002.00321	MUSCULO-SKELETAL	Ibuprofen	-508, .	01JAN95	.	PRN	HEADACHES
329.003.00073	ALIMENTARY TRACT/METAB	Bentyl	45, .	04MAR95	06MAR95	UNKNOWN	NAUSEA
		Dexatrim	13, .	31JAN95	03FEB95	UNKNOWN	DIETING
	CENTRAL NERVOUS SYSTEM	Pain Medication {Nos}	-11, .	08JAN95	.	4 TABLETS	SPRAINED ANKLE
329.003.00076	CENTRAL NERVOUS SYSTEM	Midol	., .	.	.		CRAMPS
329.003.00079	DERMATOLOGICALS	Benadryl	15, .	17MAY95	17MAY95		SORE THROAT
	RESPIRATORY	Benadryl	15, .	17MAY95	17MAY95		SORE THROAT
329.003.00082	GU SYSTEM/SEX HORMONES	Desogen-28	-344, .	01JAN95	.	X 1	BIRTH CONTROL
329.003.00090	ALIMENTARY TRACT/METAB	Enema Nos	49, .	01MAY95	01MAY95		CONSTIPATION
		Mylanta	50, .	02MAY95	.	UNKNOWN	INDIGESTION
		Senokot	50, .	02MAY95	.	UNKNOWN	CONSTIPATION
	CENTRAL NERVOUS SYSTEM	Tylenol	., .	.	.		HEADACHE
			50, .	02MAY95	02MAY95	650MG	HEADACHE
	MUSCULO-SKELETAL	Advil	3, .	16MAR95	.	400MG PRN	HEADACHE
329.003.00092	ALIMENTARY TRACT/METAB	Coke Syrup	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
		Milk Of Magnesia	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
		Mylanta	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
		Pepto Bismol	39, -20	10JUN95	10JUN95	2TBP	CRAMPS
329.003.00093	CENTRAL NERVOUS SYSTEM	Butalbital	-171, -234	01JAN95	.	1 DAILY PRN	HEADACHES
	RESPIRATORY	Albuterol	-1997,-2060	01JAN90	.	8 PUFFS DAILY PRN	ASTHMA
329.003.00247	DERMATOLOGICALS	Chloraseptic	34, -21	05MAR96	.		COLD
	RESPIRATORY	Nyquil	34, -21	05MAR96	.		COLD
329.003.00249	MUSCULO-SKELETAL	Advil	-1892, .	01JAN91	.		HEADACHE

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Treatment Group=IMIPRAMINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.003.00249	MUSCULO-SKELETAL	Advil	3, .	09MAR96	09MAR96	200 MG	HEADACHE
			38, .	13APR96	15APR96	400 MG BID	MENSTRUAL CRAMPS
	RESPIRATORY	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD
329.003.00289	CENTRAL NERVOUS SYSTEM	Pamprin	., .	.	.	2 TABS	MENSTRUAL CRAMPS
		Tylenol	., .	.	.	1000MG	HEADACHES
329.003.00314	ALIMENTARY TRACT/METAB	Pepcid Ac	44, .	04DEC96	06DEC96	ONE CAP	HEARTBURN
	ANTIINFECTIVES,SYSTEMIC	Pen-Vee-K	-111, .	03JUL96	13JUL96#	TABS 2X DAY	PHARYNGITIS
	CENTRAL NERVOUS SYSTEM	Tylenol	60, .	20DEC96	20DEC96	500 GRM	EARACHE
	MUSCULO-SKELETAL	Advil	25, .	15NOV96	17NOV96	200 MG TID	FLU
329.003.00317	CENTRAL NERVOUS SYSTEM	Tylenol	1, .	19DEC96	04FEB97	500 MG	HEADACHES
			34, .	21JAN97	21JAN97	500 MG	BACKACHE
	DERMATOLOGICALS	Benadryl	27, .	14JAN97	14JAN97	25 GM	ALLERGIES
	RESPIRATORY	Benadryl	27, .	14JAN97	14JAN97	25 GM	ALLERGIES
		Over The Counter {Asthma Nos}	., .	.	.		ASTHMA
	VARIOUS	Over The Counter {Allergenic Extract Nos}	., .	.	.		ALLERGIC
329.004.00013	ANTIINFECTIVES,SYSTEMIC	Minocin	-48, -107	01JUN94	01FEB95	200MG	ACNE
	DERMATOLOGICALS	Accutane	59, -1	15SEP94	16SEP94	40-80MG	ACNE
329.004.00014	ALIMENTARY TRACT/METAB	Vitamin C	-5, .	24NOV94	.	UNKNOWN	COMMON COLD
329.004.00211	ALIMENTARY TRACT/METAB	Antiemetic {Nos}	49, .	21MAR96	22MAR96		NAUSEA&VOMITING
		Jamieson B Complex Vitamins	., .	.	.	ONE CAP	HEALTH MAINTENANCE
		Vitamin C	., .	.	.	500MG	HEALTH MAINTENANCE
	BLOOD/BLOOD FORM ORGANS	Intravenous Fluids	49, .	21MAR96	22MAR96		DEHYDRATION
	CENTRAL NERVOUS SYSTEM	Analgesic {Nos}	49, .	21MAR96	22MAR96		MOUTH SORES
		Tylenol	38, .	10MAR96	.	2TABS	HEADACHE
329.004.00215	VARIOUS	Unknown Chinese Herbal Med	-139, .	01NOV96	11MAR97#		LOW ENERGY

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Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.004.00215	VARIOUS	Yinchia0 Tablet (Chiehtupien) {Homeopathic}	7,	.	26MAR97	26MAR97	ONE TABLET	RHINITIS AND SORE THROAT
329.005.00003	ANTIINFECTIVES,SYSTEMIC	Erythromycin	-19,	.	01SEP94	14SEP94#	750MG	EAR INFECTION
	CENTRAL NERVOUS SYSTEM	Acetaminophen	-5,	.	15SEP94	15SEP94#	650MG	HEADACHE
	DERMATOLOGICALS	Erythromycin	-19,	.	01SEP94	14SEP94#	750MG	EAR INFECTION
	RESPIRATORY	Naldecon	.,	.	.	.	20ML	FOR RELIEF OF ALLERGIES
		Tussi-Organidin	.,	.	.	.	120MG	FOR RELIEF OF ALLERGIES
	SENSORY ORGANS	Erythromycin	-19,	.	01SEP94	14SEP94#	750MG	EAR INFECTION
329.005.00006	ALIMENTARY TRACT/METAB	Tums	23,	-38	26NOV94	.	2DAILY	UPSET STOMACH
	ANTIINFECTIVES,SYSTEMIC	Ceclor	21,	-40	24NOV94	28NOV94	750MG	TONSILLITIS/STREP THROAT
			25,	-36	28NOV94	09DEC94	1000MG	TONSILLITIS
329.005.00007	CENTRAL NERVOUS SYSTEM	Compazine	195,	132	22MAY95	22MAY95		DEHYDRATION NAUSEA,VOMITING,DIARRHEA
		Compazine Suppositories	196,	133	23MAY95	24MAY95		DEHYDRATION NAUSEA,VOMITING,DIARRHEA
		Tylenol	81,	18	28JAN95	.	500MG(PRN)	LEG CRAMPS
			180,	117	07MAY95	07MAY95	500MG	HEADACHE
	DERMATOLOGICALS	Benadryl	197,	134	24MAY95	24MAY95		SEIZURE
		Caladryl Lotion	2,	-62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
	GU SYSTEM/SEX HORMONES	Birth Control Pills	-219,	-282	04APR94	.	1A DAY	IRREGULAR MENSTRUAL CYCLES
	RESPIRATORY	Benadryl	197,	134	24MAY95	24MAY95		SEIZURE
329.005.00009	CENTRAL NERVOUS SYSTEM	Tylenol	-11,	.	01DEC94	07DEC94#	500MG	HEADACHE
			5,	.	16DEC94	19DEC94	500MG	HEADACHE
			11,	.	22DEC94	27DEC94	500MG	HEADACHES
			21,	.	01JAN95	01JAN95	500MG	HEADACHE
329.005.00113	CENTRAL NERVOUS SYSTEM	Tylenol	2,	.	31JAN95	31JAN95	500 MG	H/A

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Listing of Prior and Concomitant Medications
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Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.005.00113	RESPIRATORY	Ventolin	-3591, .	01APR85	.	2 PUFFS PRN	ASTHMA
329.005.00117	ALIMENTARY TRACT/METAB	Cimetidine	41, .	27APR95	.	1200MG	GASTRITIS
		Propulsid	41, .	27APR95	.	40MG	GASTRITIS
	CENTRAL NERVOUS SYSTEM	Percocet	52, .	08MAY95	15MAY95	1X DAILY EVERY 4HRS.AS NE	PAIN
329.005.00118	CENTRAL NERVOUS SYSTEM	Tylenol	4, .	20MAY95	23MAY95	500 MG	SORE THROAT
	MUSCULO-SKELETAL	Ibuprofen	-20, .	27APR95	27APR95#	400MG	HEADACHE
	RESPIRATORY	Robitussin	3, .	19MAY95	.	4 TSP.	COUGH
329.005.00153	ANTIINFECTIVES,SYSTEMIC	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
	CENTRAL NERVOUS SYSTEM	Midol	7, -50	31JAN96	31JAN96	6 TABS	MENSTRUAL CRAMPS
		Tylenol	., .	.	17APR96	2 EXTRA STRENGTH	HEADACHE X3
			28, -29	21FEB96	21FEB96	1000 MG	HEADACHE
			38, -19	02MAR96	02MAR96	1000 MG	HEADACHE
			57, 1	21MAR96	17APR96	1000 MG	HEADACHE X3
			84, 28	17APR96	15MAY96	1000 MG	HEADACHE X2
			112, 56	15MAY96	12JUN96	1000 MG	HEADACHE X6
			140, 84	12JUN96	10JUL96	1000 MG	HEADACHE X2
			168, 112	10JUL96	05AUG96	1000 MG	HEADACHE X1
		Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
		Tylenol Extra Strength	-2, -58	23JAN96	23JAN96#	500 MG	BACK PAIN
			17, -40	10FEB96	10FEB96	1000 MG	HEADACHE
		Tylenol Gelcaps	-9, -65	16JAN96	27JAN96		COLD
	DERMATOLOGICALS	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
	MUSCULO-SKELETAL	Ibuprofen	., .	.	.	200 MG	HEADACHE
			84, 28	17APR96	15MAY96	400 MG	HEADACHE X1
	RESPIRATORY	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
	SENSORY ORGANS	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
329.005.00255	ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole/Trimethoprim Ds	36, .	08APR96	15APR96	1 X 2 DAY	UTI (URINARY TRACT INFECTION)
	DERMATOLOGICALS	Femstat	38, .	10APR96	15APR96		YEAST INFECTION
		Terazol-7	47, .	19APR96	21APR96		YEAST INFECTION
	GU SYSTEM/SEX HORMONES	Femstat	38, .	10APR96	15APR96		YEAST INFECTION

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Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.005.00255	MUSCULO-SKELETAL	Ibuprofen	-3,	.	01MAR96	03MAR96#	2 TABS	HA (HEADACHE)
			8,	.	11MAR96	11MAR96	2 TABS	HA (HEADACHE)
	RESPIRATORY	Sudafed	32,	.	04APR96	04APR96	1 X DAY	ENVIRONMENTAL ALLERGIES
			45,	.	17APR96	18APR96	1 X DAY	ENVIRONMENTAL ALLERGIES
329.005.00256	ALIMENTARY TRACT/METAB	Axid	129,	73	11JUL96	.		GI UPSET
	CENTRAL NERVOUS SYSTEM	Tylenol	1,	-56	05MAR96	07MAR96	650 MG	HA
			13,	-44	17MAR96	20MAR96	500 MG	H/A AND BACKACHE
			16,	-41	20MAR96	21MAR96		MENSTRUAL CRAMPS
		Tylenol Extra Strength	28,	-29	01APR96	01APR96		SORE THROAT
	RESPIRATORY	Sudafed	1,	-56	05MAR96	07MAR96		HA
329.005.00295	ALIMENTARY TRACT/METAB	Pepto-Bismol	-9,	.	19MAR96	19MAR96#	2TBSP	DIARRHEA
		Vitamin C	-24,	.	04MAR96	06MAR96#		COLD SYMPTOMS
	CENTRAL NERVOUS SYSTEM	Tylenol	-9,	.	19MAR96	19MAR96#	500MG	FLU-BODY ACHES
	MUSCULO-SKELETAL	Advil	-7,	.	21MAR96	21MAR96#	250MG	HEADACHE
329.005.00297	CENTRAL NERVOUS SYSTEM	Tylenol	-5,	.	14APR96	16APR96#	1 GM.	HEADCOLD & NASAL CONGESTION
			22,	.	10MAY96	11MAY96	2 TABS	HA
	RESPIRATORY	Robitussin	-5,	.	14APR96	16APR96#	4 TSP	HEADCOLD & NASAL CONGESTION
329.005.00335	CENTRAL NERVOUS SYSTEM	Tylenol	-21,	.	07FEB97	08FEB97#	500 MG	MENSTRUAL CRAMPS
			-1,	.	27FEB97	27FEB97#	500 MG	HEADACHE
			43,	.	11APR97	11APR97	500 MG	HEADACHE
			54,	.	22APR97	22APR97	500 MG	HEADACHE
	MUSCULO-SKELETAL	Ibuprofen	-20,	.	08FEB97	09FEB97#	400 MG	MENSTRUAL CRAMPS
329.006.00040	GU SYSTEM/SEX HORMONES	Loestrin	-63,	.	15DEC94	.	120	OVARIAN CYST
	MUSCULO-SKELETAL	Baclofen	-3698,	.	01JAN85	.	1TAB PRN	ASTHMA
	RESPIRATORY	Vancenase	-3698,	.	01JAN85	.	1TAB PRN	ALLERGIES
		Ventolin	-3698,	.	01JAN85	.	1TAB PRN	ALLERGIES
329.006.00041	BLOOD/BLOOD FORM ORGANS	Vitamin B12	-63,	-127	01FEB95	05APR95	500MG	VITAMIN SUPPLEMENT
	MUSCULO-SKELETAL	Advil	12,	-53	16APR95	18APR95	600MG	SORE THROAT

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329.006.00041	MUSCULO-SKELETAL	Nuprin	141, 77	23AUG95	23AUG95	TABLETSX2	HEADACHE
	RESPIRATORY	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
		Osco Brand Cold And Flu Medication {Nos}	12, -53	16APR95	18APR95	2TABS	SORE THROAT
	VARIOUS	Met-Rx {Nutritional Supplement}	134, 70	16AUG95	23AUG95	1PACKET	HEALTH MAINTENANCE
329.007.00139	CENTRAL NERVOUS SYSTEM	Bc Powder	-9, .	29APR95	01MAY95#	1PACK PRN	FRACTURED RIGHT ARM
		Tylenol	-9, .	29APR95	01MAY95#	325MG PRN	FRACTURED RIGHT ARM
	MUSCULO-SKELETAL	Advil	-9, .	29APR95	01MAY95#	200MG PRN	FRACTURED RIGHT ARM
329.007.00143	CENTRAL NERVOUS SYSTEM	Tylenol	-1, .	08NOV95	09NOV95	1000MG	COLD
329.007.00146	ALIMENTARY TRACT/METAB	Pepto Bismol	58, 5	22MAR96	22MAR96	2 TABS	UPSET STOMACH
			162, 109	04JUL96	04JUL96	2 TABS	DIARRHEA
	CENTRAL NERVOUS SYSTEM	Cyclobenzaprine	7, -47	31JAN96	31JAN96	10MG	MUSCLE SORENESS
			238, 185	18SEP96	18SEP96	1 TAB	LEFT KNEE MUSCLE SPASMS
		Tylenol	-15, -68	10JAN96	10JAN96#	1,000MG	MENSTRUAL CRAMP
			-8, -61	17JAN96	17JAN96#	500MG	WRIST PAIN(RIGHT)
		Tylenol Gelcaps	-754, -807	01JAN94	.	750MG PRN	OCCASIONAL HEADACHE
			172, 119	14JUL96	14JUL96	1,000 MG	ANXIETY
	DERMATOLOGICALS	Benadryl	-24, -77	01JAN96	.	50MG PRN	SEASONAL ALLERGIES
	MUSCULO-SKELETAL	Cyclobenzaprine	7, -47	31JAN96	31JAN96	10MG	MUSCLE SORENESS
			238, 185	18SEP96	18SEP96	1 TAB	LEFT KNEE MUSCLE SPASMS
	RESPIRATORY	Benadryl	-24, -77	01JAN96	.	50MG PRN	SEASONAL ALLERGIES
		Dimetapp	220, 167	31AUG96	01SEP96	1 TAB	NASAL ALLERGIES
		Drixoral	-16, -69	09JAN96	09JAN96#	2TABS	COLD
		Efidac	222, 169	02SEP96	06SEP96	1 TAB	NASAL ALLERGIES
		Efidac/24	178, 125	20JUL96	22JUL96	1 TAB	COLD
		Flu Relief {Nos}	12, -42	05FEB96	06FEB96	15TABS	PROPHYLACTIC - FEVER
	VARIOUS	Homeopathic Allergy Medicine	222, 169	02SEP96	07SEP96	3 TABS	NASAL ALLERGIES
329.007.00269	ALIMENTARY TRACT/METAB	Pepcid Ac	-101, .	01JAN96	.	2 TABS	UPSET STOMACH
	CENTRAL NERVOUS SYSTEM	Tylenol	., .	.	.	500-1,000	HEADACHES
			11, .	21APR96	21APR96	1TAB	FOOT PAIN
	RESPIRATORY	Pseudoephed	-101, .	01JAN96	.	30MG	ALLERGIES

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Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.007.00270	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	-8,	.	01MAY96	13MAY96	1500MG	STREP THROAT
	CENTRAL NERVOUS SYSTEM	Tylenol	-494,	.	01JAN95	.	750MG PRN	HEADACHE
	DERMATOLOGICALS	Antifungal Cream {Nos}	26,	.	03JUN96	15JUN96	3X	RINGWORM
		Benadryl	9,	.	17MAY96	19MAY96	3 TABS	POISON IVY
		Calamine Lotion	9,	.	17MAY96	19MAY96	2X	POISON IVY
		Lotrimin Cream	-10,	.	29APR96	19MAY96	2X	RINGWORM
	GU SYSTEM/SEX HORMONES	Lotrimin Cream	-10,	.	29APR96	19MAY96	2X	RINGWORM
	RESPIRATORY	Benadryl	9,	.	17MAY96	19MAY96	3 TABS	POISON IVY
329.007.00307	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	18,	.	02JUN96	07JUN96	500 MG	SINUSITIS
	CENTRAL NERVOUS SYSTEM	Tylenol	-1,	.	15MAY96	15MAY96#	1TAB	HEADACHE
	DERMATOLOGICALS	Benadryl	-45,	.	01APR96	01APR96#	1TAB	INSOMNIA
			32,	.	16JUN96	21JUN96	150 MG	RASH
	MUSCULO-SKELETAL	Advil	2,	.	17MAY96	17MAY96	1 TAB PRN	HEADACHE
			14,	.	29MAY96	29MAY96	200 MG	HEADACHE
			19,	.	03JUN96	04JUN96	200 MG	HEADACHE
		Ibuprofen	-1597,	.	01JAN92	.	2 TABS	HEADACHE
	RESPIRATORY	Actifed	31,	.	15JUN96	16JUN96	2 TABS	ALLERGIES
		Benadryl	-45,	.	01APR96	01APR96#	1TAB	INSOMNIA
			32,	.	16JUN96	21JUN96	150 MG	RASH
329.007.00308	ALIMENTARY TRACT/METAB	Imodium A-D	-2,	.	30JUN96	30JUN96#	4 TABS	NAUSEA
329.008.00159	CENTRAL NERVOUS SYSTEM	Sleep Aid {Nos}	21,	-42	03OCT95	10OCT95	1TAB PRN	INSOMNIA
		Tylenol	.,	.	.	.	2TABS PRN	HEADACHES
329.008.00187	ALIMENTARY TRACT/METAB	Levsinex	-5445,	.	01JAN81	.	1-3XYR	COLITIS
	CENTRAL NERVOUS SYSTEM	Excedrin	-332,	.	01JAN95	.	1-2TABS PRN	HEADACHES
			36,	.	03JAN96	04JAN96	2TABLETS	OCCAS.HEADACHE
		Excedrin Extra Strength	44,	.	11JAN96	12JAN96	2TABLETS	OCCAS.HEADACHE
			58,	.	25JAN96	26JAN96	2TABLETS	OCCAS.HEADACHE
		Tylenol #2	19,	.	17DEC95	.	2TABS PRN	OCCAS.HEADACHE
	GU SYSTEM/SEX HORMONES	Levlen 28	9,	.	07DEC95	.	1TAB DAILY	CONTRACEPTION
		Ovcon	-332,	.	01JAN95	.	1XDAY	BIRTH CONTROL
	MUSCULO-SKELETAL	Motrin	4,	.	02DEC95	05DEC95	2TABS PRN	NECK SPASMS
329.008.00192	ALIMENTARY TRACT/METAB	Pepcid Ac	-2,	.	03MAR96	.	1TIMES DAY	HEARTBURN

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Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.008.00192	CENTRAL NERVOUS SYSTEM	Ritalin	-643, .	01JUN94	01FEB96#	5MG/DAY	ATTENTION DEFICIT HYPERACTIVITY DISORDER
329.008.00272	CENTRAL NERVOUS SYSTEM	Tylenol	-37, -93	26FEB96	19MAR96#	500MG/WK	HEADACHES
			8, -49	10APR96	10APR96	500 MG	HEADACHE
329.008.00273	CENTRAL NERVOUS SYSTEM	Tylenol	-37, -100	10APR96	.	(ALMOST DAILY) AS NEEDED	TMJ PAIN
	MUSCULO-SKELETAL	Ansaid	-58, -121	20MAR96	10APR96#	3 PILLS/DAY	TMJ PAIN
329.009.00134	ANTIINFECTIVES,SYSTEMIC	Nizoral	-1, .	05JUL95	10JUL95	200MG	FUNGUS
	CENTRAL NERVOUS SYSTEM	Aspirin	38, .	12AUG95	.	500MG PRN	HEADACHE
		Midol	-916, .	01JAN93	.	2TABLETS	MENSTRUAL CRAMPS
	DERMATOLOGICALS	Nizoral	-1, .	05JUL95	10JUL95	200MG	FUNGUS
	GU SYSTEM/SEX HORMONES	Triphasil	-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
	MUSCULO-SKELETAL	Anaprox	-916, .	01JAN93	.	550MG PRN	MENSTRUAL CRAMPS
		Naproxen	-34, .	02JUN95	09JUN95#	500MG PRN	SPRAINED MUSCLE
329.009.00171	GU SYSTEM/SEX HORMONES	Triphasil	1, .	07NOV95	.	1TAB	BIRTH CONTROL
329.009.00172	CENTRAL NERVOUS SYSTEM	Tylenol	-681, -738	01JAN94	.	650MG	HEADACHE
329.009.00194	ALIMENTARY TRACT/METAB	Tagamet	28, -29	01JAN96	.	200MG	STOMACH ACHE
	CENTRAL NERVOUS SYSTEM	Tylenol	-703, -759	01JAN94	.	250MG PRN	ANKLE PAIN
		Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI
	RESPIRATORY	Cough Syrup {Nos}	29, -28	02JAN96	16JAN96	2TBL PRN	UPPER RESPIRATORY TRACT INFECTION
		Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI
329.009.00195	CENTRAL NERVOUS SYSTEM	Tylenol	-1809, .	01JAN91	.	650MG PRN	HEADACHE
		Tylenol Number 3	-14, .	01DEC95	02DEC95#	650MG	HEADACHE
	MUSCULO-SKELETAL	Advil	-1809, .	01JAN91	.	200MG PRN	HEADACHE
		Anaprox	-713, .	01JAN94	.	275MG PRN	MENSTRUAL CRAMPS
	RESPIRATORY	Proventil	-348, .	01JAN95	.	2PUFFS PRN	SEASONAL ALLERGIES
329.009.00203	MUSCULO-SKELETAL	Advil	-63, .	01JAN96	.	600MG	SEASONAL ALLERGIES

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329.009.00203	RESPIRATORY	Codimal Dh	-63, .	01JAN96	.	1/2TAB	SEASONAL ALLERGIES
	VARIOUS	Allergy Shots	-793, .	01JAN94	.	1X	SEASONAL ALLERGIES
329.009.00236	CENTRAL NERVOUS SYSTEM	Midol	-168, .	15JUL96	.	1 TAB PRN	MENSTRUAL CRAMPS
		Tylenol	-45, .	15NOV96	.	250 MG PRN	HEADACHES
329.009.00239	CENTRAL NERVOUS SYSTEM	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
		Excedrin	92, 35	18FEB97	17MAR97		HEADACHE
	DERMATOLOGICALS	Phenergan	41, -17	29DEC96	29DEC96	25 MG	VOMITING
		Temovate Emollient Cream	119, 62	17MAR97	.	1 APPLICATION PRN	DRY FINGERTIPS
	RESPIRATORY	Drixoral	92, 35	18FEB97	17MAR97		SINUS CONGESTION
		Phenergan	41, -17	29DEC96	29DEC96	25 MG	VOMITING
	SYSTEMIC HORMONAL	Melatonin	42, -16	30DEC96	.	1TAB	INSOMNIA
329.009.00262	CENTRAL NERVOUS SYSTEM	Tylenol	40, .	28MAR97	28MAR97	500 MG	HEADACHE
	DERMATOLOGICALS	Benadryl	27, .	15MAR97	15MAR97	1 TAB	COUGH
	RESPIRATORY	Benadryl	27, .	15MAR97	15MAR97	1 TAB	COUGH
	SENSORY ORGANS	Sulfacetamide Sodium	-7, .	10FEB97	07APR97	15 ML	EYE INFECTION (LEFT AND RIGHT EYE)
329.009.00264	CENTRAL NERVOUS SYSTEM	Aspirin	-732, .	31OCT94	.	325MG PRN	HEADACHE
	MUSCULO-SKELETAL	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE
	RESPIRATORY	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE
329.009.00301	CARDIOVASCULAR	Theo-Dur	-443, -499	01JAN95	.	600MGI	ASTHMA
	CENTRAL NERVOUS SYSTEM	Tylenol	-443, -499	01JAN95	.	375MG PRN	HEADACHES
	RESPIRATORY	Alupent	-808, -864	01JAN94	.	2PUFFS PRN	ASTHMA
		Theo-Dur	-443, -499	01JAN95	.	600MGI	ASTHMA
329.009.00305	ALIMENTARY TRACT/METAB	Imodium A-D	57, -1	02JUL96	02JUL96	4 MG	NAUSEA
329.009.00325	ALIMENTARY TRACT/METAB	Zantac	-604, -659	01JAN95	.	2TABS PRN	STOMACH UPSET
	CENTRAL NERVOUS SYSTEM	Tylenol Extra Strength	-604, -659	01JAN95	.	1TAB PRN	MENSTRUAL CRAMPS
	DERMATOLOGICALS	Benadryl	45, -11	10OCT96	.	150 MG	NASAL CONGESTION
		Desogen	27, -29	22SEP96	.	1 TAB DAILY	BIRTH CONTROL
	MUSCULO-SKELETAL	Orudis Kt	-2430,-2485	01JAN90	.	2CAPS PRN	OCCASIONAL HEADACHE

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329.009.00325	RESPIRATORY	Benadryl	45, -11	10OCT96	.	150 MG	NASAL CONGESTION
		Ventolin Inhaler	-2430,-2485	01JAN90	.	2PUFFS PRN	ASTHMA
329.009.00326	RESPIRATORY	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS
329.010.00279	ALIMENTARY TRACT/METAB	Tums	193, 137	30SEP96	30SEP96	2 TABS	STOMACH PAIN
	ANTIINFECTIVES,SYSTEMIC	Erycette 2% Cream	91, 35	20JUN96	.		ACNE
	CENTRAL NERVOUS SYSTEM	Tylenol	11, -46	01APR96	01APR96	325 MG	HEADACHE
			139, 83	07AUG96	07AUG96	325 MG	MOLAR ERUPTING
	DERMATOLOGICALS	Benadryl	162, 106	30AUG96	05SEP96	50 MG	POISON IVY
		Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
		Erycette 2% Cream	91, 35	20JUN96	.		ACNE
		Ivy Dry	161, 105	29AUG96	04SEP96		POISON IVY
		Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	RESPIRATORY	Benadryl	162, 106	30AUG96	05SEP96	50 MG	POISON IVY
	SENSORY ORGANS	Erycette 2% Cream	91, 35	20JUN96	.		ACNE
329.010.00281	CENTRAL NERVOUS SYSTEM	Tylenol	40, -22	03SEP96	03SEP96	1000 MG	HEADACHE
			146, 85	18DEC96	19DEC96	1500 MG	HEADACHE
329.011.00163	CENTRAL NERVOUS SYSTEM	Tylenol	-2519, .	01JAN89	.	500MG	MIGRAINES
			-693, .	01JAN94	.	500MG	TEMPOROMANDIBULAR JOINT SYNDROME
			-2, .	23NOV95	.	500MG	HEADACHE
			4, .	28NOV95	.	500MG	HEADACHE
	DERMATOLOGICALS	Benadryl	-4, .	21NOV95	21NOV95#	25MG	DERMATITIS
			-4, .	21NOV95	21NOV95#	OINTMENT	DERMATITIS
	RESPIRATORY	Benadryl	-4, .	21NOV95	21NOV95#	25MG	DERMATITIS
			-4, .	21NOV95	21NOV95#	OINTMENT	DERMATITIS
		Robitussin	6, .	30NOV95	01DEC95	1 1/2TSP	SORE THROAT
		Ventolin	-603, .	01APR94	.	2PUFFS	ASTHMA
329.011.00208	CENTRAL NERVOUS SYSTEM	Tylenol	-1344,-1403	01JAN93	.	1000MG	HEADACHE
	MUSCULO-SKELETAL	Aleve	-249, -308	01JAN96	.	1 TAB DAILY	HEADACHE
329.011.00209	CENTRAL NERVOUS SYSTEM	Tylenol	-254, -316	01JAN96	.	325MG	HEADACHE
	RESPIRATORY	Claritin	-72, -134	01JUL96	.	1PILL	ALLERGIES

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Treatment Group=IMIPRAMINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.011.00209	RESPIRATORY	Sudafed	20, -43	30SEP96	03OCT96	30 MG	RUNNY NOSE
329.011.00284	ANTIINFECTIVES,SYSTEMIC	Hepatitis B Vaccine	29, -28	19APR96	19APR96		VACCINATION
	CENTRAL NERVOUS SYSTEM	Tylenol	-21, -77	01MAR96	.	650MG	HEADACHE
			31, -26	21APR96	21APR96	650MG	HEADACHE
	RESPIRATORY	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT
329.011.00286	CENTRAL NERVOUS SYSTEM	Tylenol	-2348,-2416	01JAN90	.	1000MG	HEADACHE
	RESPIRATORY	Proventil	-2348,-2416	01JAN90	.	2PUFFS	ASTHMA
		Sudafed	-2348,-2416	01JAN90	.	2PILLS	SINUSITIS
329.012.00221	ALIMENTARY TRACT/METAB	Laxative (Unknown Name)	112, 49	14OCT96	01NOV96	1-2 TBSP EVERY 2ND DAY	CONSTIPATION
	CENTRAL NERVOUS SYSTEM	Aspirin	78, 15	10SEP96	10SEP96	1950 MG	HEADACHES
		Chloral Hydrate	56, -8	19AUG96	22SEP96	500 MG PRN	INSOMNIA
		Lorazepam	132, 69	03NOV96	03NOV96	8 MG	OVERDOSE
		Tylenol	-906, -969	01JAN94	.	500 MG PRN	HEADACHE
329.012.00223	CENTRAL NERVOUS SYSTEM	Tylenol	-972, .	01JAN94	.	500 MG PRN	HEADACHE
	DERMATOLOGICALS	Flonase	-107, .	15MAY96	.	1 PUFF PRN	BRONCHOSPASM
	RESPIRATORY	Flonase	-107, .	15MAY96	.	1 PUFF PRN	BRONCHOSPASM
		Sodium (Cromoglycate)	-107, .	15MAY96	.	2 DROPS PRN	ALLERGIC REACTION
	SENSORY ORGANS	Sodium (Cromoglycate)	-107, .	15MAY96	.	2 DROPS PRN	ALLERGIC REACTION
329.012.00227	ANTIINFECTIVES,SYSTEMIC	Amoxil	42, -28	28JAN97	10FEB97	750 MG	PHARYNGITIS
		Penicillin V-K	21, -49	07JAN97	15JAN97	2,400 MG	AC. PHARYNGITIS
	CENTRAL NERVOUS SYSTEM	Marijuana	32, -38	18JAN97	18JAN97	0.75 G	PT'S DECISIONS
	RESPIRATORY	Dristan	142, 73	08MAY97	09MAY97	2 TABS.	CONGESTION
		Triaminic	142, 73	08MAY97	09MAY97	3 TSP.	COUGH
329.012.00230	ALIMENTARY TRACT/METAB	Tums	15, -55	14MAR97	.	3-4 TABS	HEARTBURN
			76, 7	14MAY97	26MAY97	3-4 TABS	HEARTBURN
	ANTIINFECTIVES,SYSTEMIC	Biaxin	50, -20	18APR97	24APR97	500 MG	PHOPHYLAXIS TEETH EXTRACTION
	CENTRAL NERVOUS SYSTEM	Tylenol	32, -38	31MAR97	31MAR97	500 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.012.00230	CENTRAL NERVOUS SYSTEM	Tylenol With Codeine	50, -20	18APR97	20APR97	14 TSPS.	IMPACTED TEETH EXTRACTION
			53, -17	21APR97	21APR97	10 TSP.	IMPACTED TEETH EXTRACTION
	DERMATOLOGICALS	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION
	MUSCULO-SKELETAL	Advil	53, -17	21APR97	23APR97	600 MG	IMPACTED TEETH EXTRACTION
	RESPIRATORY	Gravol	69, -1	07MAY97	07MAY97	50 MG	NAUSEA
	SENSORY ORGANS	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION
	SYSTEMIC HORMONAL	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION

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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.001.00062	ALIMENTARY TRACT/METAB	Mylanta	-2240, .	01SEP88	01SEP93#	2TSP	STOMACH ACHE
	CENTRAL NERVOUS SYSTEM	Tylenol	-5437, .	01DEC79	.	1000MG	HEADACHE
329.001.00064	CENTRAL NERVOUS SYSTEM	Tylenol	-4013,-4067	15NOV83	.	1000MG	EAR INFECTIONS, HEADACHE
329.001.00069	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	-51, .	27DEC94	27JAN95#		PNEUMONIA
		Septra Double Strength	1, .	16FEB95	24FEB95	1TAB	PHARYNGITIS RIGHT OTITIS MEDIA
	CENTRAL NERVOUS SYSTEM	Tylenol	-51, .	27DEC94	27JAN95#	650MG	FEVER PLUS HEADACHE
329.001.00071	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	-20, .	03FEB95	13FEB95#	750MG	FLU/SINUSITIS
	CENTRAL NERVOUS SYSTEM	Tylenol	-17, .	06FEB95	12FEB95#	650MG	HEADACHE
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
	RESPIRATORY	Nyquil	-17, .	06FEB95	10FEB95#		FLU
		Robitussin Cf	-21, .	02FEB95	08FEB95#		FLU
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
329.001.00123	ANTIINFECTIVES,SYSTEMIC	Zithromax	10, .	13JAN96	18JAN96	1000MGX1	BRONCHITIS
	CENTRAL NERVOUS SYSTEM	Aspirin	12, .	15JAN96	.	650MG	MENSTRUAL CRAMPS
		Pamprin	-20, .	15DEC95	17DEC95#	2TABS	MENSTRUAL CRAMPS
		Tylenol	49, .	21FEB96	.	650MG	HEADACHE
	DERMATOLOGICALS	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS
	GU SYSTEM/SEX HORMONES	Ortho-Cept 28	18, .	21JAN96	.	1TAB 1XDAY	MENSTRUAL CRAMPS
	SENSORY ORGANS	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS
	SYSTEMIC HORMONAL	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS
329.001.00207	ANTIINFECTIVES,SYSTEMIC	Biaxin	56, .	23APR96	02MAY96	1000MG	SINUS INFECTION
	CENTRAL NERVOUS SYSTEM	Tylenol	53, .	20APR96	25APR96	650MG	HEADACHE SORE THROAT
	MUSCULO-SKELETAL	Aleve	-7, .	21FEB96	28FEB96	1TAB	STRAINED MUSCLE
	RESPIRATORY	Sudafed	-21, .	07FEB96	28FEB96	60MG	COLD SYMPTOMS
329.002.00049	CENTRAL NERVOUS SYSTEM	Aspirin	19, .	27MAR95	27MAR95	650MG	HEADACHE
329.002.00097	CENTRAL NERVOUS SYSTEM	Tylenol	-15, -73	19DEC94	26DEC94#	200MG PRN	UPPER RESPIRATORY INFECTION

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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
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Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.002.00097	CENTRAL NERVOUS SYSTEM	Tylenol	14,	-45	16JAN95	17JAN95	325MG	FLU SYMPTOMS
			29,	-30	31JAN95	07FEB95	650MG	HEADACHE
			87,	29	30MAR95	.	650PRN	HEADACHES
	DERMATOLOGICALS	Benadryl	-15,	-73	19DEC94	26DEC94#	25MG PRN	UPPER RESPIRATORY INFECTION
	RESPIRATORY	Benadryl	-15,	-73	19DEC94	26DEC94#	25MG PRN	UPPER RESPIRATORY INFECTION
329.002.00107	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	236,	180	16SEP96	26SEP96	1500 MG	STREP THROAT
329.002.00241	CENTRAL NERVOUS SYSTEM	Prozac	108,	52	23MAY96	.	10 MG	DEPRESSION
	RESPIRATORY	Cough Medicine	64,	8	09APR96	30APR96	18 TBSP	COUGH
		Dristan	-36,	-92	01JAN96	25JAN96#	2 SPRAYS	NASAL CONGESTION
329.002.00246	ALIMENTARY TRACT/METAB	Pepcid	-838,	.	01JAN94	.	PRN-10MGS	GASTROINTESTINAL DISTRESS
	MUSCULO-SKELETAL	Advil	48,	.	04JUN96	04JUN96		HEADACHE
329.002.00320	ANTIINFECTIVES,SYSTEMIC	Augmentin	117,	56	09SEP96	19SEP96		EAR INFECTION
	MUSCULO-SKELETAL	Ibuprofen	32,	-30	16JUN96	22JUN96	PRN	PAIN IN (EST) SHOULDER
329.002.00323	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	151,	93	11APR97	18APR97	250 MG	PHARYNGITIS
	CENTRAL NERVOUS SYSTEM	Unknown {Analgesic Nos}	-1,	-59	11NOV96	01DEC96		BACK PAIN
		Unknown {Analgesic}	49,	-10	30DEC96	.	UNKNOWN	HEADACHES
329.003.00080	GU SYSTEM/SEX HORMONES	Injectable Contraceptive {Nos}	-51,	.	07OCT95	.		BIRTH CONTROL
329.003.00086	CENTRAL NERVOUS SYSTEM	Tylenol	-58,	-115	01OCT94	08OCT94#	500MG	ABD.PAIN
			36,	-22	02JAN95	03JAN95	500MG	FEVER
	DERMATOLOGICALS	Caladryl Lotion	78,	21	13FEB95	25APR95	LOCAL TOPICAL	RASH
	RESPIRATORY	Afrin	-423,	-480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
		Tavist D	15,	-43	12DEC94	14DEC94		COLD
		Tavist-D	169,	112	15MAY95	19MAY95	2 TSP	COLD
329.003.00094	ALIMENTARY TRACT/METAB	Prilosec	32,	.	24NOV95	.	PRN	ACIDITY

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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.003.00094	CENTRAL NERVOUS SYSTEM	Aspirin	49,	.	11DEC95	11DEC95	500MG	HEADACHE
329.003.00252	CENTRAL NERVOUS SYSTEM	Midol	39,	.	18MAY96	18MAY96	2 TAB	HEADACHE
		Tylenol	.,	.	.	.	500 MG	HEADACHE
	DERMATOLOGICALS	Retin-A	.,	.	.	.		CYSTIC ACNE
329.003.00315	CENTRAL NERVOUS SYSTEM	Sinutab	7,	.	18NOV96	20NOV96	2	COLD
329.004.00016	ALIMENTARY TRACT/METAB	Buscopan	16,	.	28MAR95	30MAR95	10MG	STOMACH CRAMPS
	RESPIRATORY	Reactine	13,	.	25MAR95	.	10MG	ALLERGIES/HAYFEVER
		Ventodisk	-2628,	.	01JAN88	.	1XWK	ALLERGIES
329.004.00018	ANTIINFECTIVES,SYSTEMIC	Erythromycin	-9,	.	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION
	ANTINEOPLASTIC & IMMUNOSUP	Cyclen	-1583,	.	01JAN91	24MAY95	1TAB	BIRTH CONTROL
	CENTRAL NERVOUS SYSTEM	Tylenol	-1583,	.	01JAN91	03MAY95	650TO 1300MG	HEADACHES
			22,	.	24MAY95	.	325-650	HEADACHE
		Valium	26,	.	28MAY95	28MAY95	15MG	TENSION
	DERMATOLOGICALS	Erythromycin	-9,	.	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION
	GU SYSTEM/SEX HORMONES	Cyclen	-1583,	.	01JAN91	24MAY95	1TAB	BIRTH CONTROL
		Ortho Tri-Cyclen	30,	.	01JUN95	.	1TAB	BIRTH CONTROL
	RESPIRATORY	Claritin	13,	.	15MAY95	18MAY95	1TAB	POLLEN ALLERGY
		Dimetapp	-12,	.	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
		Dimetapp-C	-12,	.	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION
		Neo Citran	-12,	.	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
	SENSORY ORGANS	Erythromycin	-9,	.	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION
329.004.00020	CENTRAL NERVOUS SYSTEM	Valium	-21,	.	19OCT95	19OCT95#	5MG	ANXIETY
329.004.00213	CENTRAL NERVOUS SYSTEM	222	65,	11	05OCT96	05OCT96	375 MGS	HEADACHE
		Acetaminophen	65,	11	05OCT96	05OCT96	1000 MG	HEADACHE
			110,	56	19NOV96	19NOV96	1000 MG	HEADACHE
			122,	68	01DEC96	01DEC96	375 MG	HEADACHE

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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
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Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.004.00213	CENTRAL NERVOUS SYSTEM	Acetaminophen	150, 96	29DEC96	29DEC96	1000 MG	HEADACHE
			224, 170	13MAR97	13MAR97	1000 MG	HEADACHE
		Bufferin	3, -52	04AUG96	04AUG96	325 MGS	HEADACHE
		Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD
329.005.00010	CENTRAL NERVOUS SYSTEM	Tylenol	122, 65	13APR95	15APR95	1GM	FOOT/ANKLE INJURY
	DERMATOLOGICALS	Benadryl	81, 24	03MAR95	05MAR95		HIVES
	RESPIRATORY	Benadryl	81, 24	03MAR95	05MAR95		HIVES
329.005.00012	CENTRAL NERVOUS SYSTEM	Tylenol	37, -23	24JAN95	24JAN95	500MG	HEADACHE
	SENSORY ORGANS	Steroid Eye Drops {Nos}	165, 106	01JUN95	.		OCULAR TOXOPLASMOSIS
329.005.00111	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	37, -20	16FEB95	20FEB95	750MG	SORE THROAT-STREP THROAT?
		Augmentin	97, 41	17APR95	27APR95	750MG	SINUS INFECTION
	CENTRAL NERVOUS SYSTEM	Tylenol	-4, -60	07JAN95	14FEB95	500MG	HEADACHE/BACKACHE
			36, -21	15FEB95	20FEB95	1GM	SORE THROAT/FEVER
			65, 9	16MAR95	17MAR95	1GM	SORE THROAT
			94, 38	14APR95	15APR95	2GM	H/A,PAIN-FACE,NOSE,TEETH
			96, 40	16APR95	17APR95	2GM	H/A/SORE THROAT
		Tylenol#3	96, 40	16APR95	17APR95	60MG	H/A/SORE THROAT
	RESPIRATORY	Beconase Nasal Spray .042%	85, 29	05APR95	.	4 SPRAYS	ALLERGIES/ASTHMA
		Nasalcrom	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
		Proventil	85, 29	05APR95	07APR95	2PUFFS PRN 4XHOUR	ALLERGIES/ASTHMA
		Vancenase	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
	SENSORY ORGANS	Nasalcrom	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
	SYSTEMIC HORMONAL	Steroidal Nasal Preps. {Nos}	97, 41	17APR95	.		ALLERGIES/SINUS INFECTION
329.005.00114	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	7, -51	06FEB95	16FEB95	750MG	STREP THROAT
	CENTRAL NERVOUS SYSTEM	Tylenol	5, -53	04FEB95	08FEB95	500MG	STREP THROAT-PAIN

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Listing of Prior and Concomitant Medications
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Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.005.00114	RESPIRATORY	Ventolin Inhaler	-565, -622	15JUL93	18OCT94#	2PUFFS	ASTHMA
329.005.00115	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	19, -53	24FEB95	15MAR95	750 MG	TOOTH ACHE/SINUS INFECTION
	CENTRAL NERVOUS SYSTEM	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
	GU SYSTEM/SEX HORMONES	Birth Control Pills	-31, -102	06JAN95	.	1X	PREVENT PREGNANCY
	RESPIRATORY	Ventolin Inhaler	-27, -98	10JAN95	10JAN95#	2 PUFFS PRN	ASTHMA
		Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
329.005.00120	DERMATOLOGICALS	Topical Cream {Dermatological Nos}	., .	.	.		RASH (?FOLLICULITIS)
	RESPIRATORY	Actifed	15, .	13SEP95	14SEP95		RUNNY NOSE,COUGH
		Robitussin	19, .	17SEP95	19SEP95		COUGH
			55, .	23OCT95	23OCT95		COUGH
329.005.00253	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
		Doxycycline	26, .	04MAR96	12MAR96	200 MG BID	CHLAMYDIA
	CENTRAL NERVOUS SYSTEM	Aspirin	-6, .	02FEB96	14FEB96	650 MG	HEADACHE
		Tylenol	19, .	26FEB96	26FEB96	650 MG	HEADACHE
	MUSCULO-SKELETAL	Advil	20, .	27FEB96	27FEB96		HEADACHE
		Aleve	45, .	23MAR96	23MAR96	1 TAB	HEADACHE
	RESPIRATORY	Promethazine With Codeine	-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
		Proventil Inhaler	-10, .	29JAN96	08FEB96	3 PUFFS	BRONCHITIS
329.005.00254	CENTRAL NERVOUS SYSTEM	Bayer Aspirin	104, 49	28MAY96	28MAY96	UNKNOWN	MENSTRUAL CRAMPS
		Tylenol	-13, -68	02FEB96	06FEB96#	500MG	HEADACHE
			-4, -59	11FEB96	11FEB96#	500MG	HEADACHE
			23, -33	08MAR96	08MAR96	500MG	HEADACHE

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Appendix B.14

Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.005.00254	CENTRAL NERVOUS SYSTEM	Tylenol	53, -3	07APR96	07APR96	500MG	HEADACHE
			201, 146	02SEP96	02SEP96	500 MG	HEADACHE
			202, 147	03SEP96	03SEP96	500 MG	HEADACHE
	MUSCULO-SKELETAL	Ibuprofen	24, -32	09MAR96	09MAR96		MENSTRUAL CRAMPS
329.005.00293	ANTINEOPLASTIC & IMMUNOSUP	Depo-Provera	21, .	01APR97	01APR97		BIRTH CONTROL
	CENTRAL NERVOUS SYSTEM	Tylenol	-23, .	17FEB97	18FEB97#	1 GM	POST PARTUM PAIN
			26, .	06APR97	06APR97	500 MG	HEADACHE
			39, .	19APR97	19APR97	2 TABS	HEADACHE
	GU SYSTEM/SEX HORMONES	Depo-Provera	21, .	01APR97	01APR97		BIRTH CONTROL
	RESPIRATORY	Humibid	7, .	18MAR97	18MAR97	2 PUFFS	RESPIRATORY CONGESTION
329.005.00298	CENTRAL NERVOUS SYSTEM	Midol (Teen)	231, 175	07JAN97	09JAN97	4 TABS	MENSTRUAL CRAMPS
		Pamprin	-7, -63	15MAY96	15MAY96#	PRN	MENSTRUAL CRAMPS
			46, -11	06JUL96	07JUL96	1X DAILY TAB	MENSTRUAL CRAMPS
			167, 111	04NOV96	04NOV96	2 TABS	MENSTRUAL CRAMPS
			200, 144	07DEC96	09DEC96	1 TAB	MENSTRUAL CRAMPS
		Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
		Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
		Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION
	MUSCULO-SKELETAL	Advil	26, -31	16JUN96	16JUN96	2X DAILY TABS	RIGHT LEG PAIN
			33, -24	23JUN96	23JUN96	2X DAILY TABS	BACK PAIN
			56, -1	16JUL96	16JUL96	1X DAILY TAB	KNEE INJURY
			133, 77	01OCT96	04OCT96	800 MG	CHARLIE HORSE
		Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
		Ibuprofen	149, 93	17OCT96	17OCT96	300 MG	PULLED MUSCLE
	RESPIRATORY	Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
		Claritin	40, -17	30JUN96	01JUL96	2X DAILY TABS	SINUS CONGESTION
		Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX

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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.005.00298	RESPIRATORY	Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Allergy And Sinus	-26, -82	26APR96	26APR96#	2 DAILY PRN	ALLERGIES
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
		Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION
329.005.00331	ANTIINFECTIVES,SYSTEMIC	Augmentin	27, .	17DEC96	27DEC96	2 CAPS	SINUS INFECTION
		Zithromax	-22, .	30OCT96	06NOV96#		EAR INFECTION
	CENTRAL NERVOUS SYSTEM	Tylenol	1, .	21NOV96	21NOV96	500 MG	HEADACHE
			36, .	26DEC96	26DEC96	500 MG	HEADACHE
	MUSCULO-SKELETAL	Advil	3, .	23NOV96	23NOV96	4 CAPS	HEADACHE
	RESPIRATORY	Robitussin	23, .	13DEC96	17DEC96	2 TSP.	SINUS INFECTION
		Unknown Decongestant {Nos}	-14, .	07NOV96	17NOV96#		SINUS INFECTION
329.005.00334	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	7, .	06FEB97	16FEB97	750 MG	SORE THROAT
	CENTRAL NERVOUS SYSTEM	Tylenol	-50, .	12DEC96	19DEC96#	1 GM	POST-OP FOOT SURGERY
			32, .	03MAR97	03MAR97	500 MG	HEADACHE
			41, .	12MAR97	12MAR97	500 MG	HEADACHE
			48, .	19MAR97	20MAR97	1000 MG	FEVER
	MUSCULO-SKELETAL	Advil	48, .	19MAR97	20MAR97	800 MG	BACKACHE
329.006.00037	ANTIINFECTIVES,SYSTEMIC	Doxycycline	10, .	06FEB95	13FEB95	UNKNOWN	BRONCHITIS
	GU SYSTEM/SEX HORMONES	Ovcon 35	-119, .	01OCT94	.	1 TAB	BIRTH CONTROL
329.006.00042	ALIMENTARY TRACT/METAB	Pepto Bismol	32, -26	07JAN96	07JAN96	2/3C.	STOMACH UPSET
	CENTRAL NERVOUS SYSTEM	Acetaminophen	140, 83	24APR96	24APR96	200 MG	HEADACHE
	MUSCULO-SKELETAL	Aleve	211, 154	04JUL96	04JUL96	220 MG	DENTAL PAIN
		Ibuprofen	108, 51	23MAR96	23MAR96	600 MG	HEADACHE
			209, 152	02JUL96	02JUL96	400 MG	ORTHODONTAL/DENTAL PAIN
			210, 153	03JUL96	03JUL96	800 MG	DENTAL PAIN
			211, 154	04JUL96	04JUL96	200 MG	DENTAL PAIN
			212, 155	05JUL96	05JUL96	600 MG	DENTAL PAIN
			213, 156	06JUL96	06JUL96	400 MG	DENTAL PAIN
			216, 159	09JUL96	09JUL96	200 MG	HEADACHE
			218, 161	11JUL96	11JUL96	200 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Appendix B.14

Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.006.00042	MUSCULO-SKELETAL	Ibuprofen	220, 163	13JUL96	13JUL96	200 MG	HEADACHE
329.006.00259	ANTIINFECTIVES,SYSTEMIC	Minocin	-540, .	01DEC94	.	50MG	ACNE
329.007.00141	DERMATOLOGICALS	Benadryl	-23, .	29AUG95	30AUG95#	25MG	SLEEP ONSET INSOMNIA
	RESPIRATORY	Benadryl	-23, .	29AUG95	30AUG95#	25MG	SLEEP ONSET INSOMNIA
329.007.00144	CENTRAL NERVOUS SYSTEM	Tylenol	39, -18	14JAN96	15JAN96	1,500MG	HEADACHE
329.007.00266	ANTIINFECTIVES,SYSTEMIC	Keflex	52, .	27APR96	10MAY96	1,000MG	SORE THROAT
329.007.00267	CENTRAL NERVOUS SYSTEM	Tylenol Gelcaps	10, .	16MAR96	16MAR96	1000MG	HEADACHE
			31, .	06APR96	06APR96	1000MG	HEADACHE
	MUSCULO-SKELETAL	Advil	26, .	01APR96	01APR96	400MG	HEADACHE
329.007.00311	ALIMENTARY TRACT/METAB	Dulcolax	7, -54	09OCT96	09OCT96	1 TAB	ABDOMINAL PAIN
		Pepto Bismol	113, 53	23JAN97	24JAN97	2TSP	VOMITING AND DIARRHEA DUE TO FLU SYMPTOM
	ANTIINFECTIVES,SYSTEMIC	Bactrim	-27, -87	06SEP96	20SEP96#	2 TAB	BRONCHITIS
			21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
		Sulfatrim	166, 106	17MAR97	31MAR97	1,000 MG	BRONCHITIS
	CENTRAL NERVOUS SYSTEM	Effexor	-155, -215	01MAY96	27SEP96#	1 TAB PRN	PRIOR PRESCRIPTION FOR DEPRESSION
	DERMATOLOGICALS	Flonase	21, -40	23OCT96	23NOV96	2 SPRAYS	SINUSITIS
	MUSCULO-SKELETAL	Naprosyn	47, -14	18NOV96	22NOV96	1000 MG	KNEE PAIN
	RESPIRATORY	Albuterol	166, 106	17MAR97	24MAR97	1 TSP.	BRONCHITIS
		Entex La	21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
		Flonase	21, -40	23OCT96	23NOV96	2 SPRAYS	SINUSITIS
		Proventil	-27, -87	06SEP96	13SEP96#	2 TSP	BRONCHITIS
		Sudafed	85, 25	26DEC96	26DEC96	1TAB	SINUS CONGESTION
		Unknown Cough Syrup	166, 106	17MAR97	24MAR97	1 TSP	BRONCHITIS
329.008.00162	ANTIINFECTIVES,SYSTEMIC	Antibiotic {Nos}	29, -37	29NOV95	09DEC95		BRONCHITIS
			37, -29	07DEC95	17DEC95		EYE INFECTION
329.008.00191	ANTIINFECTIVES,SYSTEMIC	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
329.008.00191	DERMATOLOGICALS	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE
	SENSORY ORGANS	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE
329.009.00128	RESPIRATORY	Dimetapp	-830, .	01JAN93	.	4TABS PRN	SEASONAL ALLERGIES
329.009.00135	CENTRAL NERVOUS SYSTEM	Elavil	-9, .	23SEP95	24SEP95#	25MG	DEPRESSION
		Paxil	36, .	06NOV95	.	10MG	DEPRESSION
	MUSCULO-SKELETAL	Aleve	-274, .	01JAN95	.	220MG PRN	HEADACHES
	SYSTEMIC HORMONAL	Synthroid	-1370, .	01JAN92	.	150MG	HYPOTHYROID
329.009.00136	CENTRAL NERVOUS SYSTEM	Midol	-1005, .	01JAN93	.	2 TABS PRN	MENSTRUAL CRAMPS
	MUSCULO-SKELETAL	Advil	-275, .	01JAN95	.	750 MG PRN	OCCASSIONAL HEADACHE
	RESPIRATORY	Drixoral	-275, .	01JAN95	.	500 PRN	SINUS CONGESTION
329.009.00169	DERMATOLOGICALS	Elimite	36, -30	05DEC95	05DEC95	5 %	SCABIES
329.009.00174	ALIMENTARY TRACT/METAB	Pepto Bismol	13, -45	03DEC95	07DEC95	2TBS.PRN	FLU
	CENTRAL NERVOUS SYSTEM	Excedrin	-689, -746	01JAN94	.	500 MG PRN	HEADACHES
			13, -45	03DEC95	07DEC95	500MG	FLU
	MUSCULO-SKELETAL	Daypro	-13, -70	08NOV95	.	600MG PRN	TMJ
	RESPIRATORY	Drixoral	-385, -442	01NOV94	.	2TABS PRN	ALLERGIES
329.009.00197	ALIMENTARY TRACT/METAB	Pepcid	-58, -112	01NOV95	.	20MG PRN	STOMACH PAIN
	ANTIINFECTIVES,SYSTEMIC	Augmentin	174, 120	19JUN96	23JUN96	1000 MG	SCALP LACERATIONS
	MUSCULO-SKELETAL	Advil	-362, -416	01JAN95	.	200MG PRN	HEADACHE
329.009.00198	ANTIINFECTIVES,SYSTEMIC	Tetanus {Toxoid}	48, .	18FEB96	18FEB96	1CC	VACCINATION(FACIAL CUTS)
	CENTRAL NERVOUS SYSTEM	Tylenol	-366, .	01JAN95	.	650MG PRN	HEADACHE
	GU SYSTEM/SEX HORMONES	Triphasil	-1096, .	01JAN93	.	1PILL	BIRTH CONTROL
	RESPIRATORY	Robitussin	-366, .	01JAN95	.	2TBLS	FLU SYMPTOMS
329.009.00200	CENTRAL NERVOUS SYSTEM	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
		Tylenol	-752, .	01JAN94	.	500MG	HEADACHE
	RESPIRATORY	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
329.009.00202	ANTIINFECTIVES,SYSTEMIC	Metacycline	-415, .	01JAN95	.	1TAB	SEASONAL ALLERGY
	CENTRAL NERVOUS SYSTEM	Midol	-50, .	01JAN96	.	2TABS PRN	MENSTRUAL CRAMPS
		Tylenol	-415, .	01JAN95	.	650 PRN	HEADACHES

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Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
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Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.009.00202	GU SYSTEM/SEX HORMONES	Ortho Novum	-50,	.	01JAN96	.	1PILL	BIRTH CONTROL
329.009.00237	DERMATOLOGICALS	Accutane	.,	.	.	.		ACNE
329.009.00238	CENTRAL NERVOUS SYSTEM	Tylenol	-681,	.	01JAN95	.	325MG PRN	HEADACHES
			50,	.	31DEC96	.	250 MG	HEADACHE
	RESPIRATORY	Sudafed	38,	.	19DEC96	31DEC96	60 MG	CONGESTION
329.009.00276	ALIMENTARY TRACT/METAB	Imodium	70,	.	31MAR97	31MAR97	1 TAB PRN	STOMACH VIRUS
	CENTRAL NERVOUS SYSTEM	Tylenol	-386,	.	01JAN96	.	500 MG PRN	OCCASIONAL HEADACHE
			-314,	.	13MAR96	.	500 MG PRN	SORE THROAT
	MUSCULO-SKELETAL	Aleve	53,	.	14MAR97	14MAR97	440 MG	SORE THROAT
	RESPIRATORY	Robitussin	51,	.	12MAR97	18MAR97	1 TSP PRN	SORE THROAT
329.009.00302	MUSCULO-SKELETAL	Advil	-86,	.	01JAN96	20MAR96#	500MG	TENDONITIS
329.009.00306	BLOOD/BLOOD FORM ORGANS	Feosol Liquid	44,	.	24JUL96	.	4 TSP.	ANEMIA
329.009.00312	ALIMENTARY TRACT/METAB	Zantac	-308,	.	01JAN96	.	300 MG PRN	STOMACH ULCER
	GU SYSTEM/SEX HORMONES	Tri-Levlen	-1038,	.	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
	MUSCULO-SKELETAL	Ibuprofen	-673,	.	01JAN95	.	400 MG PRN	OCCASIONAL HEADACHE
	RESPIRATORY	Claritin	-308,	.	01JAN96	.	10 MG	SINUS ALLERGIES
		Entex	-308,	.	01JAN96	.	4 TABS	SINUS ALLERGIES
329.009.00327	ALIMENTARY TRACT/METAB	Dicyclomine	-624,	.	01JAN95	.	20 MG PRN	STOMACH ACHE
		Mylanta Double Strength	-624,	.	01JAN95	.	800 MG PRN	STOMACHE
		Zantac	-624,	.	01JAN95	.	150 MG PRN	STOMACH ACHE
	CENTRAL NERVOUS SYSTEM	Tylenol	-989,	.	01JAN94	.	1000 MG PRN	OCCASIONAL HEADACHE
	DERMATOLOGICALS	Benadryl	-259,	.	01JAN96	.	25 MG PRN	INSECT BITES
	MUSCULO-SKELETAL	Midol Ib	-989,	.	01JAN94	.	400 MG PRN	MENSTRUAL CRAMPS
	RESPIRATORY	Benadryl	-259,	.	01JAN96	.	25 MG PRN	INSECT BITES
		Codimal La	-259,	.	01JAN96	.	24 MG PRN	SINUS ALLERGIES CONGESTION
329.009.00330	ANTIINFECTIVES,SYSTEMIC	Augmentin	-20,	.	01OCT96	.	750 MG	BROKEN EAR DRUM
	CENTRAL NERVOUS SYSTEM	Cylert	-13,	.	08OCT96	08OCT96#	37.5 MG	ADHD
329.010.00263	CENTRAL NERVOUS SYSTEM	Tylenol	6,	.	14AUG96	14AUG96	375 MG	HEADACHE

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Appendix B.14

Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.010.00263	CENTRAL NERVOUS SYSTEM	Tylenol	9,	.	17AUG96	17AUG96	500 MG	HEADACHE
	MUSCULO-SKELETAL	Ibuprofen	33,	.	10SEP96	10SEP96	400 MG	ACHE IN SIDE
	RESPIRATORY	Entex	45,	.	22SEP96	23SEP96	250 MG	CONGESTION
329.010.00277	CENTRAL NERVOUS SYSTEM	Aspirin	.,	.	.	.	PRN	HEADACHE
	MUSCULO-SKELETAL	Aleve	159,	103	06AUG96	06AUG96	220 MG	HEADACHE
329.010.00282	ANTIINFECTIVES,SYSTEMIC	Amoxicillin	-17,	.	09JUL96	14JUL96#	750 MG	BRONCHITIS
	CENTRAL NERVOUS SYSTEM	Tylenol	21,	.	15AUG96	15AUG96	1000 MG	BACKACHE
			39,	.	02SEP96	02SEP96	1000 MG	HEADACHE
	MUSCULO-SKELETAL	Motrin	56,	.	19SEP96	19SEP96	800 MG	MENSTRUAL CRAMPS
329.011.00164	MUSCULO-SKELETAL	Advil	19,	.	09JAN96	.	400MG	HEADACHE BACKACHE
329.011.00210	CENTRAL NERVOUS SYSTEM	Tylenol	.,	.	.	.	650MG	HEADACHE
329.011.00285	CENTRAL NERVOUS SYSTEM	Tylenol	-503,	.	01JAN95	.	500MG	HEADACHE
	MUSCULO-SKELETAL	Motrin	18,	.	04JUN96	.	400 MG	TOOTHACHE
329.012.00027	ANTIINFECTIVES,SYSTEMIC	Erythromycin	-8,	.	28NOV95	08DEC95	1000MG	OTITIS MEDIA
	CENTRAL NERVOUS SYSTEM	Entrophen	19,	.	24DEC95	.	2TABS BID	"NECK SPASM"
		Lorazepam	16,	.	21DEC95	26DEC95	0.5MGX1DAY	ANXIETY
		Tylenol	-1069,	.	01JAN93	.	975MG PRN	HEADACHE
			-15,	.	21NOV95	07DEC95	975MG PRN	OTITIS MEDIA
	DERMATOLOGICALS	Erythromycin	-8,	.	28NOV95	08DEC95	1000MG	OTITIS MEDIA
	MUSCULO-SKELETAL	Anaprox	-25,	.	11NOV95	17NOV95#	550MG PRN	HEADACHES
	RESPIRATORY	Becloforte	-127,	.	01AUG95	20NOV95#	4MCG/PRN	ASTHMA
		Intal	-96,	.	01SEP95	.	40MG	ASTHMA
		Neo-Citran	10,	.	15DEC95	17DEC95	1TAB	COLD
		Sudafed	10,	.	15DEC95	17DEC95	1TAB	COLD
		Ventolin	-461,	.	01SEP94	17NOV95#	200MCG/PRN	ASTHMA
			10,	.	15DEC95	.	200MCG/PRN	ASTHMA
	SENSORY ORGANS	Erythromycin	-8,	.	28NOV95	08DEC95	1000MG	OTITIS MEDIA
		Garasone	-9,	.	27NOV95	08DEC95	4GTTS 4XDAY	OTITIS MEDIA
		Intal	-96,	.	01SEP95	.	40MG	ASTHMA
329.012.00217	ALIMENTARY TRACT/METAB	Pepto Bismol	29,	.	18JUN96	19JUN96	PRN	FLU
	CENTRAL NERVOUS SYSTEM	Sinutab	16,	.	05JUN96	05JUN96	1DOSE	COLD
		Tylenol	-81,	.	01MAR96	.	PRN 500MG	HEADACHE

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Appendix B.14

Listing of Prior and Concomitant Medications
by Treatment Group and by Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	ATC Level I	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
329.012.00217	CENTRAL NERVOUS SYSTEM	Zoloft	30,	.	19JUN96	.	100 MG	DEPRESSION
	DERMATOLOGICALS	Pulmicort	29,	.	18JUN96	19JUN96	400 MG	ASTHMA
	RESPIRATORY	Pulmicort	29,	.	18JUN96	19JUN96	400 MG	ASTHMA
		Robitussin	21,	.	10JUN96	12JUN96	2TBSP/DAY	COLD
329.012.00218	CENTRAL NERVOUS SYSTEM	Clonazepam	-34,	-92	13MAY96	16MAY96#	1MG	ANXIETY
		Tylenol	-8,	-66	08JUN96	08JUN96#	500 MG	HEADACHE
			26,	-33	11JUL96	11JUL96	500 MG	HEADACHE
329.012.00224	ANTIINFECTIVES,SYSTEMIC	Amoxil	87,	21	11DEC96	18DEC96	750 MG	STREP THROAT
	CENTRAL NERVOUS SYSTEM	Tylenol	16,	-51	01OCT96	01OCT96	325 MG PRN	TOOTHACHE (ORTHODONTIST APPT)
			25,	-42	10OCT96	.	650 MG PRN	MENSTRUAL CRAMPS
	RESPIRATORY	Gravol	108,	42	01JAN97	01JAN97	1 1/2 TAB	DIFFICULTY FALLING ASLEEP
329.012.00225	ANTIINFECTIVES,SYSTEMIC	Pediazole	124,	60	29MAR97	07APR97	40 CC	EAR INFECTION
	MUSCULO-SKELETAL	Ibuprofen	237,	173	20JUL97	23JUL97	300 MG	PREVENT PAIN FROM SPRAINED WRIST
	RESPIRATORY	Bricanyl Inhaler	130,	66	04APR97	08APR97	1 MG Q4H PRN	BRONCHOSPASM
		Prednisone	130,	66	04APR97	09APR97	50 MG	BRONCHOSPASM
		Ventolin	130,	66	04APR97	04APR97	5 MG	BRONCHOSPASM
	SYSTEMIC HORMONAL	Prednisone	130,	66	04APR97	09APR97	50 MG	BRONCHOSPASM

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PAROXETINE - PROTOCOL 329

Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.001.00063	100.0	WEEK 1	15NOV94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	22NOV94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	29NOV94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	06DEC94	40	12	28	7.0	4	100.0	100.0
		WEEK 5	13DEC94	40	12	28	7.0	4	100.0	100.0
329.001.00065	100.0	WEEK 1	21NOV94	20	8	12	6.0	2	100.0	100.0
		WEEK 2	.	20	.	.	.	2	.	.
329.001.00068	100.0	WEEK 1	15FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	22FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	01MAR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	08MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	15MAR95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	22MAR95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	29MAR95	60	18	42	7.0	6	100.0	100.0
		WEEK 8	05APR95	60	18	42	7.0	6	100.0	100.0
329.001.00072	100.0	WEEK 1	27MAR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	03APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	10APR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	13APR95	40	28	12	3.0	4	100.0	100.0
329.001.00121	99.5	WEEK 1	11APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	18APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	26APR95	30	7	23	8.0	3	96.0	95.8
		WEEK 4	02MAY95	40	16	24	6.0	4	100.0	100.0
		WEEK 5	09MAY95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	16MAY95	50	15	35	7.0	5	100.0	100.0
		WEEK 7	23MAY95	50	15	35	7.0	5	100.0	100.0
		WEEK 8	30MAY95	50	15	35	7.0	5	100.0	100.0
		WEEK 12	27JUN95	200	70	130	28.0	5	93.0	92.9
		WEEK 16	24JUL95	200	67	133	27.0	5	99.0	98.5
		WEEK 20	21AUG95	200	66	134	28.0	5	96.0	95.7
		DOWN TITRATION	05SEP95	34	0	34	15.0	5	100.0	45.3
329.001.00205	87.5	WEEK 1	14FEB96	20	6	14	7.0	2	100.0	100.0
329.001.00206	98.7	WEEK 1	28FEB96	20	6	14	7.0	2	100.0	100.0

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PAROXETINE - PROTOCOL 329

Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.001.00206	98.7	WEEK 2	06MAR96	20	5	15	7.0	2	100.0	107.1
		WEEK 3	13MAR96	30	11	19	7.0	3	90.0	90.5
		WEEK 4	20MAR96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	26MAR96	50	20	30	6.0	5	100.0	100.0
		WEEK 6	03APR96	60	12	48	8.0	6	100.0	100.0
		WEEK 7	10APR96	60	18	42	7.0	6	100.0	100.0
		WEEK 8	17APR96	60	18	42	7.0	6	100.0	100.0
329.002.00055	98.4	WEEK 1	30JUN94	20	7	13	6.5	2	100.0	100.0
		WEEK 2	07JUL94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	14JUL94	30	7	23	7.0	3	100.0	109.5
		WEEK 4	21JUL94	40	12	28	7.0	5	100.0	80.0
		WEEK 5	28JUL94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	04AUG94	60	18	42	7.0	6	100.0	100.0
		WEEK 7	11AUG94	60	18	42	7.0	6	100.0	100.0
		WEEK 8	18AUG94	60	18	42	7.0	6	100.0	100.0
		WEEK 12	15SEP94	240	72	168	28.0	6	100.0	100.0
		WEEK 16	13OCT94	240	72	168	28.0	6	100.0	100.0
		WEEK 20	10NOV94	240	.	.	.	6	.	.
		DOWN TITRATION	15NOV94	44	0	44	16.0	5	100.0	100.0
				44	0	44	16.0	4	100.0	100.0
				44	0	44	16.0	3	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
329.002.00058	97.9	WEEK 1	29SEP94	20	2	18	9.0	2	100.0	100.0
		WEEK 2	07OCT94	20	4	16	8.0	2	100.0	100.0
		WEEK 3	13OCT94	30	12	18	6.0	3	100.0	100.0
		WEEK 4	20OCT94	40	17	23	7.0	4	82.0	82.1
		WEEK 5	27OCT94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	03NOV94	60	18	42	7.0	6	100.0	100.0
		WEEK 7	10NOV94	60	18	42	7.0	6	100.0	100.0
		WEEK 8	17NOV94	60	18	42	7.0	6	100.0	100.0
		WEEK 12	15DEC94	240	48	192	28.0	6	122.0	114.3
		WEEK 16	13JAN95	240	60	180	28.0	6	107.0	6.0
			27JAN95	240	219	21	14.0	6	25.0	6.0
329.002.00099	88.9	WEEK 1	07MAR95	20	12	8	5.0	2	80.0	80.0
		WEEK 2	14MAR95	20	7	13	7.0	2	93.0	92.9

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00099	88.9	WEEK 3	21MAR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	28MAR95	40	15	25	7.0	4	89.0	89.3
		WEEK 5	04APR95	40	15	25	7.0	4	89.0	89.3
		WEEK 6	11APR95	50	21	29	7.0	5	82.0	82.9
		WEEK 7	18APR95	60	20	40	7.0	6	95.0	95.2
		WEEK 8	25APR95	60	21	39	6.0	6	108.0	108.3
		WEEK 12	23MAY95	240	81	159	28.0	6	95.0	94.6
		WEEK 16	27JUN95	240	63	177	35.0	6	84.0	84.3
		WEEK 20	01AUG95	240	61	179	34.0	6	87.0	87.7
		WEEK 24	31AUG95	240	108	132	30.0	6	73.3	73.3
		WEEK 28	28SEP95	240	114	126	28.0	6	75.0	75.0
		WEEK 32	26OCT95	240	132	108	28.0	6	64.0	64.3
		DOWN TITRATION	10JAN96	44	5	39	15.0	5	89.0	88.6
				44	5	39	15.0	4	89.0	88.6
				44	5	39	15.0	3	89.0	88.6
				44	5	39	15.0	2	89.0	88.6
				44	5	39	15.0	2	89.0	88.6
329.002.00102	94.0	WEEK 1	18APR95	20	8	12	6.0	2	100.0	100.0
		WEEK 2	25APR95	20	8	12	7.0	2	85.7	85.7
		WEEK 3	02MAY95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	09MAY95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	16MAY95	50	20	30	7.0	5	85.7	85.7
		WEEK 6	23MAY95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	30MAY95	60	18	42	7.0	6	100.0	100.0
		WEEK 8	06JUN95	60	27	33	7.0	6	78.6	78.6
		WEEK 12	13JUL95	240	38	202	37.0	6	91.0	91.0
		WEEK 16	10AUG95	240	87	153	28.0	6	91.0	91.1
		WEEK 20	12SEP95	240	75	165	33.0	6	83.3	83.3
		WEEK 24	10OCT95	240	90	150	28.0	6	89.0	89.3
		WEEK 28	09NOV95	240	78	162	30.0	6	90.0	90.0
		WEEK 32	05DEC95	240	138	102	25.0	6	68.0	68.0
		DOWN TITRATION	05DEC95	44	12	32	15.0	5	73.0	76.2
				44	12	32	15.0	4	73.0	76.2
				44	12	32	15.0	3	73.0	76.2
				44	12	32	15.0	2	73.0	76.2
				44	12	32	15.0	1	73.0	76.2

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00105	100.0	WEEK 1	03AUG95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	10AUG95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	17AUG95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	.	40	.	.	.	.	.	.
329.002.00106	100.6	WEEK 1	03AUG95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	08AUG95	20	10	10	5.0	2	100.0	100.0
		WEEK 3	17AUG95	30	2	28	9.0	3	103.0	103.7
		WEEK 4	24AUG95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	31AUG95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	05SEP95	50	25	25	5.0	5	100.0	100.0
		WEEK 7	12SEP95	60	18	42	7.0	6	100.0	100.0
		WEEK 8	.	60	.	.	.	6	.	.
329.002.00242	99.6	WEEK 1	14FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	21FEB96	20	7	13	7.0	2	93.0	92.9
		WEEK 3	29FEB96	30	12	18	7.0	3	85.7	85.7
		WEEK 4	06MAR96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	14MAR96	50	12	38	8.0	5	95.0	95.0
		WEEK 6	20MAR96	50	10	40	7.0	5	114.0	114.3
		WEEK 7	28MAR96	60	12	48	7.0	6	110.0	114.3
		WEEK 8	05APR96	60	18	42	7.0	6	100.0	100.0
		WEEK 12	08MAY96	240	42	198	33.0	6	100.0	100.0
		WEEK 16	05JUN96	240	93	147	28.0	6	87.0	87.5
329.002.00245	103.8	WEEK 1	04APR96	20	7	13	7.0	2	92.0	92.9
		WEEK 2	.	20	6	14	.	2	.	.
329.002.00319	99.1	WEEK 1	07MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	21MAY96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	28MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	04JUN96	50	17	33	7.0	5	94.0	94.3
		WEEK 6	11JUN96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	18JUN96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	25JUN96	50	15	35	7.0	5	100.0	100.0
		WEEK 12	23JUL96	200	60	140	28.0	5	100.0	100.0
		WEEK 16	15AUG96	200	85	115	23.0	5	100.0	100.0
		WEEK 20	24SEP96	200	2	198	40.0	5	99.0	99.0
		WEEK 24	22OCT96	200	60	140	28.0	5	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
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Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00319	99.1	WEEK 28	19NOV96	200	60	140	28.0	5	100.0	100.0
		WEEK 32	17DEC96	200	60	140	28.0	5	100.0	100.0
		DOWN TITRATION	30DEC96	44	0	20	14.0	5	100.0	64.5
				44	0	20	14.0	4	100.0	64.5
				44	0	20	14.0	3	100.0	64.5
				44	0	20	14.0	2	100.0	64.5
				44	0	20	14.0	1	100.0	64.5
329.003.00075	88.8	WEEK 1	01FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	08FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	15FEB95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	21FEB95	40	16	24	7.0	4	84.0	85.7
		WEEK 5	01MAR95	50	10	40	8.0	5	100.0	100.0
		WEEK 6	08MAR95	40	19	21	7.0	4	100.0	75.0
		WEEK 7	15MAR95	40	27	13	7.0	4	92.0	46.4
		WEEK 8	22MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 12	19APR95	160	54	106	28.0	4	94.0	94.6
		WEEK 16	17MAY95	160	56	104	28.0	4	107.0	92.9
		WEEK 20	14JUN95	160	62	98	28.0	4	87.0	87.5
		WEEK 24	12JUL95	160	74	86	28.0	4	76.0	76.8
		WEEK 28	09AUG95	160	98	62	29.0	4	108.0	53.4
		WEEK 32	13SEP95	160	86	74	35.0	4	53.0	52.9
		DOWN TITRATION	01NOV95	26	12	14	.	3	.	70.0
				26	12	14	.	2	.	70.0
				26	12	14	.	2	.	70.0
329.003.00077	86.5	WEEK 1	13MAR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	20MAR95	20	8	12	7.0	2	86.0	85.7
		WEEK 3	27MAR95	30	12	18	7.0	3	86.0	85.7
		WEEK 4	05APR95	40	10	30	9.0	4	83.0	83.3
		WEEK 5	12APR95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	19APR95	50	18	32	7.0	5	91.0	91.4
		WEEK 7	26APR95	50	21	29	7.0	5	83.0	82.9
		WEEK 8	03MAY95	50	21	29	7.0	5	83.0	82.9
		WEEK 12	07JUN95	200	94	106	34.0	5	62.0	62.4
		WEEK 16	.	200	.	.	.	5	.	.
329.003.00081	90.3	WEEK 1	18DEC95	20	7	13	7.0	2	93.0	92.9

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00081	90.3	WEEK 2	28DEC95	20	1	19	10.0	2	95.0	95.0
		WEEK 3	03JAN96	30	13	17	6.0	3	94.0	94.4
		WEEK 4	10JAN96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	17JAN96	50	17	33	7.0	5	94.0	94.3
		WEEK 6	24JAN96	50	22	28	7.0	5	80.0	80.0
		WEEK 7	31JAN96	50	19	31	7.0	5	89.0	88.6
		WEEK 8	07FEB96	60	.	.	.	6	.	.
329.003.00087	.	WEEK 1	03FEB95	20	.	.	.	2	.	.
329.003.00089	96.3	WEEK 1	14MAR95	20	7	13	7.0	2	93.0	92.9
		WEEK 2	21MAR95	20	5	15	7.0	2	110.0	107.1
		WEEK 3	28MAR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	04APR95	40	11	29	7.0	4	100.0	103.6
		WEEK 5	11APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	18APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	25APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	02MAY95	40	21	19	7.0	4	90.0	67.9
329.003.00091	102.6	WEEK 1	28MAR95	20	10	10	4.0	2	120.0	125.0
		WEEK 2	04APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	11APR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	18APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	25APR95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	02MAY95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	09MAY95	60	12	48	7.0	6	100.0	114.3
		WEEK 8	16MAY95	60	18	42	7.0	6	100.0	100.0
		WEEK 12	16JUN95	240	57	183	30.0	6	102.0	101.7
		WEEK 16	14JUL95	240	78	162	28.0	6	96.0	96.4
		WEEK 20	10AUG95	240	0	.	26.0	6	.	.
		WEEK 24	05SEP95	240	72	168	28.0	6	100.0	100.0
		WEEK 28	03OCT95	240	72	168	27.0	6	104.0	103.7
		WEEK 32	07NOV95	240	72	168	31.0	6	90.0	90.3
		DOWN TITRATION	02JAN96	44	0	44	55.0	5	100.0	100.0
				44	0	44	55.0	4	100.0	100.0
				44	0	44	55.0	3	100.0	100.0
				44	0	44	55.0	2	100.0	100.0
				44	0	44	55.0	2	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00248	87.1	WEEK 1	05MAR96	20	12	8	4.0	2	100.0	100.0
		WEEK 2	12MAR96	20	7	13	7.0	2	100.0	92.9
		WEEK 3	19MAR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	26MAR96	40	16	24	7.0	4	85.0	85.7
		WEEK 5	02APR96	50	19	31	8.0	5	75.0	77.5
		WEEK 6	11APR96	60	24	36	9.0	6	67.0	66.7
		WEEK 7	16APR96	60	33	27	6.0	6	75.0	75.0
		WEEK 8	23APR96	60	18	42	7.0	6	100.0	100.0
329.003.00250	112.3	WEEK 1	19MAR96	20	9	11	6.0	2	91.6	91.7
		WEEK 2	26MAR96	20	8	12	8.0	2	85.0	75.0
		WEEK 3	02APR96	30	12	18	7.0	3	85.0	85.7
		WEEK 4	12APR96	40	6	34	10.0	4	85.0	85.0
		WEEK 5	16APR96	50	0	50	7.0	5	142.8	142.9
		WEEK 6	23APR96	60	30	30	5.0	6	100.0	100.0
		WEEK 7	30APR96	60	0	60	7.0	6	142.0	142.9
		WEEK 8	09MAY96	50	0	50	9.0	5	111.0	111.1
		WEEK 12	28MAY96	80	0	80	.	6	.	86.0
				80	0	80	.	5	.	86.0
329.003.00292	77.2	WEEK 1	16AUG96	20	5	16	10.0	2	80.0	80.0
		WEEK 2	21AUG96	20	14	6	5.0	2	60.0	60.0
		WEEK 3	30AUG96	30	9	21	9.0	3	78.0	77.8
		WEEK 4	04SEP96	40	26	14	5.0	4	70.0	70.0
		WEEK 6	18SEP96	40	0	40	14.0	4	71.4	71.4
		WEEK 7	25SEP96	40	18	22	8.0	4	69.0	68.8
		WEEK 8	04OCT96	40	10	30	9.0	4	83.0	83.3
		WEEK 12	.	120	0	.	.	4	.	.
329.003.00313	112.5	WEEK 1	21MAY96	20	11	9	5.0	2	90.0	90.0
		WEEK 2	28MAY96	20	.	.	.	2	.	.
329.004.00015	97.9	WEEK 1	14DEC94	20	7	13	7.0	2	100.0	92.9
		WEEK 2	21DEC94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28DEC94	30	10	20	8.0	3	95.0	83.3
		WEEK 4	04JAN95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	11JAN95	40	14	26	7.0	4	93.0	92.9
		WEEK 6	18JAN95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	25JAN95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	03FEB95	40	6	34	9.0	4	94.0	94.4

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Listing of Drug Dispensing Data by Treatment Group and Patient
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Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.004.00015	97.9	WEEK 12	27FEB95	160	64	96	24.0	4	100.0	100.0
		WEEK 16	22MAR95	160	70	90	23.0	4	98.0	97.8
		WEEK 20	19APR95	160	50	110	27.0	4	100.0	101.9
		WEEK 24	17MAY95	160	48	112	28.0	4	100.0	100.0
		DOWN TITRATION	29JUN95	44	18	26	15.0	4	100.0	81.3
				44	18	26	15.0	2	100.0	81.3
				44	18	26	15.0	2	100.0	81.3
				44	18	26	15.0	2	100.0	81.3
329.004.00017	98.5	WEEK 1	30MAR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	06APR95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	13APR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	20APR95	40	14	26	7.0	4	98.0	92.9
		WEEK 5	26APR95	40	14	26	6.0	4	100.0	108.3
		WEEK 6	03MAY95	50	17	33	7.0	5	98.0	94.3
		WEEK 7	10MAY95	50	15	35	7.0	5	100.0	100.0
		WEEK 8	17MAY95	50	15	35	7.0	5	100.0	100.0
		WEEK 12	14JUN95	200	65	135	29.0	5	100.0	93.1
		WEEK 16	13JUL95	200	58	142	29.0	5	100.0	97.9
		WEEK 20	10AUG95	200	60	140	29.0	5	100.0	96.6
		WEEK 24	06SEP95	200	77	123	28.0	5	98.0	87.9
		WEEK 28	04OCT95	200	69	131	29.0	5	100.0	90.3
		WEEK 32	01NOV95	200	68	132	29.0	5	100.0	91.0
		DOWN TITRATION	14NOV95	44	14	30	13.0	4	100.0	88.2
				44	14	30	13.0	3	100.0	88.2
				44	14	30	13.0	2	100.0	88.2
				44	14	30	13.0	2	100.0	88.2
329.004.00019	100.0	WEEK 1	07JUN95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14JUN95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	.	30	.	.	.	.	.	.
329.004.00212	88.2	WEEK 1	10JUN96	20	7	13	7.0	2	100.0	92.9
		WEEK 2	21JUN96	20	0	20	11.0	2	100.0	90.9
		WEEK 3	28JUN96	30	18	12	7.0	3	57.0	57.1
329.004.00214	91.1	WEEK 1	09OCT96	20	10	10	5.0	2	100.0	100.0
		WEEK 2	15OCT96	20	8	12	7.0	2	86.0	85.7

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.004.00214	91.1	WEEK 3	21OCT96	30	13	17	7.0	3	81.0	81.0
		WEEK 4	01NOV96	40	2	38	11.0	4	95.0	86.4
		WEEK 5	11NOV96	50	4	46	10.0	5	100.0	92.0
		WEEK 6	18NOV96	50	22	28	8.0	5	70.0	70.0
		WEEK 7	25NOV96	40	14	26	8.0	4	93.0	81.3
		WEEK 8	03DEC96	40	12	28	8.0	4	93.0	87.5
		WEEK 12	30DEC96	160	70	90	27.0	4	83.0	83.3
329.005.00002	99.6	WEEK 1	01JUN94	20	5	15	7.0	2	107.0	107.1
		WEEK 2	08JUN94	20	7	13	7.0	2	93.0	92.9
		WEEK 3	15JUN94	30	10	20	7.0	3	95.0	95.2
		WEEK 4	23JUN94	40	10	30	8.0	4	94.0	93.8
		WEEK 5	30JUN94	50	13	37	8.0	5	92.5	92.5
		WEEK 6	07JUL94	60	18	42	7.0	6	100.0	100.0
		WEEK 7	14JUL94	60	27	33	6.0	6	91.0	91.7
		WEEK 8	20JUL94	60	15	45	7.0	6	107.0	107.1
		WEEK 12	17AUG94	240	54	186	31.0	6	100.0	100.0
		WEEK 16	15SEP94	240	63	177	29.5	6	100.0	100.0
		WEEK 20	18OCT94	240	39	201	33.0	6	101.0	101.5
		WEEK 24	.	240	.	.	.	6	.	.
329.005.00004	92.2	WEEK 1	20OCT94	20	1	19	10.0	2	95.0	95.0
		WEEK 2	27OCT94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	03NOV94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	10NOV94	40	12	28	7.0	4	100.0	100.0
		WEEK 5	17NOV94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	23NOV94	60	24	36	6.0	6	100.0	100.0
		WEEK 7	01DEC94	60	12	48	8.0	6	100.0	100.0
		WEEK 8	08DEC94	60	36	24	7.0	6	57.0	57.1
		WEEK 12	05JAN95	240	84	156	28.0	6	92.0	92.9
		DOWN TITRATION	26JAN95	44	2	42	21.0	5	100.0	40.0
329.005.00008	98.7	WEEK 1	23NOV94	20	7	13	7.0	2	93.0	92.9
		WEEK 2	30NOV94	20	8	12	7.0	2	85.0	85.7
		WEEK 3	07DEC94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	14DEC94	40	12	28	7.0	4	100.0	100.0
		WEEK 5	21DEC94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	28DEC94	60	18	42	7.0	6	100.0	100.0
		WEEK 7	03JAN95	60	18	42	7.0	6	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00008	98.7	WEEK 8	10JAN95	60	24	36	6.0	6	100.0	100.0
		WEEK 12	06FEB95	200	50	150	30.0	5	100.0	100.0
		WEEK 16	08MAR95	200	50	150	30.0	5	100.0	100.0
		WEEK 20	10MAY95	200	53	147	63.0	5	0.5	46.7
329.005.00011	98.7	WEEK 1	20DEC94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	27DEC94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	03JAN95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	09JAN95	40	16	24	6.0	4	100.0	100.0
		WEEK 5	17JAN95	50	10	40	8.0	5	100.0	100.0
		WEEK 6	23JAN95	60	24	36	6.0	6	100.0	100.0
		WEEK 7	31JAN95	60	15	45	7.5	6	100.0	100.0
		WEEK 8	07FEB95	60	18	42	7.0	6	100.0	100.0
		WEEK 12	09MAR95	240	57	183	30.5	6	100.0	100.0
		WEEK 16	06APR95	240	99	141	27.0	6	87.0	87.0
		WEEK 20	03MAY95	240	96	144	26.0	6	92.0	92.3
		WEEK 24	.	200	.	.	.	5	.	.
329.005.00109	100.0	WEEK 1	05JAN95	20	8	12	6.0	2	100.0	100.0
		WEEK 2	12JAN95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	19JAN95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	26JAN95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	02FEB95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	08FEB95	40	16	24	6.0	4	100.0	100.0
		WEEK 7	16FEB95	40	8	32	8.0	4	100.0	100.0
		WEEK 8	21FEB95	40	20	20	5.0	4	100.0	100.0
		WEEK 12	23MAR95	160	42	118	29.5	4	100.0	100.0
		WEEK 16	24APR95	160	38	122	32.0	4	95.0	95.3
		WEEK 20	25MAY95	160	72	.	30.0	4	.	.
329.005.00112	93.6	WEEK 1	01FEB95	20	8	12	6.0	2	100.0	100.0
		WEEK 2	08FEB95	20	5	15	7.0	2	100.0	107.1
		WEEK 3	15FEB95	30	11	19	7.0	3	90.0	90.5
		WEEK 4	23FEB95	40	12	28	8.0	4	87.0	87.5
		WEEK 5	01MAR95	40	15	25	6.0	4	100.0	104.2
		WEEK 6	08MAR95	40	14	26	7.0	4	93.0	92.9
		WEEK 7	15MAR95	40	16	24	7.0	4	86.0	85.7
		WEEK 8	22MAR95	40	14	26	7.0	4	93.0	92.9
		WEEK 12	19APR95	160	99	61	28.0	4	54.0	54.5

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00112	93.6	DOWN TITRATION	21JUN95	20	3	17	60.0	2	85.0	85.0
				20	3	17	60.0	2	85.0	85.0
329.005.00116	98.0	WEEK 1	13FEB95	20	8	12	6.0	2	100.0	100.0
		WEEK 2	20FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	27FEB95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	09MAR95	40	2	38	10.0	4	95.0	95.0
		WEEK 5	16MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	23MAR95	40	14	26	7.0	4	93.0	92.9
		WEEK 7	30MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	06APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 12	04MAY95	160	46	114	28.5	4	100.0	100.0
		WEEK 16	31MAY95	160	50	110	27.5	4	100.0	100.0
		WEEK 20	28JUN95	200	60	140	28.0	5	100.0	100.0
		DOWN TITRATION	26JUL95	44	12	32	28.0	4	100.0	118.5
				44	12	32	28.0	3	100.0	118.5
				44	12	32	28.0	2	100.0	118.5
				44	12	32	28.0	1	100.0	118.5
329.005.00119	89.0	WEEK 1	18JUL95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	26JUL95	20	6	14	8.0	2	87.5	87.5
		WEEK 3	02AUG95	30	11	19	7.0	3	90.0	90.5
		WEEK 4	08AUG95	40	16	24	6.0	4	100.0	100.0
		WEEK 5	15AUG95	50	15	35	6.0	5	116.0	116.7
		WEEK 6	23AUG95	60	6	45	8.0	6	94.0	93.8
		WEEK 7	29AUG95	60	51	18	6.0	6	50.0	50.0
		WEEK 8	08SEP95	60	3	57	10.0	6	95.0	95.0
		WEEK 12	03OCT95	240	99	141	25.0	6	94.0	94.0
		WEEK 16	30OCT95	240	78	162	27.0	6	100.0	100.0
		WEEK 20	28NOV95	240	77	.	28.0	6	.	.
		DOWN TITRATION	02JAN96	44	.	.	.	.	.	.
329.005.00151	94.8	WEEK 1	14SEP95	20	4	16	8.0	2	100.0	100.0
		WEEK 2	20SEP95	20	8	12	6.0	2	100.0	100.0
		WEEK 3	28SEP95	30	6	24	8.0	3	100.0	100.0
		WEEK 4	03OCT95	40	20	20	5.0	4	100.0	100.0
		WEEK 5	11OCT95	40	12	28	8.0	4	87.5	87.5

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00151	94.8	WEEK 6	19OCT95	40	10	30	8.0	4	93.8	93.8
		WEEK 7	26OCT95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	02NOV95	40	16	24	7.0	4	85.7	85.7
		WEEK 12	28NOV95	160	78	82	28.0	4	73.0	73.2
		WEEK 16	02JAN96	160	34	126	35.0	4	90.0	90.0
		WEEK 20	31JAN96	200	88	112	27.0	5	83.0	83.0
		WEEK 24	27FEB96	200	86	114	27.0	5	84.0	84.4
		WEEK 28	27MAR96	200	69	131	28.0	5	94.0	93.6
		WEEK 32	01MAY96	200	50	150	35.0	5	86.0	85.7
		DOWN TITRATION	21MAY96	44	.	.	.	4	.	.
329.005.00152	.	WEEK 1	02NOV95	20	.	.	.	2	.	.
329.005.00257	97.0	WEEK 1	18MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	25MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	01APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	08APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	15APR96	40	16	24	7.0	4	86.0	85.7
		WEEK 6	22APR96	40	14	26	7.0	4	93.0	92.9
		WEEK 7	29APR96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	06MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 12	03JUN96	200	63	137	28.0	5	98.0	97.9
		WEEK 16	08JUL96	200	33	167	35.0	5	95.0	95.4
		WEEK 20	07AUG96	200	61	139	30.0	5	93.0	92.7
		WEEK 24	27AUG96	200	110	90	20.0	5	90.0	90.0
		WEEK 28	01OCT96	200	35	165	34.0	5	97.0	97.1
		WEEK 32	21OCT96	150	50	100	20.0	5	100.0	100.0
		DOWN TITRATION	05NOV96	44	11	33	14.0	4	79.0	97.1
				44	11	33	14.0	3	79.0	97.1
				44	11	33	14.0	2	79.0	97.1
				44	11	33	14.0	2	79.0	97.1
329.005.00258	100.8	WEEK 1	19MAR96	20	7	13	7.0	2	93.0	92.9
		WEEK 2	26MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	02APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	09APR96	40	10	28	7.0	4	100.0	100.0
		WEEK 5	18APR96	50	5	45	9.0	5	100.0	100.0
		WEEK 6	23APR96	60	33	27	5.0	6	90.0	90.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00258	100.8	WEEK 7	30APR96	60	12	48	7.0	6	100.0	114.3
		WEEK 8	07MAY96	60	18	42	7.0	6	100.0	100.0
329.005.00299	99.0	WEEK 1	18JUN96	20	0	20	10.0	2	100.0	100.0
		WEEK 2	25JUN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	02JUL96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	10JUL96	40	8	32	8.0	4	100.0	100.0
		WEEK 6	22JUL96	48	2	46	12.0	4	96.0	95.8
		WEEK 7	31JUL96	40	4	36	9.0	4	100.0	100.0
		WEEK 8	07AUG96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	03SEP96	160	48	112	27.0	4	103.0	103.7
		WEEK 16	01OCT96	160	50	110	28.0	4	98.0	98.2
		WEEK 20	29OCT96	200	71	129	27.0	5	96.0	95.6
		WEEK 24	05NOV96	200	165	35	7.0	5	100.0	100.0
		DOWN TITRATION	19NOV96	34	2	32	13.0	4	100.0	118.5
				34	2	32	13.0	3	100.0	118.5
				34	2	32	13.0	2	100.0	118.5
				34	2	32	13.0	1	100.0	118.5
329.005.00300	94.2	WEEK 1	26SEP96	20	9	11	14.0	2	79.0	39.3
		WEEK 2	03OCT96	20	6	13	7.0	2	93.0	92.9
		WEEK 3	10OCT96	30	8	22	7.0	3	104.0	104.8
		WEEK 4	17OCT96	40	13	27	7.0	4	96.0	96.4
		WEEK 5	24OCT96	40	14	26	7.0	4	95.0	92.9
		WEEK 6	31OCT96	40	15	25	7.0	4	89.0	89.3
		WEEK 7	07NOV96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	14NOV96	40	14	26	7.0	4	93.0	92.9
329.005.00333	93.8	WEEK 1	31JAN97	20	4	16	8.0	2	100.0	100.0
		WEEK 2	06FEB97	20	8	12	6.0	2	100.0	100.0
		WEEK 3	13FEB97	30	9	21	7.0	3	100.0	100.0
		WEEK 4	20FEB97	40	14	26	7.0	4	93.0	92.9
		WEEK 5	26FEB97	40	24	16	6.0	4	66.0	66.7
329.005.00336	94.9	WEEK 1	12MAR97	20	4	16	8.0	2	100.0	100.0
		WEEK 2	19MAR97	20	6	14	7.0	2	100.0	100.0
		WEEK 3	25MAR97	30	12	18	6.0	3	100.0	100.0
		WEEK 4	02APR97	40	8	32	8.0	4	100.0	100.0
		WEEK 5	09APR97	40	12	28	7.0	4	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00336	94.9	WEEK 6	16APR97	40	16	24	28.0	4	86.0	21.4
		WEEK 7	23APR97	40	12	28	7.0	4	100.0	100.0
		WEEK 8	30APR97	40	14	26	6.5	4	100.0	100.0
329.006.00038	103.1	WEEK 1	22FEB95	20	7	13	6.5	2	100.0	100.0
		WEEK 2	03MAR95	20	2	18	9.0	2	100.0	100.0
		WEEK 3	08MAR95	30	14	16	5.0	3	100.0	106.7
		WEEK 4	15MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	22MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	29MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	05APR95	40	14	26	6.5	4	100.0	100.0
		WEEK 8	12APR95	40	0	40	7.0	4	143.0	142.9
329.006.00039	96.9	WEEK 1	13FEB95	20	9	11	5.0	2	100.0	110.0
		WEEK 2	22FEB95	20	2	18	9.0	2	100.0	100.0
		WEEK 3	01MAR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	08MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	17MAR95	40	4	36	9.0	4	100.0	100.0
		WEEK 6	22MAR95	40	16	24	6.0	4	100.0	100.0
		WEEK 7	29MAR95	50	20	30	6.0	5	100.0	100.0
		WEEK 8	05APR95	50	0	50	10.0	5	100.0	100.0
		WEEK 12	01MAY95	150	52	98	20.5	5	95.0	95.6
		DOWN TITRATION	01MAY95	34	0	34	10.0	4	100.0	113.3
				34	0	34	10.0	3	100.0	113.3
				34	0	34	10.0	2	100.0	113.3
				34	0	34	10.0	1	100.0	113.3
329.006.00260	87.3	WEEK 1	26JUL96	20	7	13	8.0	2	81.0	81.3
		WEEK 2	01AUG96	20	9	11	6.0	2	100.0	91.7
		WEEK 3	07AUG96	30	12	18	6.0	3	100.0	100.0
		WEEK 4	14AUG96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	21AUG96	50	17	33	7.0	5	94.0	94.3
		WEEK 6	28AUG96	50	22	28	7.0	5	80.0	80.0
		WEEK 7	04SEP96	50	19	31	7.0	5	89.0	88.6
		WEEK 8	18SEP96	50	10	40	10.0	5	80.0	80.0
		WEEK 12	09OCT96	200	77	123	25.0	5	98.0	98.4
		WEEK 16	06NOV96	200	45	155	31.0	5	100.0	100.0
		WEEK 20	05DEC96	200	77	123	26.0	5	95.0	94.6

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.006.00260	87.3	DOWN TITRATION	17DEC96	34	2	32	13.0	4	100.0	94.1
				34	2	32	13.0	3	100.0	94.1
				34	2	32	13.0	2	100.0	94.1
				34	2	32	13.0	1	100.0	94.1
329.006.00261	94.3	WEEK 1	03DEC96	20	8	12	7.0	2	86.0	85.7
		WEEK 2	10DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	17DEC96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	24DEC96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	02JAN97	50	5	45	9.0	5	100.0	100.0
		WEEK 6	09JAN97	50	17	33	7.0	5	94.0	94.3
		WEEK 7	15JAN97	50	20	30	6.0	5	100.0	100.0
		WEEK 8	23JAN97	50	17	33	8.0	5	83.0	82.5
		WEEK 12	20FEB97	200	116	84	28.0	5	60.0	60.0
		WEEK 16	02APR97	200	125	75	41.0	5	37.0	36.6
		DOWN TITRATION	30APR97	44	14	30	28.0	5	.	61.2
				44	14	30	28.0	4	.	61.2
				44	14	30	28.0	3	.	61.2
				44	14	30	28.0	2	.	61.2
				44	14	30	28.0	1	.	61.2
329.007.00140	100.5	WEEK 1	21SEP95	20	7	13	6.5	2	100.0	100.0
		WEEK 2	28SEP95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	05OCT95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	12OCT95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	18OCT95	40	16	24	6.0	4	100.0	100.0
		WEEK 6	26OCT95	40	8	32	8.0	4	100.0	100.0
		WEEK 7	02NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	09NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 12	22NOV95	160	110	50	13.0	4	96.0	96.2
		DOWN TITRATION	.	44	.	.	.	4	.	.
329.007.00142	88.8	WEEK 1	26OCT95	20	4	16	8.0	2	100.0	100.0
		WEEK 2	02NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	09NOV95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	16NOV95	40	14	26	7.0	4	93.0	92.9
		WEEK 5	22NOV95	50	20	30	6.0	5	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.007.00142	88.8	WEEK 6	30NOV95	50	10	40	8.0	5	100.0	100.0
		WEEK 7	21DEC95	60	48	12	21.0	6	20.0	9.5
329.007.00145	100.0	WEEK 1	18JAN96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	25JAN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	01FEB96	30	10	20	7.0	3	95.0	95.2
		WEEK 4	08FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	12FEB96	50	31	19	4.0	5	95.0	95.0
		WEEK 6	21FEB96	50	3	47	9.0	5	104.0	104.4
		WEEK 7	26FEB96	50	25	25	5.0	5	100.0	100.0
		WEEK 8	07MAR96	60	0	60	10.0	6	100.0	100.0
		WEEK 12	04APR96	240	72	168	28.0	6	100.0	100.0
		WEEK 16	02MAY96	240	72	168	28.0	6	100.0	100.0
		WEEK 20	30MAY96	320	197	123	28.0	5	98.1	99.2
				320	197	123	28.0	4	98.1	99.2
		WEEK 24	27JUN96	160	48	112	28.0	4	100.0	100.0
		WEEK 28	25JUL96	160	46	114	28.0	4	102.0	101.8
		WEEK 32	23AUG96	160	44	116	29.0	4	96.0	100.0
		DOWN TITRATION	.	25	0	.	.	3	.	.
329.007.00265	.	WEEK 1	15FEB96	20	.	.	.	2	.	.
		WEEK 2	.	20	.	.	.	2	.	.
329.007.00268	97.1	WEEK 1	11APR96	20	0	20	10.0	2	100.0	100.0
		WEEK 2	18APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	25APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	02MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	09MAY96	40	18	22	7.0	4	79.0	78.6
		WEEK 6	16MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	.	50	10	40	8.0	5	100.0	100.0
		WEEK 8	30MAY96	50	20	30	6.0	5	100.0	100.0
		WEEK 12	27JUN96	200	60	140	28.0	5	100.0	100.0
		WEEK 16	01AUG96	200	26	174	35.0	5	99.0	99.4
		WEEK 20	30AUG96	240	63	177	29.0	6	102.0	101.7
		WEEK 24	30SEP96	240	54	186	31.0	6	100.0	100.0
		WEEK 28	07NOV96	200	11	189	38.0	5	99.0	99.5
		WEEK 32	05DEC96	200	59	141	28.0	5	101.0	100.7
		DOWN TITRATION	02JAN97	32	0	32	13.5	4	100.0	59.3

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.007.00294	90.5	WEEK 1	10MAR97	20	0	20	10.5	2	95.0	95.2
		WEEK 2	17MAR97	20	7	13	7.0	2	93.0	92.9
		WEEK 3	28MAR97	30	1	29	11.0	3	88.0	87.9
		WEEK 4	03APR97	40	16	24	6.0	4	100.0	100.0
		WEEK 5	10APR97	50	22	28	7.0	5	80.0	80.0
		DOWN TITRATION	.	44	.	.	.	4	.	.
329.007.00309	96.7	WEEK 1	18JUL96	20	14	6	3.0	2	100.0	100.0
		WEEK 2	25JUL96	20	8	12	7.0	2	86.0	85.7
		WEEK 3	01AUG96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	08AUG96	40	16	24	7.0	4	86.0	85.7
		WEEK 5	15AUG96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	23AUG96	40	8	32	8.0	4	100.0	100.0
		WEEK 7	30AUG96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	05SEP96	40	16	24	6.0	4	100.0	100.0
		WEEK 12	03OCT96	160	44	116	28.0	4	104.0	103.6
		WEEK 16	31OCT96	160	36	112	28.0	4	100.0	100.0
		WEEK 20	13DEC96	160	2	170	43.0	4	97.0	98.8
		WEEK 24	09JAN97	160	55	105	27.0	4	97.0	97.2
		WEEK 28	10FEB97	160	48	112	32.0	4	87.0	87.5
		WEEK 32	13MAR97	200	48	152	31.0	5	98.0	98.1
		DOWN TITRATION	26MAR97	32	0	32	13.0	4	100.0	61.5
329.007.00310	83.4	WEEK 1	03OCT96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	10OCT96	20	8	12	7.0	2	86.0	85.7
		WEEK 3	17OCT96	30	11	19	7.0	3	90.0	90.5
		WEEK 4	28OCT96	40	2	38	11.0	4	86.0	86.4
		WEEK 5	31OCT96	40	28	12	3.0	4	100.0	100.0
		WEEK 6	08NOV96	40	12	28	8.0	4	88.0	87.5
		WEEK 7	18NOV96	40	20	20	10.0	4	50.0	50.0
		WEEK 8	25NOV96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	02JAN97	160	12	148	38.0	4	97.0	97.4
		WEEK 16	14FEB97	160	0	160	43.0	4	93.0	93.0
		WEEK 20	13MAR97	160	58	102	27.0	4	94.0	94.4
		WEEK 24	17APR97	160	40	120	35.0	4	86.0	85.7
		WEEK 28	15MAY97	160	60	100	28.0	4	89.0	89.3
		WEEK 32	12JUN97	160	51	109	28.0	4	97.0	97.3

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.007.00310	83.4	DOWN TITRATION	26JUN97	25	0	25	11.5	3	100.0	72.5
329.007.00318	.	WEEK 1	.	20	0	.	.	2	.	.
329.008.00157	76.8	WEEK 1	05SEP95	20	8	12	7.0	2	92.0	85.7
		WEEK 2	12SEP95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	20SEP95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	26SEP95	40	20	20	6.0	4	83.0	83.3
		WEEK 5	04OCT95	40	16	24	7.0	4	86.0	85.7
		WEEK 6	10OCT95	40	22	18	6.0	4	92.0	75.0
		WEEK 7	16OCT95	40	30	10	6.0	4	42.0	41.7
		WEEK 8	24OCT95	40	16	24	7.0	4	86.0	85.7
		WEEK 12	23NOV95	160	32	128	29.0	4	110.0	110.3
		WEEK 16	15DEC95	160	114	46	22.0	4	52.0	52.3
		WEEK 20	23JAN96	160	44	116	38.0	4	76.0	76.3
		WEEK 24	20FEB96	160	120	40	28.0	4	35.0	35.7
329.008.00160	96.7	WEEK 1	10NOV95	20	2	18	9.0	2	100.0	100.0
		WEEK 2	20NOV95	20	2	18	10.0	2	90.0	90.0
		WEEK 3	27NOV95	30	10	20	7.0	3	95.0	95.2
		WEEK 4	05DEC95	40	.	.	.	4	.	.
		WEEK 5	13DEC95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	20DEC95	50	10	40	7.0	5	114.0	114.3
		WEEK 7	27DEC95	50	15	35	7.0	5	100.0	100.0
		WEEK 8	05JAN96	50	5	45	9.0	5	100.0	100.0
		WEEK 12	31JAN96	200	70	130	26.0	5	100.0	100.0
		WEEK 16	05MAR96	200	43	157	34.0	5	92.0	92.4
		WEEK 20	09APR96	200	28	172	34.0	5	101.0	101.2
		WEEK 24	16MAY96	200	20	180	36.0	5	100.0	100.0
		WEEK 28	18JUN96	200	60	140	34.0	5	82.0	82.4
		WEEK 32	23JUL96	200	57	143	35.0	5	81.0	81.7
		DOWN TITRATION	23JUL96	.	.	.	.	5	.	.
				.	.	.	.	4	.	.
				.	.	.	.	3	.	.
				.	.	.	.	2	.	.
				.	.	.	.	1	.	.
329.008.00188	92.4	WEEK 1	10JAN96	20	7	13	6.0	2	108.0	108.3

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Listing of Drug Dispensing Data by Treatment Group and Patient
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Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.008.00188	92.4	WEEK 2	17JAN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	24JAN96	30	12	18	7.0	3	85.0	85.7
		WEEK 4	31JAN96	40	10	30	7.0	4	107.0	107.1
		WEEK 5	07FEB96	50	33	17	7.0	5	48.0	48.6
		WEEK 6	14FEB96	60	21	39	7.0	6	93.0	92.9
		WEEK 7	21FEB96	60	27	33	7.0	6	78.0	78.6
		WEEK 8	27FEB96	60	6	54	7.0	6	128.0	128.6
329.008.00271	83.5	WEEK 1	18MAR96	20	7	13	8.0	2	81.0	81.3
		WEEK 2	25MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	01APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	08APR96	40	14	26	8.0	4	81.0	81.3
		WEEK 5	15APR96	40	16	24	7.0	4	85.0	85.7
		WEEK 6	22APR96	50	20	30	7.0	5	86.0	85.7
		WEEK 7	02MAY96	60	3	57	10.0	6	95.0	95.0
		WEEK 8	14MAY96	60	18	42	10.0	6	70.0	70.0
		WEEK 12	10JUN96	240	129	111	27.0	6	102.0	68.5
		WEEK 16	12JUL96	240	81	99	31.0	6	53.0	53.2
		WEEK 20	09AUG96	240	.	.	.	6	.	.
		WEEK 24	06SEP96	240	.	.	.	6	.	.
		WEEK 28	07OCT96	240	75	165	28.0	6	98.0	98.2
		WEEK 32	05NOV96	240	.	.	.	6	.	.
		DOWN TITRATION	05NOV96	44	.	.	.	5	.	.
				44	.	.	.	4	.	.
				44	.	.	.	3	.	.
				44	.	.	.	2	.	.
				44	.	.	.	1	.	.
329.008.00275	98.7	WEEK 1	15MAY96	20	5	15	7.0	2	107.0	107.1
		WEEK 2	21MAY96	20	8	12	6.0	2	100.0	100.0
		WEEK 3	28MAY96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	04JUN96	40	14	26	8.0	4	81.0	81.3
		WEEK 5	11JUN96	40	.	.	7.0	5	.	.
		WEEK 6	25JUN96	50	.	.	.	5	.	.
		WEEK 8	02JUL96	60	.	.	.	6	.	.
		WEEK 12	23JUL96	200	136	64	21.0	5	60.0	61.0
		WEEK 16	20AUG96	200	60	140	28.0	5	100.0	100.0
		WEEK 20	16SEP96	200	76	124	27.0	5	91.0	91.9
		WEEK 24	21OCT96	200	.	.	.	5	.	.

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.008.00275	98.7	WEEK 28	25NOV96	200	32	168	35.0	5	96.0	96.0
		WEEK 32	16DEC96	240	152	48	21.0	5	45.0	45.7
329.009.00130	87.3	WEEK 1	25APR95	20	11	9	7.0	2	64.0	64.3
		WEEK 2	02MAY95	20	8	12	7.0	2	86.0	85.7
		WEEK 3	09MAY95	30	13	17	7.0	3	81.0	81.0
		WEEK 4	16MAY95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	23MAY95	40	14	26	7.0	4	93.0	92.9
		WEEK 6	30MAY95	40	18	22	7.0	4	79.0	78.6
		WEEK 7	06JUN95	40	14	26	7.0	4	93.0	92.9
		WEEK 8	13JUN95	40	15	25	7.0	4	89.0	89.3
		WEEK 16	07AUG95	160	6	154	54.0	4	71.0	71.3
		WEEK 20	19SEP95	160	38	122	43.0	4	71.0	70.9
		WEEK 24	03OCT95	160	128	32	14.0	4	57.0	57.1
		DOWN TITRATION	31OCT95	32	0	32	13.0	4	100.0	94.1
				32	0	32	13.0	3	100.0	94.1
				32	0	32	13.0	2	100.0	94.1
				32	0	32	13.0	2	100.0	94.1
329.009.00131	92.6	WEEK 1	09MAY95	20	9	11	7.0	2	79.0	78.6
		WEEK 2	16MAY95	20	11	9	7.0	2	64.0	64.3
		WEEK 3	23MAY95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	30MAY95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	06JUN95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	13JUN95	40	14	26	7.0	4	93.0	92.9
		WEEK 7	20JUN95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	27JUN95	40	16	24	7.0	4	86.0	85.7
		WEEK 12	25JUL95	162	66	96	29.0	4	83.0	82.8
		WEEK 16	24AUG95	160	54	106	30.0	4	88.0	88.3
		WEEK 20	26SEP95	160	150	10	3.0	4	83.0	83.3
329.009.00133	91.2	WEEK 1	20JUN95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	27JUN95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	05JUL95	30	6	24	8.0	3	100.0	100.0
		WEEK 4	11JUL95	40	16	24	6.0	4	100.0	100.0
		WEEK 5	18JUL95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	27JUL95	120	75	45	9.0	6	83.0	83.3
329.009.00138	50.0	WEEK 1	17OCT95	20	16	4	7.0	2	29.0	28.6

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
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Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00170	97.5	WEEK 1	14NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	21NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28NOV95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	05DEC95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	12DEC95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	21DEC95	60	6	54	9.0	6	100.0	100.0
		WEEK 7	29DEC95	60	15	45	8.0	6	94.0	93.8
		WEEK 8	03JAN96	50	28	22	5.0	5	88.0	88.0
		WEEK 12	29JAN96	200	89	111	26.0	5	85.0	85.4
		WEEK 16	26FEB96	200	84	116	28.0	5	82.9	82.9
		WEEK 20	01APR96	200	35	165	35.0	5	94.0	94.3
		WEEK 24	22APR96	200	152	48	21.0	5	46.0	45.7
		WEEK 28	23MAY96	200	66	134	31.0	5	86.0	86.5
		WEEK 32	24JUN96	200	78	122	33.0	5	74.0	73.9
		DOWN TITRATION	10JUL96	44	16	28	15.0	4	76.0	82.4
				44	16	28	15.0	3	76.0	82.4
				44	16	28	15.0	2	76.0	82.4
				44	16	28	15.0	2	76.0	82.4
329.009.00173	94.1	WEEK 1	27NOV95	20	13	7	7.0	2	50.0	50.0
		WEEK 2	04DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	11DEC95	30	12	18	7.0	3	86.0	85.7
		WEEK 4	18DEC95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	29DEC95	50	1	49	11.0	5	89.0	89.1
		WEEK 6	08JAN96	50	0	50	10.0	5	100.0	100.0
		WEEK 7	15JAN96	40	10	30	7.0	4	100.0	107.1
		WEEK 8	22JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	26FEB96	160	46	114	35.0	4	81.0	81.4
		DOWN TITRATION	25MAR96	44	.	.	.	4	.	.
329.009.00193	100.0	WEEK 1	05DEC95	20	4	14	7.0	2	100.0	100.0
		WEEK 2	12DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	19DEC95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	27DEC95	40	8	32	8.0	4	100.0	100.0
		WEEK 5	05JAN96	50	5	45	9.0	5	100.0	100.0
		WEEK 6	09JAN96	50	30	20	4.0	5	100.0	100.0
		WEEK 7	16JAN96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	24JAN96	50	10	40	8.0	5	100.0	100.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00196	96.8	WEEK 1	27DEC95	20	3	17	9.0	2	94.0	94.4
		WEEK 2	02JAN96	20	8	12	6.0	2	100.0	100.0
		WEEK 3	08JAN96	30	12	18	6.0	3	100.0	100.0
		WEEK 4	15JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	22JAN96	50	18	32	7.0	5	91.0	91.4
		WEEK 6	29JAN96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	05FEB96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	12FEB96	50	18	32	7.0	5	91.0	91.4
		DOWN TITRATION	26FEB96	44	12	32	14.0	4	100.0	57.1
329.009.00201	95.9	WEEK 1	13FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	20FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28FEB96	30	6	24	8.0	3	100.0	100.0
		WEEK 4	05MAR96	40	16	24	6.0	4	100.0	100.0
		WEEK 5	12MAR96	40	16	24	7.0	4	86.0	85.7
		WEEK 6	19MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	26MAR96	40	14	26	7.0	4	93.0	92.9
		WEEK 8	02APR96	50	17	33	7.0	5	94.0	94.3
329.009.00204	91.0	WEEK 1	26MAR96	20	7	13	7.0	2	93.0	92.9
		WEEK 2	02APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	09APR96	30	11	19	7.0	3	91.0	90.5
		WEEK 4	16APR96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	23APR96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	30APR96	40	16	24	7.0	4	86.0	85.7
		WEEK 7	07MAY96	40	14	26	7.0	4	93.0	92.9
		WEEK 8	14MAY96	40	16	24	7.0	4	86.0	85.7
		WEEK 12	11JUN96	160	86	74	28.0	4	66.0	66.1
		WEEK 16	09JUL96	160	62	98	28.0	4	88.0	87.5
		WEEK 20	13AUG96	160	38	122	35.0	4	87.0	87.1
		WEEK 24	10SEP96	160	74	86	28.0	4	77.0	76.8
		WEEK 28	14OCT96	160	44	116	34.0	4	85.0	85.3
329.009.00235	97.3	WEEK 1	23DEC96	20	11	9	5.0	2	90.0	90.0
		WEEK 2	30DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	06JAN97	30	9	21	7.0	3	100.0	100.0
		WEEK 4	15JAN97	40	8	32	9.0	4	89.0	88.9
		WEEK 5	20JAN97	40	20	20	5.0	4	100.0	100.0
		WEEK 6	27JAN97	40	12	28	7.0	4	100.0	100.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00235	97.3	WEEK 7	03FEB97	40	12	28	7.0	4	100.0	100.0
		WEEK 8	10FEB97	40	12	28	7.0	4	100.0	100.0
		WEEK 12	17MAR97	160	19	141	35.0	4	100.0	100.7
		WEEK 16	14APR97	160	50	110	28.0	4	98.0	98.2
		DOWN TITRATION	28APR97	44	16	28	14.0	4	100.0	93.3
				44	16	28	14.0	3	100.0	93.3
				44	16	28	14.0	2	100.0	93.3
				44	16	28	14.0	2	100.0	93.3
329.009.00240	86.7	WEEK 1	21JAN97	20	7	13	7.0	2	93.0	92.9
		WEEK 2	28JAN97	20	7	13	7.0	2	93.0	92.9
		WEEK 3	04FEB97	30	12	18	7.0	3	86.0	85.7
		WEEK 4	11FEB97	40	14	26	7.0	4	93.0	92.9
		WEEK 5	18FEB97	40	14	22	7.0	4	79.0	78.6
		WEEK 6	25FEB97	50	17	33	7.0	5	94.0	94.3
		WEEK 7	04MAR97	50	19	31	7.0	5	89.0	88.6
329.009.00303	98.9	WEEK 1	09APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	16APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	23APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	30APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	07MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	14MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	22MAY96	40	8	32	8.0	4	100.0	100.0
		WEEK 8	28MAY96	40	18	22	6.0	4	92.0	91.7
		WEEK 12	25JUN96	160	50	110	29.0	4	95.0	94.8
		WEEK 16	30JUL96	160	24	136	34.0	4	100.0	100.0
		WEEK 20	27AUG96	160	50	110	28.0	4	98.0	98.2
		WEEK 24	25SEP96	160	46	114	29.0	4	98.0	98.3
		WEEK 28	30OCT96	160	22	138	35.0	4	99.0	98.6
		WEEK 32	10DEC96	160	0	160	41.0	4	98.0	97.6
		DOWN TITRATION	15JAN97	44	16	28	36.0	4	100.0	93.3
				44	16	28	36.0	3	100.0	93.3
				44	16	28	36.0	2	100.0	93.3
				44	16	28	36.0	2	100.0	93.3
329.009.00304	100.0	WEEK 1	16APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	23APR96	20	6	14	7.0	2	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00304	100.0	WEEK 3	30APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	07MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	14MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	21MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	28MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	04JUN96	50	15	35	7.0	5	100.0	100.0
		WEEK 12	02JUL96	200	62	138	28.0	5	99.0	98.6
		WEEK 16	30JUL96	200	121	79	28.0	5	56.0	56.4
		WEEK 20	27AUG96	200	62	138	28.0	5	99.0	98.6
		WEEK 24	23SEP96	200	74	126	27.0	5	93.0	93.3
		WEEK 28	21OCT96	200	103	97	28.0	5	69.0	69.3
		DOWN TITRATION	04NOV96	44	23	21	14.0	4	57.0	63.6
				44	23	21	14.0	3	57.0	63.6
				44	23	21	14.0	2	57.0	63.6
				44	23	21	14.0	2	57.0	63.6
329.009.00324	97.1	WEEK 1	04NOV96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	11NOV96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	18NOV96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	25NOV96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	02DEC96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	09DEC96	40	10	30	7.0	4	107.0	107.1
		WEEK 7	16DEC96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	27DEC96	40	0	40	11.0	4	91.0	90.9
329.009.00328	.	WEEK 1	.	20	.	.	.	2	.	.
329.009.00329	87.0	WEEK 1	16OCT96	20	10	10	7.0	2	71.0	71.4
		WEEK 2	23OCT96	20	7	13	7.0	2	93.0	92.9
		WEEK 3	29OCT96	30	15	15	6.0	3	83.0	83.3
		WEEK 4	05NOV96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	12NOV96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	19NOV96	40	16	24	7.0	4	86.0	85.7
		WEEK 7	26NOV96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	03DEC96	50	25	25	7.0	5	71.0	71.4
329.010.00182	101.0	WEEK 3	12JAN96	70	9	61	25.0	3	81.3	81.3
		WEEK 4	19JAN96	40	0	40	10.0	4	100.0	100.0
		WEEK 5	.	40	.	.	.	4	.	.

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.010.00278	89.5	WEEK 1	16FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	23FEB96	20	6	14	7.0	4	100.0	50.0
		WEEK 3	01MAR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	08MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	15MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	22MAR96	50	20	30	7.0	5	86.0	85.7
		WEEK 7	29MAR96	60	24	36	7.0	6	86.0	85.7
		WEEK 8	05APR96	60	18	42	7.0	6	100.0	100.0
		WEEK 12	03MAY96	258	114	144	28.0	6	86.0	85.7
		WEEK 16	31MAY96	240	102	138	28.0	6	82.0	82.1
		WEEK 20	27JUN96	240	84	156	27.0	6	96.0	96.3
		WEEK 24	25JUL96	240	87	153	27.0	6	95.0	94.4
		WEEK 28	22AUG96	240	78	162	28.0	6	96.0	96.4
		WEEK 32	19SEP96	240	96	144	28.0	6	86.0	85.7
		DOWN TITRATION	09OCT96	44	0	44	16.0	5	100.0	100.0
				44	0	44	16.0	4	100.0	100.0
				44	0	44	16.0	3	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
329.010.00280	94.5	WEEK 1	24MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	31MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	07JUN96	30	12	18	7.0	3	86.0	85.7
		WEEK 4	14JUN96	40	16	24	7.0	4	86.0	85.7
		WEEK 5	21JUN96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	27JUN96	50	25	25	6.0	5	83.0	83.3
		WEEK 7	03JUL96	60	24	36	6.0	6	100.0	100.0
		WEEK 8	11JUL96	60	12	48	8.0	6	100.0	100.0
		WEEK 12	21AUG96	273	168	105	42.0	6	97.0	41.7
329.011.00283	93.2	WEEK 1	14FEB96	20	7	13	7.0	2	93.0	92.9
		WEEK 2	21FEB96	20	7	13	7.0	2	93.0	92.9
		WEEK 3	29FEB96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	07MAR96	40	16	24	7.0	4	86.0	85.7
		WEEK 5	15MAR96	40	12	28	8.0	4	87.5	87.5
		WEEK 6	22MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	28MAR96	40	16	24	6.0	4	100.0	100.0
		WEEK 8	04APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	.	160	.	.	.	4	.	.

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.011.00288	90.9	WEEK 1	01AUG96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	09AUG96	20	5	15	8.0	2	94.0	93.8
		WEEK 3	19AUG96	30	0	30	10.0	3	100.0	100.0
		WEEK 4	29AUG96	40	2	38	10.0	4	95.0	95.0
		WEEK 5	04SEP96	40	17	23	7.0	4	82.0	82.1
329.012.00025	99.1	WEEK 1	31OCT95	20	5	15	7.5	2	100.0	100.0
		WEEK 2	07NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	14NOV95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	21NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	28NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	05DEC95	50	15	35	7.0	5	100.0	100.0
		WEEK 7	12DEC95	60	18	42	7.0	6	100.0	100.0
		WEEK 8	19DEC95	60	15	45	7.5	6	100.0	100.0
329.012.00220	94.3	WEEK 1	22JUN96	20	11	9	5.0	2	90.0	90.0
		WEEK 2	28JUN96	20	8	12	6.0	2	100.0	100.0
		WEEK 3	05JUL96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	12JUL96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	19JUL96	50	17	33	7.0	5	94.0	94.3
		WEEK 6	29JUL96	50	6	44	9.5	5	93.0	92.6
		WEEK 7	06AUG96	50	13	37	8.5	5	87.0	87.1
		WEEK 8	16AUG96	50	0	50	9.5	5	105.0	105.3
		WEEK 12	13SEP96	200	96	104	28.0	5	74.0	74.3
		WEEK 16	11OCT96	200	54	146	29.0	5	101.0	100.7
		WEEK 20	08NOV96	200	60	140	28.0	5	100.0	100.0
		WEEK 24	06DEC96	200	135	65	14.0	5	93.0	92.9
		DOWN TITRATION	.	34	.	.	.	5	.	.
329.012.00222	94.6	WEEK 1	05JUL96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	12JUL96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	19JUL96	30	11	19	7.0	3	90.0	90.5
		WEEK 4	29JUL96	40	4	36	9.0	4	100.0	100.0
		WEEK 5	06AUG96	40	8	32	8.5	4	94.0	94.1
		WEEK 6	13AUG96	50	18	32	7.0	5	91.0	91.4
		WEEK 7	20AUG96	50	14	36	7.0	5	103.0	102.9
		WEEK 8	30AUG96	50	5	45	9.5	5	95.0	94.7
		WEEK 12	27SEP96	200	107	93	29.0	5	74.0	64.1

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.012.00226	100.0	WEEK 1	10DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	20DEC96	20	0	20	10.0	2	100.0	100.0
		WEEK 3	23DEC96	30	30	0	3.0	0	.	.
329.012.00228	87.5	WEEK 1	27MAR97	20	13	7	8.0	2	44.0	43.8
329.012.00231	102.8	WEEK 1	17MAR97	20	0	20	10.0	2	100.0	100.0
		WEEK 2	24MAR97	20	5	15	7.5	2	100.0	100.0
		WEEK 3	02APR97	30	2	28	9.0	3	104.0	103.7
		WEEK 4	09APR97	40	10	30	7.0	4	107.0	107.1
		WEEK 5	17APR97	40	8	32	8.0	4	100.0	100.0
		WEEK 6	25APR97	40	8	32	8.0	4	100.0	100.0
		WEEK 7	01MAY97	50	18	32	6.0	5	107.0	106.7
		WEEK 8	07MAY97	50	20	30	6.0	5	100.0	100.0
		WEEK 12	04JUN97	200	63	137	28.0	5	98.0	97.9
		WEEK 16	30JUN97	200	104	96	76.0	5	74.0	25.3
		WEEK 20	05AUG97	200	52	148	36.0	5	.	82.2
		DOWN TITRATION	19AUG97	34	9	25	13.0	4	83.0	73.5
				34	9	25	13.0	3	83.0	73.5
				34	9	25	13.0	2	83.0	73.5
				34	9	25	13.0	2	83.0	73.5

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.001.00061	100.0	WEEK 1	04AUG94	20	8	12	6.0	2	100.0	100.0
		WEEK 2	11AUG94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	18AUG94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	25AUG94	40	12	28	7.0	4	100.0	100.0
		WEEK 5	01SEP94	40	12	28	7.0	4	100.0	100.0
329.001.00066	100.0	WEEK 1	28NOV94	20	8	12	6.0	2	100.0	100.0
		WEEK 2	05DEC94	20	6	14	7.0	2	100.0	100.0
329.001.00067	100.0	WEEK 1	29NOV94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	06DEC94	20	6	14	7.0	2	100.0	100.0
329.001.00070	100.0	WEEK 1	28FEB95	20	8	12	6.0	2	100.0	100.0
		WEEK 2	08MAR95	20	4	16	8.0	2	100.0	100.0
		WEEK 3	15MAR95	30	9	21	7.0	3	100.0	100.0
329.001.00122	100.0	WEEK 1	27JUN95	20	5	15	7.0	2	100.0	107.1
		WEEK 2	05JUL95	20	5	15	8.0	2	94.0	93.8
		WEEK 3	11JUL95	30	12	18	6.0	3	100.0	100.0
		WEEK 4	18JUL95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	25JUL95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	01AUG95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	08AUG95	40	10	30	7.5	4	100.0	100.0
		WEEK 8	16AUG95	40	10	30	7.5	4	100.0	100.0
		WEEK 12	12SEP95	160	52	108	27.0	4	100.0	100.0
		WEEK 16	10OCT95	160	48	112	28.0	4	100.0	100.0
		WEEK 20	07NOV95	160	48	112	28.0	4	100.0	100.0
		WEEK 24	05DEC95	160	48	112	28.0	4	100.0	100.0
329.002.00050	89.8	WEEK 1	29MAR95	20	9	11	7.0	2	78.6	78.6
		WEEK 2	05APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	12APR95	30	11	19	7.0	3	90.5	90.5
329.002.00056	95.1	WEEK 1	26JUL94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	02AUG94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	09AUG94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	16AUG94	40	12	28	7.0	4	100.0	100.0
329.002.00057	97.5	WEEK 1	15SEP94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	22SEP94	20	5	15	7.0	2	100.0	107.1

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00057	97.5	WEEK 3	29SEP94	30	10	20	7.0	3	95.0	95.2
		WEEK 4	06OCT94	40	12	28	7.0	4	100.0	100.0
		WEEK 5	13OCT94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	20OCT94	60	18	42	7.0	6	100.0	100.0
		WEEK 7	27OCT94	60	18	42	7.0	6	100.0	100.0
		WEEK 8	03NOV94	60	18	42	7.0	6	100.0	100.0
		WEEK 12	01DEC94	240	72	168	28.0	6	100.0	100.0
		WEEK 16	29DEC94	240	75	165	28.0	6	98.0	98.2
		DOWN TITRATION	11JAN95	44	0	44	16.0	5	100.0	100.0
				44	0	44	16.0	4	100.0	100.0
				44	0	44	16.0	3	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
329.002.00098	95.1	WEEK 1	10JAN95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	18JAN95	20	4	16	8.0	2	100.0	100.0
		WEEK 3	24JAN95	30	12	18	6.0	3	100.0	100.0
		WEEK 4	31JAN95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	07FEB95	50	18	32	7.0	5	91.0	91.4
		WEEK 6	14FEB95	60	20	40	7.0	6	95.0	95.2
		WEEK 7	21FEB95	50	18	32	7.0	5	91.0	91.4
		WEEK 8	02MAR95	90	55	35	8.0	5	100.0	92.1
				90	55	35	8.0	4	100.0	92.1
329.002.00100	98.6	WEEK 1	14MAR95	20	7	13	7.0	2	92.0	92.9
		WEEK 2	21MAR95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	28MAR95	30	11	19	7.0	3	85.0	90.5
		WEEK 4	04APR95	40	8	32	7.0	4	114.0	114.3
		WEEK 5	11APR95	40	14	26	7.0	4	93.0	92.9
		WEEK 6	18APR95	50	15	35	7.0	5	100.0	100.0
		WEEK 7	25APR95	50	18	32	7.0	5	91.0	91.4
		WEEK 8	04MAY95	50	3	47	9.0	5	104.0	104.4
		WEEK 12	30MAY95	200	73	127	26.0	5	93.0	97.7
		WEEK 16	27JUN95	200	.	.	.	5	.	.
329.002.00103	98.6	WEEK 1	27APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	02MAY95	20	10	10	5.0	2	100.0	100.0
		WEEK 3	09MAY95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	16MAY95	40	12	28	7.0	4	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00103	98.6	WEEK 5	25MAY95	40	6	34	9.0	4	94.0	94.4
		WEEK 6	30MAY95	40	20	20	5.0	4	100.0	100.0
		WEEK 7	06JUN95	50	15	35	7.0	5	100.0	100.0
		WEEK 8	15JUN95	50	6	44	9.0	5	98.0	97.8
		WEEK 12	13JUL95	200	66	134	28.0	5	95.0	95.7
		WEEK 16	10AUG95	240	86	154	28.0	5	110.0	110.0
		DOWN TITRATION	25AUG95	44	4	40	15.0	5	91.0	108.1
				44	4	40	15.0	4	91.0	108.1
				44	4	40	15.0	3	91.0	108.1
				44	4	40	15.0	2	91.0	108.1
				44	4	40	15.0	1	91.0	108.1
329.002.00104	100.4	WEEK 1	11MAY95	20	5	15	7.0	2	107.0	107.1
		WEEK 2	18MAY95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	25MAY95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	01JUN95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	09JUN95	50	10	40	8.0	5	100.0	100.0
		WEEK 6	16JUN95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	22JUN95	60	24	36	6.0	6	100.0	100.0
		WEEK 8	29JUN95	60	18	42	7.0	6	100.0	100.0
		WEEK 12	25JUL95	240	93	147	26.0	6	94.0	94.2
		WEEK 16	29AUG95	240	36	204	35.0	6	97.0	97.1
		WEEK 20	03OCT95	240	42	198	35.0	6	94.0	94.3
		WEEK 24	06NOV95	240	51	189	34.0	6	92.0	92.6
		WEEK 28	06DEC95	240	36	204	30.0	6	94.0	113.3
		WEEK 32	02JAN96	240	87	153	27.0	6	94.0	94.4
		DOWN TITRATION	17JAN96	44	0	44	16.0	5	100.0	118.9
				44	0	44	16.0	4	100.0	118.9
				44	0	44	16.0	3	100.0	118.9
				44	0	44	16.0	2	100.0	118.9
				44	0	44	16.0	1	100.0	118.9
329.002.00243	96.2	WEEK 1	21MAR96	20	5	15	7.0	2	107.0	107.1
		WEEK 2	28MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	04APR96	30	9	21	7.0	3	100.0	100.0
		DOWN TITRATION	.	44	.	.	.	3	.	.

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00244	93.7	WEEK 1	28MAR96	20	7	13	7.0	2	92.0	92.9
		WEEK 2	04APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	11APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	18APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	25APR96	40	12	28	7.0	5	100.0	80.0
		WEEK 6	02MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	09MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	16MAY96	60	18	42	7.0	6	100.0	100.0
		WEEK 12	23MAY96	300	227	73	7.0	6	103.0	109.0
				300	227	73	7.0	5	103.0	109.0
		DOWN TITRATION	12JUN96	44	10	34	15.0	4	100.0	89.5
				44	10	34	15.0	3	100.0	89.5
				44	10	34	15.0	2	100.0	89.5
				44	10	34	15.0	2	100.0	89.5
329.002.00321	58.3	WEEK 1	30MAY96	20	6	14	7.0	2	100.0	100.0
329.002.00322	94.5	WEEK 1	16JAN97	20	7	13	7.0	2	92.0	92.9
		WEEK 2	23JAN97	20	7	13	7.0	2	93.0	92.9
		WEEK 3	30JAN97	30	9	21	7.0	3	100.0	100.0
		WEEK 4	04FEB97	40	20	20	5.0	4	100.0	100.0
		WEEK 5	13FEB97	40	4	36	9.0	4	100.0	100.0
329.003.00073	92.0	WEEK 1	25JAN95	20	6	14	6.0	2	110.0	116.7
		WEEK 2	03FEB95	20	2	18	9.0	2	100.0	100.0
		WEEK 3	07FEB95	30	18	12	4.0	3	108.0	100.0
		WEEK 4	14FEB95	40	19	21	7.0	3	100.0	100.0
		WEEK 5	22FEB95	40	8	32	8.0	4	100.0	100.0
		WEEK 6	01MAR95	50	22	28	7.0	5	80.0	80.0
		WEEK 7	08MAR95	50	37	13	3.0	5	87.0	86.7
329.003.00076	99.5	WEEK 1	07FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14FEB95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	21FEB95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	27FEB95	40	16	24	6.0	4	100.0	100.0
		WEEK 5	06MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	13MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	20MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	27MAR95	40	12	28	7.0	4	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00076	99.5	WEEK 12	03MAY95	160	26	134	37.0	4	101.0	90.5
		WEEK 16	31MAY95	160	52	108	28.0	4	96.0	96.4
		WEEK 20	28JUN95	160	62	98	28.0	4	88.0	87.5
		WEEK 24	02AUG95	160	38	122	34.0	4	88.0	89.7
		WEEK 28	06SEP95	160	.	.	35.0	4	47.0	.
		WEEK 32	11OCT95	160	.	.	.	4	.	.
329.003.00079	100.0	WEEK 1	10MAY95	20	.	.	7.0	2	.	.
		WEEK 2	19MAY95	20	2	18	9.0	2	100.0	100.0
		WEEK 3	.	30	.	.	.	3	.	.
329.003.00082	80.9	WEEK 1	28DEC95	20	2	18	17.0	2	53.0	52.9
		WEEK 2	03JAN96	20	9	11	6.0	2	92.0	91.7
		WEEK 3	11JAN96	30	7	23	8.0	3	96.0	95.8
		WEEK 4	17JAN96	40	16	24	7.0	4	86.0	85.7
		WEEK 5	.	50	.	.	.	5	.	.
329.003.00088	89.8	WEEK 1	09MAR95	20	2	18	18.0	2	100.0	50.0
		WEEK 2	14MAR95	20	10	10	5.0	2	100.0	100.0
		WEEK 3	21MAR95	30	8	22	7.0	3	110.0	104.8
		WEEK 4	30MAR95	40	6	34	9.0	4	94.0	94.4
		WEEK 5	04APR95	40	32	8	5.0	2	80.0	80.0
		WEEK 6	11APR95	40	26	14	7.0	4	62.0	50.0
329.003.00090	100.0	WEEK 1	28MAR95	20	2	18	14.0	2	64.0	64.3
		WEEK 2	04APR95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	11APR95	30	8	22	7.0	3	104.0	104.8
		WEEK 4	18APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	25APR95	40	18	22	7.0	4	78.0	78.6
		WEEK 6	02MAY95	50	4	46	7.0	5	130.0	131.4
		WEEK 7	09MAY95	40	14	26	7.0	4	92.0	92.9
		WEEK 8	16MAY95	40	16	24	7.0	4	86.0	85.7
329.003.00092	82.0	WEEK 1	11MAY95	20	2	18	9.0	2	100.0	100.0
		WEEK 2	16MAY95	20	10	10	5.0	2	100.0	100.0
		WEEK 3	26MAY95	30	2	28	10.0	3	93.0	93.3
		WEEK 4	02JUN95	40	15	25	7.0	4	89.0	89.3
		WEEK 5	06JUN95	40	30	10	4.0	4	63.0	62.5
		WEEK 6	13JUN95	40	20	20	7.0	4	71.0	71.4
		WEEK 7	20JUN95	40	.	.	.	4	.	.

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00092	82.0	WEEK 8	30JUN95	40	14	26	10.0	4	65.0	65.0
		WEEK 12	08AUG95	160	16	144	39.0	4	92.0	92.3
		WEEK 16	05SEP95	160	62	98	27.0	4	91.0	90.7
		WEEK 20	26SEP95	160	84	76	21.0	4	90.0	90.5
		WEEK 24	07NOV95	160	32	128	37.0	4	100.0	80.0
				160	32	128	37.0	0	100.0	80.0
				160	32	128	37.0	4	100.0	80.0
		WEEK 28	05DEC95	160	60	100	28.0	4	80.0	89.3
		WEEK 32	02JAN96	160	68	92	27.0	4	71.0	85.2
		DOWN TITRATION	18JAN96	44	0	44	16.0	5	100.0	100.0
				44	0	44	16.0	4	100.0	100.0
				44	0	44	16.0	3	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
329.003.00093	80.7	WEEK 1	27JUN95	20	8	12	7.0	2	86.0	85.7
		WEEK 2	06JUL95	20	12	8	10.0	2	40.0	40.0
		WEEK 3	21JUL95	30	1	29	14.0	3	69.0	69.0
		WEEK 4	25JUL95	40	28	12	4.0	4	75.0	75.0
		WEEK 5	01AUG95	50	23	27	7.0	5	77.0	77.1
		WEEK 6	10AUG95	60	12	48	9.0	6	89.0	88.9
		WEEK 7	.	60	27	33	6.0	6	92.0	91.7
		WEEK 8	22AUG95	60	24	36	6.0	6	100.0	100.0
		WEEK 12	03OCT95	291	222	69	17.0	6	68.0	67.6
329.003.00247	90.2	WEEK 1	06FEB96	20	9	11	5.0	2	110.0	110.0
		WEEK 2	13FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	20FEB96	30	6	24	7.0	3	110.0	114.3
		WEEK 4	27FEB96	40	14	26	7.0	4	101.0	92.9
		WEEK 5	07MAR96	40	8	32	8.0	4	100.0	100.0
		WEEK 6	12MAR96	40	24	16	4.0	4	100.0	100.0
		WEEK 7	21MAR96	40	24	16	9.0	4	44.0	44.4
		WEEK 8	26MAR96	40	13	27	5.0	4	108.0	135.0
		WEEK 12	30APR96	160	109	.	.	4	.	.
		WEEK 16	21MAY96	160	56	104	21.0	4	124.0	123.8
		WEEK 20	.	160	.	.	.	4	.	.
329.003.00249	102.1	WEEK 1	12MAR96	20	10	10	5.0	2	100.0	100.0
		WEEK 2	19MAR96	20	7	13	8.0	2	81.3	81.3

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00249	102.1	WEEK 3	26MAR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	02APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	09APR96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	16APR96	60	18	42	7.0	6	100.0	100.0
		WEEK 7	23APR96	60	12	48	7.0	6	114.0	114.3
		WEEK 8	30APR96	60	18	42	7.0	6	100.0	100.0
329.003.00289	100.0	WEEK 1	06MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	13MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	20MAR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	27MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	03APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	10APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	17APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	24APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	22MAY96	160	48	112	28.0	4	100.0	100.0
		WEEK 16	20JUN96	160	42	118	29.0	4	101.0	101.7
		WEEK 20	19JUL96	160	44	116	29.0	4	100.0	100.0
		WEEK 24	16AUG96	160	52	108	28.0	4	96.0	96.4
		WEEK 28	13SEP96	160	48	112	28.0	4	100.0	100.0
		WEEK 32	11OCT96	160	48	112	28.0	4	100.0	100.0
		DOWN TITRATION	23OCT96	26	0	26	12.0	3	100.0	100.0
				26	0	26	12.0	2	100.0	100.0
				26	0	26	12.0	2	100.0	100.0
329.003.00290	91.7	WEEK 1	20MAR96	20	2	18	9.0	2	100.0	100.0
		WEEK 2	22MAR96	20	16	4	2.0	2	100.0	100.0
329.003.00314	79.4	WEEK 1	29OCT96	20	8	12	8.0	2	85.7	75.0
		WEEK 2	05NOV96	20	14	6	7.0	2	42.8	42.9
		WEEK 3	14NOV96	30	5	25	10.0	3	83.0	83.3
		WEEK 4	26NOV96	40	.	.	13.0	4	.	.
		WEEK 5	03DEC96	40	14	26	8.0	4	75.0	81.3
		WEEK 6	10DEC96	40	18	22	7.0	4	78.0	78.6
		WEEK 7	17DEC96	40	10	30	8.0	4	94.0	93.8
		WEEK 8	23DEC96	120	48	72	14.0	5	103.0	72.0
				120	48	72	14.0	5	103.0	72.0
329.003.00317	99.1	WEEK 1	23DEC96	20	12	8	5.0	2	80.0	80.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00317	99.1	WEEK 2	.	20	7	13	7.0	2	93.0	92.9
		WEEK 3	07JAN97	30	5	25	8.0	3	104.0	104.2
		WEEK 4	14JAN97	40	12	28	7.0	4	100.0	100.0
		WEEK 5	21JAN97	40	12	28	7.0	4	100.0	100.0
		WEEK 6	28JAN97	50	15	35	7.0	5	100.0	100.0
		WEEK 7	04FEB97	60	18	42	7.0	6	100.0	100.0
		WEEK 8	11FEB97	60	18	42	7.0	6	100.0	100.0
329.004.00013	99.5	WEEK 1	26JUL94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	02AUG94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	09AUG94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	15AUG94	40	18	22	6.0	4	92.0	91.7
		WEEK 5	23AUG94	40	5	35	8.0	4	109.0	109.4
		WEEK 6	31AUG94	40	8	32	8.0	4	100.0	100.0
		WEEK 7	08SEP94	40	8	32	8.0	4	100.0	100.0
		WEEK 8	16SEP94	40	10	30	8.0	4	94.0	93.8
		WEEK 12	11OCT94	160	62	98	25.0	4	98.0	98.0
		WEEK 16	08NOV94	260	138	122	29.0	4	100.0	98.4
				260	138	122	29.0	5	100.0	98.4
		WEEK 20	06DEC94	200	61	139	29.0	5	96.0	95.9
		WEEK 24	10JAN95	200	25	175	34.0	5	100.0	102.9
		WEEK 28	07FEB95	200	62	138	28.0	5	99.0	98.6
		WEEK 32	10MAR95	200	45	155	31.0	5	100.0	100.0
		DOWN TITRATION	31MAR95	44	10	34	21.0	4	100.0	100.0
				44	10	34	21.0	3	100.0	100.0
				44	10	34	21.0	2	100.0	100.0
				44	10	34	21.0	2	100.0	100.0
329.004.00014	56.7	WEEK 1	05DEC94	20	9	11	6.0	2	100.0	91.7
		WEEK 2	13DEC94	20	14	6	8.0	2	37.5	37.5
329.004.00211	93.2	WEEK 1	08FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	16FEB96	20	5	15	8.0	2	100.0	93.8
		WEEK 3	23FEB96	30	9	21	8.0	3	100.0	87.5
		WEEK 4	29FEB96	40	16	24	7.0	4	100.0	85.7
		WEEK 5	07MAR96	40	14	26	8.0	4	100.0	81.3
		WEEK 6	14MAR96	40	14	26	7.0	4	100.0	92.9
		WEEK 7	25MAR96	40	16	24	12.0	4	72.0	50.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.004.00215	93.6	WEEK 1	27MAR97	20	6	14	7.0	2	100.0	100.0
		WEEK 2	03APR97	20	6	14	7.0	2	100.0	100.0
		WEEK 3	10APR97	30	9	21	7.0	3	100.0	100.0
		WEEK 4	15APR97	40	20	20	5.0	4	100.0	100.0
		WEEK 5	24APR97	40	6	34	9.0	4	94.0	94.4
		WEEK 6	29APR97	40	26	14	5.0	4	70.0	70.0
329.005.00003	92.3	WEEK 1	27SEP94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	04OCT94	20	10	10	7.0	2	71.0	83.3
				20	10	10	7.0	1	71.0	83.3
329.005.00006	100.4	WEEK 1	14NOV94	20	0	20	10.0	2	100.0	100.0
		WEEK 2	21NOV94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28NOV94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	05DEC94	40	12	28	7.0	4	100.0	100.0
		WEEK 5	12DEC94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	19DEC94	60	17	43	7.0	6	100.0	102.4
		WEEK 7	27DEC94	60	12	48	8.0	6	100.0	100.0
		WEEK 8	03JAN95	60	18	42	7.0	6	100.0	100.0
		WEEK 12	02FEB95	240	60	180	30.0	6	100.0	100.0
		WEEK 16	27FEB95	240	90	150	25.0	6	100.0	100.0
		WEEK 20	05APR95	240	21	219	37.0	6	98.0	98.6
		WEEK 24	12APR95	240	198	42	7.0	6	100.0	100.0
		DOWN TITRATION	28APR95	44	2	42	16.0	5	100.0	113.5
				44	2	42	16.0	4	100.0	113.5
				44	2	42	16.0	3	100.0	113.5
				44	2	42	16.0	2	100.0	113.5
				44	2	42	16.0	1	100.0	113.5
329.005.00007	95.6	WEEK 1	23NOV94	20	4	16	15.0	2	100.0	53.3
		WEEK 2	30NOV94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	07DEC94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	14DEC94	40	22	18	7.0	4	64.0	64.3
		WEEK 5	21DEC94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	28DEC94	60	18	42	7.0	6	100.0	100.0
		WEEK 7	04JAN95	50	15	35	7.0	5	100.0	100.0
		WEEK 8	11JAN95	50	15	35	7.0	5	100.0	100.0
		WEEK 12	15FEB95	200	25	175	35.0	5	100.0	100.0
		WEEK 16	22MAR95	200	25	175	35.0	5	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00007	95.6	WEEK 20	19APR95	200	60	140	28.0	5	100.0	100.0
		WEEK 24	17MAY95	200	55	145	37.0	5	78.0	78.4
		WEEK 28	09AUG95	200	185	15	3.0	5	100.0	100.0
329.005.00009	100.0	WEEK 1	19DEC94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	27DEC94	20	4	16	8.0	2	100.0	100.0
		WEEK 3	03JAN95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	11JAN95	40	8	32	8.0	4	100.0	100.0
		WEEK 5	18JAN95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	25JAN95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	31JAN95	50	20	30	6.0	5	100.0	100.0
		WEEK 8	07FEB95	50	15	35	7.0	5	100.0	100.0
329.005.00110	88.9	WEEK 1	18JAN95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	25JAN95	20	18	2	7.0	2	14.3	14.3
329.005.00113	73.6	WEEK 1	08FEB95	20	3	17	9.0	2	95.0	94.4
		WEEK 2	16FEB95	20	5	15	8.0	2	94.0	93.8
		WEEK 3	23FEB95	30	12	18	7.0	3	85.0	85.7
		WEEK 4	02MAR95	40	26	14	7.0	4	43.0	50.0
329.005.00117	93.3	WEEK 1	27MAR95	20	2	18	9.0	2	100.0	100.0
		WEEK 2	03APR95	20	5	15	7.0	2	107.0	107.1
		WEEK 3	10APR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	17APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	24APR95	40	16	24	7.0	4	85.0	85.7
		WEEK 6	01MAY95	40	14	26	7.0	4	92.0	92.9
		WEEK 7	08MAY95	40	20	20	7.0	4	71.0	71.4
		WEEK 8	15MAY95	40	12	28	7.0	4	100.0	100.0
329.005.00118	105.3	WEEK 1	24MAY95	20	5	15	7.5	2	100.0	100.0
		WEEK 2	30MAY95	20	9	11	6.0	2	92.0	91.7
		WEEK 3	06JUN95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	14JUN95	40	7	33	8.0	4	103.0	103.1
		WEEK 5	20JUN95	50	19	31	7.0	5	88.0	88.6
		WEEK 6	27JUN95	60	12	48	7.0	6	114.0	114.3
329.005.00153	98.6	WEEK 1	01FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	08FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	15FEB96	30	10	20	7.0	3	95.2	95.2

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00153	98.6	WEEK 4	22FEB96	40	14	26	7.0	4	92.8	92.9
		WEEK 5	29FEB96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	06MAR96	50	20	30	6.0	5	100.0	100.0
		WEEK 7	14MAR96	50	10	40	8.0	5	100.0	100.0
		WEEK 8	21MAR96	50	15	35	7.0	5	100.0	100.0
		WEEK 12	17APR96	200	65	135	27.0	5	100.0	100.0
		WEEK 16	15MAY96	240	72	168	28.0	6	100.0	100.0
		WEEK 20	12JUN96	240	72	168	28.0	6	100.0	100.0
		WEEK 24	10JUL96	240	75	165	28.0	6	98.0	98.2
		WEEK 28	05AUG96	240	90	150	26.0	6	96.0	96.2
		WEEK 32	04SEP96	240	78	162	30.0	6	90.0	90.0
		DOWN TITRATION	25SEP96	44	13	31	16.0	5	65.0	81.6
				44	13	31	16.0	4	65.0	81.6
				44	13	31	16.0	3	65.0	81.6
				44	13	31	16.0	2	65.0	81.6
				44	13	31	16.0	2	65.0	81.6
329.005.00255	99.1	WEEK 1	11MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	18MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	25MAR96	30	11	19	7.0	3	90.0	90.5
		WEEK 4	01APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	08APR96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	15APR96	60	18	42	7.0	6	100.0	100.0
		WEEK 7	23APR96	50	10	40	8.0	5	100.0	100.0
		WEEK 8	29APR96	50	20	30	6.0	5	100.0	100.0
329.005.00256	94.1	WEEK 1	12MAR96	20	7	13	7.0	2	93.0	92.9
		WEEK 2	21MAR96	20	3	17	9.0	2	94.0	94.4
		WEEK 3	26MAR96	30	15	15	5.0	3	100.0	100.0
		WEEK 4	02APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	11APR96	50	8	42	9.0	5	93.0	93.3
		WEEK 6	16APR96	50	27	23	5.0	5	92.0	92.0
		WEEK 7	23APR96	50	18	29	7.0	5	82.0	82.9
		WEEK 8	30APR96	60	18	42	7.0	6	100.0	100.0
		WEEK 12	28MAY96	240	81	156	28.0	6	93.0	92.9
		WEEK 16	02JUL96	240	90	150	34.0	6	74.0	73.5
		DOWN TITRATION	18JUL96	44	10	34	15.0	5	77.0	77.3
				44	10	34	15.0	4	77.0	77.3

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00256	94.1	DOWN TITRATION	18JUL96	44	10	34	15.0	3	77.0	77.3
				44	10	34	15.0	2	77.0	77.3
				44	10	34	15.0	2	77.0	77.3
329.005.00295	90.4	WEEK 1	04APR96	20	7	13	7.0	2	93.0	92.9
		WEEK 2	11APR96	20	8	12	7.0	2	86.0	85.7
		WEEK 3	18APR96	30	7	23	7.0	3	100.0	109.5
		WEEK 4	24APR96	40	16	24	6.0	4	100.0	100.0
		WEEK 5	06MAY96	40	0	40	10.0	4	100.0	100.0
		WEEK 6	09MAY96	40	28	12	3.0	4	100.0	100.0
		WEEK 7	16MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	22MAY96	50	39	11	4.0	5	55.0	55.0
329.005.00297	90.3	WEEK 1	26APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	02MAY96	20	8	12	6.0	2	100.0	100.0
		WEEK 3	14MAY96	30	0	30	12.0	3	84.0	83.3
329.005.00332	100.0	WEEK 1	19DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	26DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	02JAN97	30	9	21	7.0	3	100.0	100.0
		WEEK 4	09JAN97	40	12	28	7.0	4	100.0	100.0
		WEEK 5	16JAN97	50	15	35	7.0	5	100.0	100.0
		WEEK 6	23JAN97	60	18	42	7.0	6	100.0	100.0
		WEEK 7	30JAN97	60	18	42	7.0	6	100.0	100.0
		WEEK 8	06FEB97	60	18	42	7.0	6	100.0	100.0
329.005.00335	93.9	WEEK 1	07MAR97	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14MAR97	20	6	14	7.0	2	100.0	100.0
		WEEK 3	21MAR97	30	9	21	7.0	3	100.0	100.0
		WEEK 4	27MAR97	40	16	24	6.0	4	100.0	100.0
		WEEK 5	03APR97	50	15	35	7.0	5	100.0	100.0
		WEEK 6	10APR97	40	14	26	7.0	4	93.0	92.9
		WEEK 7	17APR97	40	14	26	7.0	4	95.0	92.9
		WEEK 8	24APR97	40	16	24	7.0	4	86.0	85.7
329.006.00040	96.2	WEEK 1	22FEB95	20	7	13	7.0	2	100.0	92.9
		WEEK 2	01MAR95	20	8	12	7.0	2	83.0	85.7
329.006.00041	99.6	WEEK 1	10APR95	20	11	9	5.0	2	90.0	90.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.006.00041	99.6	WEEK 2	19APR95	20	2	18	9.0	2	100.0	100.0
		WEEK 3	24APR95	30	15	15	5.0	3	100.0	100.0
		WEEK 4	01MAY95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	08MAY95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	15MAY95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	24MAY95	40	4	36	9.0	4	100.0	100.0
		WEEK 8	31MAY95	110	30	80	15.0	5	100.0	100.0
				110	30	80	15.0	6	100.0	100.0
		WEEK 12	05JUL95	240	81	159	27.0	6	98.0	98.1
		WEEK 16	31JUL95	240	113	127	26.0	6	81.0	81.4
		WEEK 20	24AUG95	240	118	122	24.0	6	85.0	84.7
		WEEK 24	21SEP95	240	90	150	28.0	6	89.0	89.3
		WEEK 28	24OCT95	240	60	180	31.0	6	94.0	96.8
		WEEK 32	21NOV95	240	90	150	168	6	89.0	14.9
		DOWN TITRATION	05DEC95	44	3	41	15.0	5	91.0	113.9
				44	3	41	15.0	4	91.0	113.9
				44	3	41	15.0	3	91.0	113.9
				44	3	41	15.0	2	91.0	113.9
				44	3	41	15.0	1	91.0	113.9
329.007.00139	77.8	WEEK 1	18MAY95	20	5	15	9.5	2	79.0	78.9
		WEEK 2	25MAY95	20	7	13	7.0	2	93.0	92.9
329.007.00143	96.2	WEEK 1	16NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	22NOV95	20	9	11	6.0	2	92.0	91.7
		DOWN TITRATION	07DEC95	20	0	20	10.0	2	100.0	100.0
329.007.00146	100.0	WEEK 1	01FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	05FEB96	20	12	8	4.0	2	100.0	100.0
		WEEK 3	12FEB96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	19FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	26FEB96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	04MAR96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	11MAR96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	18MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	15APR96	160	47	112	28.0	4	100.0	100.0
		WEEK 16	13MAY96	320	198	122	28.0	5	100.0	100.0
				320	198	122	28.0	4	100.0	100.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.007.00146	100.0	WEEK 20	06JUN96	160	64	96	24.0	4	100.0	100.0
		WEEK 24	08JUL96	160	30	130	32.0	4	102.0	101.6
		WEEK 28	05AUG96	160	48	112	28.0	4	100.0	100.0
		WEEK 32	09SEP96	160	22	138	35.0	4	99.0	98.6
		DOWN TITRATION	23SEP96	28	0	28	12.5	4	100.0	93.3
				28	0	28	12.5	3	100.0	93.3
				28	0	28	12.5	2	100.0	93.3
				28	0	28	12.5	2	100.0	93.3
329.007.00269	93.3	WEEK 1	18APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	25APR96	20	6	14	7.0	2	100.0	100.0
329.007.00270	93.4	WEEK 1	16MAY96	20	7	13	7.0	2	93.0	92.9
		WEEK 2	23MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	30MAY96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	06JUN96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	13JUN96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	20JUN96	40	14	26	7.0	4	95.0	92.9
329.007.00307	93.6	WEEK 1	23MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	30MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	06JUN96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	13JUN96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	20JUN96	40	15	25	7.0	4	89.0	89.3
329.007.00308	.	WEEK 1	11JUL96	20	.	.	.	1	.	.
329.008.00159	89.8	WEEK 1	19SEP95	20	7	13	6.0	2	108.0	108.3
		WEEK 2	27SEP95	20	7	13	8.0	2	81.0	81.3
		WEEK 3	03OCT95	30	12	18	6.0	3	100.0	100.0
		WEEK 4	10OCT95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	16OCT95	50	22	28	6.0	5	93.0	93.3
		WEEK 6	24OCT95	50	10	40	8.0	5	100.0	100.0
		WEEK 7	31OCT95	50	19	31	7.0	5	89.0	88.6
		WEEK 8	14NOV95	40	0	40	13.0	4	77.0	76.9
		WEEK 12	26DEC95	160	20	140	42.0	4	83.0	83.3
		WEEK 16	23JAN96	160	.	.	27.0	4	.	.
		WEEK 20	.	160	.	.	.	.	.	.

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.008.00161	90.9	WEEK 1	22NOV95	20	9	11	5.0	2	110.0	110.0
		WEEK 2	29NOV95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	07DEC95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	15DEC95	40	8	32	8.0	4	100.0	100.0
		WEEK 5	27DEC95	40	8	32	12.0	4	67.0	66.7
		WEEK 7	03JAN96	40	12	28	8.0	4	87.0	87.5
		WEEK 8	10JAN96	40	8	32	8.0	4	100.0	100.0
		WEEK 12	10JAN96	160	.	.	.	4	.	.
329.008.00187	95.5	WEEK 1	07DEC95	20	5	15	8.0	2	93.0	93.8
		WEEK 2	14DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	21DEC95	30	9	21	6.0	3	117.0	116.7
		WEEK 4	28DEC95	40	12	28	6.0	4	117.0	116.7
		WEEK 5	04JAN96	40	16	24	6.0	4	100.0	100.0
		WEEK 6	11JAN96	40	13	27	7.0	4	96.0	96.4
		WEEK 7	18JAN96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	26JAN96	40	12	28	8.0	4	88.0	87.5
329.008.00192	59.0	WEEK 1	11MAR96	20	8	12	7.0	2	85.0	85.7
		WEEK 2	18MAR96	20	9	11	6.0	2	92.0	91.7
		WEEK 3	25MAR96	30	25	5	6.0	3	28.0	27.8
		WEEK 4	03APR96	40	.	.	9.0	4	.	.
		WEEK 5	12APR96	40	22	18	6.0	4	75.0	75.0
329.008.00272	98.4	WEEK 1	10APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	17APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	26APR96	30	3	27	8.0	3	112.0	112.5
		WEEK 4	01MAY96	40	25	15	4.0	4	93.0	93.8
		WEEK 5	07MAY96	40	16	24	7.0	4	85.0	85.7
		WEEK 6	.	40	2	38	8.0	4	118.0	118.8
		WEEK 7	22MAY96	40	18	22	7.0	4	78.0	78.6
		WEEK 8	29MAY96	40	12	28	6.0	4	116.0	116.7
		WEEK 12	26JUN96	160	46	114	28.0	4	101.0	101.8
		WEEK 16	24JUL96	160	48	112	28.0	4	100.0	100.0
		WEEK 20	21AUG96	160	.	.	.	4	.	.
		WEEK 24	18SEP96	160	.	.	.	4	.	.
329.008.00273	97.3	WEEK 1	24MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	31MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	10JUN96	30	0	30	12.0	3	83.0	83.3

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.008.00273	97.3	WEEK 4	17JUN96	40	14	26	8.0	4	81.0	81.3
		WEEK 5	24JUN96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	01JUL96	50	.	.	7.0	5	.	.
		WEEK 7	11JUL96	60	0	60	11.0	6	100.0	90.9
		WEEK 8	19JUL96	60	15	45	11.0	6	68.0	68.2
		WEEK 12	04SEP96	240	.	.	.	6	.	.
		WEEK 16	.	240	.	.	.	6	.	.
329.009.00127	75.2	WEEK 1	17APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	24APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	01MAY95	30	11	19	7.0	3	91.0	90.5
		WEEK 4	08MAY95	40	28	12	7.0	4	43.0	42.9
		WEEK 5	15MAY95	40	20	20	7.0	4	71.5	71.4
329.009.00132	94.8	WEEK 1	30MAY95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	06JUN95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	13JUN95	30	10	20	7.0	3	95.0	95.2
		WEEK 4	20JUN95	40	16	24	7.0	4	86.0	85.7
		WEEK 5	27JUN95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	05JUL95	40	8	32	8.0	4	100.0	100.0
		WEEK 7	11JUL95	40	16	24	6.0	4	100.0	100.0
		WEEK 8	19JUL95	40	12	28	8.0	4	88.0	87.5
		WEEK 12	24AUG95	160	24	136	36.0	4	94.0	94.4
		WEEK 16	15SEP95	160	84	76	22.0	4	86.0	86.4
		WEEK 20	24OCT95	160	46	114	30.0	4	97.0	95.0
		DOWN TITRATION	08DEC95	58	19	25	12.0	4	89.0	83.3
				58	19	25	12.0	3	89.0	83.3
				58	19	25	12.0	2	89.0	83.3
				58	19	25	12.0	2	89.0	83.3
329.009.00134	99.5	WEEK 1	14JUL95	20	5	15	8.0	2	97.0	93.8
		WEEK 2	19JUL95	20	10	10	5.0	2	100.0	100.0
		WEEK 3	26JUL95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	03AUG95	40	8	32	8.0	4	100.0	100.0
		WEEK 5	08AUG95	40	20	20	5.0	4	100.0	100.0
		WEEK 6	15AUG95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	24AUG95	40	4	36	9.0	4	100.0	100.0
		WEEK 8	29AUG95	40	20	20	5.0	4	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00134	99.5	DOWN TITRATION	12SEP95	44	18	26	11.0	3	100.0	78.8
329.009.00137	99.5	WEEK 1	17OCT95	20	7	13	7.0	2	100.0	92.9
		WEEK 2	24OCT95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	31OCT95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	07NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	14NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	21NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	28NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	05DEC95	40	12	28	7.0	4	100.0	100.0
329.009.00171	50.0	WEEK 1	14NOV95	20	12	8	7.0	2	57.0	57.1
329.009.00172	97.9	WEEK 1	20NOV95	20	8	12	7.0	2	86.0	85.7
		WEEK 2	27NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	04DEC95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	11DEC95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	21DEC95	40	2	38	10.0	4	95.0	95.0
		WEEK 6	27DEC95	40	16	24	6.0	4	100.0	100.0
		WEEK 7	03JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	09JAN96	40	16	24	6.0	4	100.0	100.0
		WEEK 12	07FEB96	160	46	114	29.0	4	98.0	98.3
		WEEK 16	04MAR96	160	70	90	26.0	4	87.0	86.5
		WEEK 20	01APR96	160	62	98	28.0	4	88.0	87.5
		WEEK 24	29APR96	160	67	93	28.0	4	83.0	83.0
		WEEK 28	10JUN96	160	27	133	42.0	4	79.0	79.2
		WEEK 32	08JUL96	160	66	94	28.0	4	84.0	83.9
		DOWN TITRATION	22JUL96	44	16	28	14.0	4	100.0	93.3
				44	16	28	14.0	3	100.0	93.3
				44	16	28	14.0	2	100.0	93.3
				44	16	28	14.0	2	100.0	93.3
329.009.00194	100.0	WEEK 1	12DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	19DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	27DEC95	30	6	24	8.0	3	100.0	100.0
		WEEK 4	02JAN96	40	16	24	6.0	4	100.0	100.0
		WEEK 5	09JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	16JAN96	40	12	28	7.0	4	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00194	100.0	WEEK 7	23JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	30JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	27FEB96	160	56	104	28.0	4	93.0	92.9
		WEEK 16	02APR96	160	20	140	35.0	4	100.0	100.0
		WEEK 20	30APR96	160	63	97	28.0	4	87.0	86.6
		WEEK 24	04JUN96	160	26	134	35.0	4	96.0	95.7
		DOWN TITRATION	.	44	.	.	.	4	.	.
329.009.00195	98.5	WEEK 1	19DEC95	20	12	8	4.0	2	100.0	100.0
		WEEK 2	27DEC95	20	4	16	8.0	2	100.0	100.0
		WEEK 3	02JAN96	30	13	17	6.0	3	94.0	94.4
		WEEK 4	08JAN96	40	16	24	6.0	4	100.0	100.0
329.009.00199	82.7	WEEK 1	23JAN96	20	7	13	7.0	2	93.0	92.9
		WEEK 2	29JAN96	20	11	9	6.0	2	75.0	75.0
		WEEK 3	07FEB96	30	6	24	9.0	3	89.0	88.9
		WEEK 4	14FEB96	40	16	24	7.0	4	86.0	85.7
		WEEK 5	21FEB96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	28FEB96	50	21	29	7.0	5	83.0	82.9
		WEEK 7	06MAR96	50	23	27	7.0	5	77.0	77.1
		WEEK 8	13MAR96	50	25	25	7.0	5	71.0	71.4
329.009.00203	90.7	WEEK 1	11MAR96	20	5	14	7.0	2	100.0	100.0
		WEEK 2	19MAR96	20	5	15	8.0	2	94.0	93.8
		WEEK 3	26MAR96	30	10	20	7.0	3	95.0	95.2
329.009.00236	88.0	WEEK 1	06JAN97	20	7	13	7.0	2	93.0	92.9
		WEEK 2	15JAN97	20	4	16	9.0	2	89.0	88.9
		WEEK 3	20JAN97	30	15	15	5.0	3	100.0	100.0
		WEEK 4	27JAN97	40	18	22	7.0	4	79.0	78.6
329.009.00239	91.3	WEEK 1	25NOV96	20	8	12	6.0	2	100.0	100.0
		WEEK 2	02DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	09DEC96	30	10	20	7.0	3	95.0	95.2
		WEEK 4	16DEC96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	23DEC96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	30DEC96	40	24	16	7.0	4	57.0	57.1
		WEEK 7	06JAN97	40	16	24	7.0	4	86.0	85.7
		WEEK 8	15JAN97	40	4	36	9.0	4	100.0	100.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00239	91.3	WEEK 12	18FEB97	160	28	132	34.0	4	97.0	97.1
		WEEK 16	17MAR97	160	72	88	27.0	4	81.0	81.5
		WEEK 20	14APR97	160	64	96	28.0	4	86.0	85.7
		WEEK 24	12MAY97	160	48	.	28.0	4	.	.
329.009.00262	94.9	WEEK 1	24FEB97	20	6	14	7.0	2	100.0	100.0
		WEEK 2	03MAR97	20	6	14	7.0	2	100.0	100.0
		WEEK 3	07MAR97	30	20	10	4.0	3	83.0	83.3
		WEEK 4	17MAR97	40	0	40	10.0	4	100.0	100.0
		WEEK 5	24MAR97	40	12	28	7.0	4	100.0	100.0
		WEEK 6	31MAR97	40	12	28	7.0	4	100.0	100.0
		WEEK 7	07APR97	40	12	28	7.0	4	100.0	100.0
		WEEK 8	14APR97	40	16	24	7.0	4	86.0	85.7
329.009.00264	93.4	WEEK 1	08NOV96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	11NOV96	20	15	5	3.0	2	83.0	83.3
		WEEK 3	18NOV96	30	10	20	7.0	3	95.0	95.2
		WEEK 4	25NOV96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	02DEC96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	11DEC96	40	10	30	9.0	4	83.0	83.3
		WEEK 7	16DEC96	40	20	20	5.0	4	100.0	100.0
		WEEK 8	23DEC96	40	12	28	7.0	4	100.0	100.0
329.009.00301	100.0	WEEK 1	26MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	05APR96	20	1	19	10.0	2	95.0	95.0
		WEEK 3	12APR96	30	8	22	7.0	3	105.0	104.8
		WEEK 4	16APR96	40	24	16	4.0	4	100.0	100.0
		WEEK 5	23APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	30APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	07MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	14MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	11JUN96	160	94	66	28.0	4	59.0	58.9
		DOWN TITRATION	25JUN96	44	16	28	15.0	4	100.0	93.3
				44	16	28	15.0	3	100.0	93.3
				44	16	28	15.0	2	100.0	93.3
				44	16	28	15.0	2	100.0	93.3
329.009.00305	92.7	WEEK 1	14MAY96	20	7	13	7.0	2	93.0	92.9
		WEEK 2	21MAY96	20	6	14	7.0	2	100.0	100.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00305	92.7	WEEK 3	28MAY96	30	12	18	7.0	3	86.0	85.7
		WEEK 4	04JUN96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	11JUN96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	19JUN96	40	12	28	8.0	4	88.0	87.5
		WEEK 7	25JUN96	40	18	22	6.0	4	92.0	91.7
		WEEK 8	03JUL96	40	12	28	8.0	4	88.0	87.5
		WEEK 12	06AUG96	160	49	111	35.0	4	79.0	79.3
		WEEK 16	27AUG96	160	93	67	21.0	4	80.0	79.8
		WEEK 20	24SEP96	160	64	96	28.0	4	86.0	85.7
		WEEK 24	29OCT96	160	40	120	35.0	4	86.0	85.7
		WEEK 28	03DEC96	160	38	122	35.0	4	87.0	87.1
		WEEK 32	10JAN97	160	30	130	38.0	4	86.0	85.5
		DOWN TITRATION	28JAN97	44	20	24	18.0	4	86.0	80.0
				44	20	24	18.0	3	86.0	80.0
				44	20	24	18.0	2	86.0	80.0
				44	20	24	18.0	2	86.0	80.0
329.009.00325	98.9	WEEK 1	03SEP96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	09SEP96	20	8	12	6.0	2	100.0	100.0
		WEEK 3	16SEP96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	23SEP96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	30SEP96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	10OCT96	40	2	38	10.0	4	95.0	95.0
		WEEK 7	14OCT96	40	24	16	4.0	4	100.0	100.0
		WEEK 8	21OCT96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	18NOV96	160	52	108	28.0	4	96.0	96.4
		WEEK 16	16DEC96	160	60	100	28.0	4	89.0	89.3
		DOWN TITRATION	30DEC96	44	16	28	12.0	4	100.0	93.3
				44	16	28	12.0	3	100.0	93.3
				44	16	28	12.0	2	100.0	93.3
				44	16	28	12.0	2	100.0	93.3
329.009.00326	93.4	WEEK 1	09SEP96	20	12	8	4.0	2	100.0	100.0
		WEEK 2	16SEP96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	23SEP96	30	8	21	7.0	3	100.0	100.0
		WEEK 4	30SEP96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	07OCT96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	17OCT96	40	12	28	10.0	4	70.0	70.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00326	93.4	WEEK 7	24OCT96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	28OCT96	40	24	16	4.0	4	100.0	100.0
		WEEK 12	25NOV96	160	48	112	28.0	4	100.0	100.0
		WEEK 16	16DEC96	160	76	84	21.0	4	100.0	100.0
		DOWN TITRATION	28DEC96	44	16	28	12.0	4	100.0	93.3
				44	16	28	12.0	3	100.0	93.3
				44	16	28	12.0	2	100.0	93.3
				44	16	28	12.0	2	100.0	93.3
329.010.00279	100.4	WEEK 1	29MAR96	20	3	17	7.0	2	120.0	121.4
		WEEK 2	05APR96	20	8	12	7.0	2	86.0	85.7
		WEEK 3	12APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	19APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	25APR96	50	20	30	6.0	5	100.0	100.0
		WEEK 6	03MAY96	60	12	48	8.0	6	100.0	100.0
		WEEK 7	10MAY96	60	18	42	7.0	6	100.0	100.0
		WEEK 8	17MAY96	60	18	42	7.0	6	100.0	100.0
		WEEK 12	14JUN96	276	111	165	28.0	6	98.0	98.2
		WEEK 16	11JUL96	240	78	162	27.0	6	100.0	100.0
		WEEK 20	08AUG96	240	72	168	28.0	6	100.0	100.0
		WEEK 24	05SEP96	240	70	170	28.0	6	101.0	101.2
		WEEK 28	02OCT96	240	78	162	27.0	6	100.0	100.0
		WEEK 32	06NOV96	240	85	155	34.0	6	90.0	84.7
				240	85	155	34.0	5	90.0	84.7
		DOWN TITRATION	22NOV96	44	0	44	16.0	5	100.0	100.0
				44	0	44	16.0	4	100.0	100.0
				44	0	44	16.0	3	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
329.010.00281	100.8	WEEK 1	02AUG96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	09AUG96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	19AUG96	30	0	30	10.0	3	100.0	100.0
		WEEK 4	26AUG96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	04SEP96	50	3	47	10.0	5	94.0	94.0
		WEEK 6	09SEP96	60	30	30	6.0	6	83.3	83.3
		WEEK 7	18SEP96	60	6	54	9.0	6	100.0	100.0
		WEEK 8	25SEP96	60	18	42	7.0	6	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.010.00281	100.8	WEEK 12	25OCT96	240	60	180	30.0	6	100.0	100.0
		WEEK 16	20NOV96	240	93	147	26.0	6	94.0	94.2
		WEEK 20	20DEC96	240	78	162	30.0	6	90.0	90.0
		WEEK 24	03JAN97	240	156	84	14.0	6	100.0	100.0
		DOWN TITRATION	29JAN97	44	0	44	16.0	5	100.0	100.0
				44	0	44	16.0	4	100.0	100.0
				44	0	44	16.0	3	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
				44	0	44	16.0	2	100.0	100.0
329.011.00163	97.2	WEEK 1	01DEC95	20	8	12	7.0	2	85.7	85.7
		WEEK 2	11DEC95	20	0	20	10.0	2	100.0	100.0
		WEEK 3	18DEC95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	27DEC95	40	24	16	9.0	4	44.4	44.4
329.011.00208	100.0	WEEK 1	11SEP96	20	8	12	6.0	2	100.0	100.0
		WEEK 2	17SEP96	20	8	12	6.0	2	100.0	100.0
		WEEK 3	26SEP96	30	3	27	9.0	3	100.0	100.0
		WEEK 4	03OCT96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	10OCT96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	17OCT96	60	18	42	7.0	6	100.0	100.0
		WEEK 7	24OCT96	60	18	42	7.0	6	100.0	100.0
		WEEK 8	03NOV96	60	0	60	10.0	6	100.0	100.0
		WEEK 12	08NOV96	240	213	27	5.0	6	100.0	90.0
		DOWN TITRATION	23NOV96	44	16	28	.	5	.	75.7
				44	16	28	.	4	.	75.7
				44	16	28	.	3	.	75.7
				44	16	28	.	2	.	75.7
				44	16	28	.	1	.	75.7
329.011.00209	98.6	WEEK 1	19SEP96	20	2	18	9.0	2	100.0	100.0
		WEEK 2	26SEP96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	03OCT96	30	11	19	7.0	3	90.0	90.5
		WEEK 4	11OCT96	40	8	32	8.0	4	100.0	100.0
		WEEK 5	17OCT96	40	16	24	6.0	4	100.0	100.0
		WEEK 6	24OCT96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	01NOV96	40	8	32	8.0	4	100.0	100.0
		WEEK 8	11NOV96	50	1	49	10.0	5	98.0	98.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.011.00209	98.6	WEEK 12	18DEC96	200	25	175	37.0	5	95.0	94.6
		DOWN TITRATION	18DEC96	44	.	.	.	5	.	.
329.011.00284	100.0	WEEK 1	28MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	05APR96	20	4	16	8.0	2	100.0	100.0
		WEEK 3	11APR96	30	12	18	6.0	3	100.0	100.0
		WEEK 4	19APR96	40	8	32	8.0	4	100.0	100.0
		WEEK 5	25APR96	40	16	24	6.0	4	100.0	100.0
		WEEK 6	02MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	09MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	16MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 12	10JUN96	200	85	115	25.0	5	92.0	92.0
		WEEK 16	08JUL96	200	73	127	28.0	5	90.7	90.7
		WEEK 20	05AUG96	200	60	140	28.0	5	100.0	100.0
		WEEK 24	.	200	.	.	.	5	.	.
329.011.00286	95.1	WEEK 1	14JUN96	20	2	18	9.0	2	100.0	100.0
		WEEK 2	21JUN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28JUN96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	08JUL96	40	2	38	10.0	4	95.0	95.0
		WEEK 5	17JUL96	50	8	42	9.0	5	93.0	93.3
		WEEK 6	24JUL96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	02AUG96	60	15	45	9.0	6	83.0	83.3
		WEEK 8	09AUG96	60	0	60	10.0	6	100.0	100.0
		WEEK 12	17SEP96	240	54	186	36.0	6	86.0	86.1
		WEEK 16	24OCT96	240	87	153	37.0	6	69.0	68.9
		WEEK 20	25NOV96	240	84	156	32.0	6	81.0	81.3
		WEEK 24	30DEC96	240	69	171	35.0	6	81.4	81.4
		WEEK 28	30DEC96	240	.	.	.	6	.	.
329.012.00026	.	WEEK 1	05DEC95	20	.	.	.	2	.	.
		WEEK 2	05DEC95	20	.	.	.	2	.	.
329.012.00219	99.0	WEEK 1	07JUN96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14JUN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	24JUN96	30	0	30	10.0	3	100.0	100.0
		WEEK 4	02JUL96	40	8	32	8.0	4	100.0	100.0
		WEEK 5	09JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	16JUL96	40	12	28	7.0	4	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.012.00219	99.0	WEEK 7	23JUL96	40	14	26	7.0	4	93.0	92.9
		WEEK 8	30JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	30AUG96	160	42	118	32.0	4	92.0	92.2
		WEEK 16	26SEP96	160	70	90	28.0	4	80.0	80.4
		WEEK 20	25OCT96	160	70	90	29.0	4	78.0	77.6
		WEEK 24	22NOV96	160	66	94	27.0	4	87.0	87.0
		WEEK 28	20DEC96	160	62	98	27.0	4	91.0	90.7
		WEEK 32	24JAN97	160	76	84	29.0	4	72.0	72.4
329.012.00221	100.0	WEEK 1	02JUL96	20	5	15	7.0	2	107.0	107.1
		WEEK 2	09JUL96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	16JUL96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	23JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	30JUL96	50	10	40	8.5	5	94.0	94.1
		WEEK 6	09AUG96	40	2	38	9.5	4	100.0	100.0
		WEEK 7	19AUG96	40	4	36	9.5	4	95.0	94.7
		WEEK 8	27AUG96	40	6	34	8.5	4	100.0	100.0
		WEEK 12	23SEP96	160	55	105	28.0	4	94.0	93.8
		WEEK 16	21OCT96	160	54	106	28.0	4	95.0	94.6
		WEEK 20	04NOV96	160	108	52	13.0	4	100.0	100.0
329.012.00223	98.5	WEEK 1	06SEP96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	16SEP96	20	.	.	.	2	.	.
		WEEK 3	23SEP96	30	8	22	7.5	3	98.0	97.8
		WEEK 4	01OCT96	40	10	30	8.0	4	94.0	93.8
329.012.00227	91.7	WEEK 1	27DEC96	20	3	17	9.0	2	94.0	94.4
		WEEK 2	06JAN97	20	16	4	10.0	2	80.0	20.0
		WEEK 3	15JAN97	30	4	26	9.0	3	96.0	96.3
		WEEK 4	24JAN97	40	4	36	9.0	4	100.0	100.0
		WEEK 5	04FEB97	44	0	44	11.0	4	100.0	100.0
		WEEK 6	14FEB97	40	2	38	10.0	4	95.0	95.0
		WEEK 7	20FEB97	50	20	30	6.0	5	100.0	100.0
		WEEK 8	25FEB97	50	25	25	5.0	5	100.0	100.0
		WEEK 12	27MAR97	240	72	168	30.0	6	93.0	93.3
		WEEK 16	25APR97	240	72	168	29.0	6	97.0	96.6
		WEEK 20	26MAY97	240	72	168	31.0	6	90.0	90.3
		WEEK 24	25JUN97	240	69	171	29.0	6	98.0	98.3
		WEEK 28	21JUL97	240	93	147	26.0	6	94.0	94.2
		WEEK 32	19AUG97	240	111	129	29.0	6	74.0	74.1

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.012.00227	91.7	DOWN TITRATION	24SEP97	42	10	32	16.0	5	76.0	72.7
				42	10	32	16.0	4	76.0	72.7
				42	10	32	16.0	3	76.0	72.7
				42	10	32	16.0	2	76.0	72.7
				42	10	32	16.0	2	76.0	72.7
329.012.00230	91.4	WEEK 1	07MAR97	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14MAR97	20	7	13	7.0	2	93.0	92.9
		WEEK 3	24MAR97	30	4	26	10.0	3	86.0	86.7
		WEEK 4	03APR97	40	0	40	10.0	4	100.0	100.0
		WEEK 5	11APR97	40	12	28	8.0	4	88.0	87.5
		WEEK 6	23APR97	40	0	40	10.0	4	100.0	100.0
		WEEK 7	02MAY97	40	8	32	11.0	4	73.0	72.7
		WEEK 8	08MAY97	50	20	30	6.0	5	100.0	100.0
		WEEK 12	16MAY97	200	181	19	5.0	5	76.0	76.0
		DOWN TITRATION	26MAY97	48	22	26	13.0	4	81.2	83.9
				48	22	26	13.0	3	81.2	83.9
				48	22	26	13.0	2	81.2	83.9
				48	22	26	13.0	2	81.2	83.9

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.001.00062	84.9	WEEK 1	27OCT94	20	8	12	7.0	2	86.0	85.7
		WEEK 2	03NOV94	20	10	10	7.0	2	71.0	71.4
		WEEK 3	10NOV94	30	10	20	7.0	3	95.0	95.2
		WEEK 4	15NOV94	40	20	20	5.0	4	100.0	100.0
329.001.00064	100.0	WEEK 1	16NOV94	20	8	12	6.0	2	100.0	100.0
		WEEK 2	22NOV94	20	8	12	6.0	2	100.0	100.0
		WEEK 3	29NOV94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	06DEC94	40	12	28	7.0	4	100.0	100.0
		WEEK 5	13DEC94	40	12	28	7.0	4	100.0	100.0
		WEEK 6	20DEC94	40	12	28	7.0	4	100.0	100.0
		WEEK 7	27DEC94	40	12	28	7.0	4	100.0	100.0
		WEEK 8	03JAN95	40	12	28	7.0	4	100.0	100.0
		WEEK 12	31JAN95	160	48	112	28.0	4	100.0	100.0
		WEEK 16	28FEB95	160	48	112	28.0	4	100.0	100.0
		WEEK 20	28MAR95	160	48	112	28.0	4	100.0	100.0
		DOWN TITRATION	14APR95	25	0	25	17.0	4	100.0	36.8
329.001.00069	100.0	WEEK 1	23FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	02MAR95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	09MAR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	16MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	23MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 6	30MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	06APR95	50	15	35	7.0	5	100.0	100.0
		WEEK 8	13APR95	60	18	42	7.0	6	100.0	100.0
329.001.00071	100.0	WEEK 1	02MAR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	09MAR95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	16MAR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	23MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	30MAR95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	06APR95	50	8	42	7.0	6	100.0	100.0
		WEEK 7	13APR95	60	18	42	7.0	6	100.0	100.0
		WEEK 8	20APR95	60	18	42	7.0	6	100.0	100.0
329.001.00123	97.5	WEEK 1	12JAN96	20	4	16	8.0	2	100.0	100.0
		WEEK 2	18JAN96	20	8	12	6.0	2	100.0	100.0
		WEEK 3	25JAN96	30	9	21	7.0	3	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.001.00123	97.5	WEEK 4	01FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	08FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	15FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	22FEB96	40	16	24	7.0	4	86.0	85.7
329.001.00207	100.0	WEEK 1	06MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	13MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	20MAR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	26MAR96	40	16	24	6.0	4	100.0	100.0
		WEEK 5	03APR96	40	8	32	8.0	4	100.0	100.0
		WEEK 6	10APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	17APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	24APR96	40	12	28	7.0	4	100.0	100.0
329.002.00049	97.6	WEEK 1	15MAR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	22MAR95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	29MAR95	30	10	20	7.0	3	95.0	95.2
		WEEK 4	05APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	12APR95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	19APR95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	27APR95	60	17	43	7.5	6	93.0	95.6
		WEEK 8	05MAY95	60	12	48	7.5	6	94.0	106.7
329.002.00059	96.3	WEEK 1	17NOV94	20	5	15	7.0	2	107.0	107.1
		WEEK 2	23NOV94	20	8	12	6.0	2	100.0	100.0
		WEEK 3	01DEC94	30	6	24	8.0	3	100.0	100.0
		WEEK 4	08DEC94	40	16	24	7.0	4	86.0	85.7
		WEEK 5	15DEC94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	22DEC94	60	18	42	7.0	6	100.0	100.0
		WEEK 7	29DEC94	60	18	42	7.0	6	100.0	100.0
		WEEK 8	05JAN95	60	18	42	7.0	6	100.0	100.0
329.002.00060	99.2	WEEK 1	07FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	21FEB95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	28FEB95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	07MAR95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	14MAR95	60	17	43	7.0	6	102.0	102.4
		WEEK 7	21MAR95	60	21	39	7.0	6	92.8	92.9
		WEEK 8	28MAR95	60	18	42	7.0	6	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00060	99.2	WEEK 12	25APR95	240	120	120	28.0	6	71.0	71.4
329.002.00097	96.4	WEEK 1	10JAN95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	18JAN95	20	7	13	8.0	2	81.0	81.3
		WEEK 3	24JAN95	30	12	18	6.0	3	100.0	100.0
		WEEK 4	31JAN95	40	14	26	6.0	4	108.0	108.3
		WEEK 5	07FEB95	50	18	32	7.0	5	91.0	91.4
		WEEK 6	14FEB95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	21FEB95	60	18	42	7.0	6	100.0	100.0
		WEEK 8	02MAR95	60	9	51	9.0	6	94.0	94.4
		WEEK 12	30MAR95	240	117	123	28.0	6	73.0	73.2
		WEEK 16	27APR95	240	51	189	28.0	6	112.0	112.5
		WEEK 20	23MAY95	240	90	150	26.0	6	96.0	96.2
		WEEK 24	29JUN95	240	104	136	37.0	6	61.0	61.3
		WEEK 28	01AUG95	240	87	153	32.0	6	80.0	79.7
		WEEK 32	05SEP95	240	57	183	34.0	6	89.0	89.7
		DOWN TITRATION	01NOV95	44	0	44	15.0	5	116.0	118.9
				44	0	44	15.0	4	116.0	118.9
				44	0	44	15.0	3	116.0	118.9
				44	0	44	15.0	2	116.0	118.9
				44	0	44	15.0	1	116.0	118.9
329.002.00101	94.2	WEEK 1	04APR95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	13APR95	20	7	13	8.0	2	81.0	81.3
		WEEK 3	20APR95	30	13	17	7.0	3	80.9	81.0
		WEEK 4	27APR95	40	14	26	7.0	4	92.8	92.9
		WEEK 5	04MAY95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	11MAY95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	18MAY95	60	21	39	7.0	6	92.8	92.9
		WEEK 8	25MAY95	60	18	42	7.0	6	100.0	100.0
		WEEK 12	22JUN95	.	.	.	28.0	6	94.0	.
		WEEK 16	27JUN95	.	3	12	5.0	6	100.0	40.0
		DOWN TITRATION	11JUL95	44	0	44	14.0	5	100.0	137.5
				44	0	44	14.0	4	100.0	137.5
				44	0	44	14.0	3	100.0	137.5
				44	0	44	14.0	2	100.0	137.5
				44	0	44	14.0	1	100.0	137.5

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00107	96.2	WEEK 1	01FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	08FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	13FEB96	30	15	15	5.0	3	100.0	100.0
		WEEK 4	20FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	27FEB96	40	16	24	7.0	4	86.0	85.7
		WEEK 6	05MAR96	40	14	26	7.0	4	93.0	92.9
		WEEK 7	15MAR96	50	2	48	10.0	5	96.0	96.0
		WEEK 8	21MAR96	60	24	36	6.0	6	100.0	100.0
		WEEK 12	23APR96	240	120	120	33.0	6	60.0	60.6
		WEEK 16	21MAY96	240	82	158	28.0	6	94.0	94.0
		WEEK 20	20JUN96	240	39	201	30.0	6	111.0	111.7
		WEEK 24	18JUL96	240	39	201	35.0	6	95.0	95.7
		WEEK 28	29AUG96	240	30	210	35.0	6	100.0	100.0
		WEEK 32	26SEP96	240	66	174	29.0	6	100.0	100.0
		DOWN TITRATION	09OCT96	44	0	44	16.0	5	100.0	55.0
329.002.00241	98.6	WEEK 1	13FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	22FEB96	20	2	18	9.0	2	100.0	100.0
		WEEK 3	27FEB96	30	18	12	5.0	3	80.0	80.0
		WEEK 4	05MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	12MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	19MAR96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	26MAR96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	02APR96	60	18	42	7.0	6	100.0	100.0
		WEEK 12	30APR96	240	75	165	28.0	6	98.0	98.2
		WEEK 16	.	240	.	.	.	6	.	.
329.002.00246	95.7	WEEK 1	25APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	02MAY96	20	7	13	7.0	2	93.0	92.9
		WEEK 3	09MAY96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	16MAY96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	23MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	30MAY96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	04JUN96	50	25	25	5.0	5	100.0	100.0
		WEEK 8	18JUN96	120	46	74	14.0	6	88.0	88.1
329.002.00320	99.2	WEEK 1	23MAY96	20	5	15	7.0	2	107.0	107.1
		WEEK 2	30MAY96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	04JUN96	30	13	17	5.0	3	113.0	113.3

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.002.00320	99.2	WEEK 4	18JUN96	80	25	54	14.0	4	96.0	96.4
		WEEK 5	25JUN96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	02JUL96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	09JUL96	60	18	42	7.0	6	100.0	100.0
		WEEK 8	16JUL96	60	21	39	7.0	6	92.0	92.9
		WEEK 12	13AUG96	240	74	166	28.0	6	99.0	98.8
		WEEK 16	17SEP96	240	47	193	34.0	6	95.0	94.6
		WEEK 20	.	240	195	45	8.0	6	94.0	93.8
		DOWN TITRATION	08OCT96	44	0	44	12.0	5	100.0	73.3
329.002.00323	92.3	WEEK 1	19NOV96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	26NOV96	20	6	14	7.0	4	100.0	50.0
		WEEK 3	05DEC96	30	3	27	9.0	3	100.0	100.0
		WEEK 4	10DEC96	40	20	20	5.0	4	100.0	100.0
		WEEK 5	17DEC96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	26DEC96	40	6	34	9.0	4	94.0	94.4
		WEEK 7	02JAN97	40	12	28	7.0	4	100.0	100.0
		WEEK 8	09JAN97	40	12	28	7.0	4	100.0	100.0
		WEEK 12	04FEB97	160	57	103	26.0	4	99.0	99.0
		WEEK 16	04MAR97	160	50	110	28.0	4	99.0	98.2
		WEEK 20	03APR97	200	50	150	30.0	5	100.0	100.0
		WEEK 24	30APR97	200	67	133	27.0	5	98.0	98.5
		WEEK 28	27MAY97	200	67	133	29.0	5	91.0	91.7
		WEEK 32	12JUN97	200	120	80	16.0	5	100.0	100.0
		DOWN TITRATION	26JUN97	34	0	34	14.0	5	100.0	87.2
				34	0	34	14.0	4	100.0	87.2
				34	0	34	14.0	3	100.0	87.2
				34	0	34	14.0	2	100.0	87.2
				34	0	34	14.0	1	100.0	87.2
329.003.00074	85.4	WEEK 1	01FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	08FEB95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	15FEB95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	21FEB95	40	18	22	6.0	4	92.0	91.7
		WEEK 5	01MAR95	50	12	38	8.0	5	95.0	95.0
		WEEK 6	15MAR95	60	3	57	15.0	6	63.0	63.3
		WEEK 8	22MAR95	60	21	39	7.0	6	93.0	92.9
		WEEK 12	19APR95	240	66	174	28.0	6	103.5	103.6

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00074	85.4	WEEK 16	17MAY95	240	78	162	27.0	6	100.0	100.0
		WEEK 20	19JUN95	240	73	167	34.0	6	68.0	81.9
		WEEK 24	24JUL95	240	61	179	35.0	6	85.0	85.2
		WEEK 28	30AUG95	240	51	189	37.0	6	85.0	85.1
		WEEK 32	11OCT95	240	0	240	42.0	6	95.0	95.2
		DOWN TITRATION	.	44	.	.	.	5	.	.
329.003.00078	100.0	WEEK 1	02MAY95	20	8	12	6.0	2	100.0	100.0
		WEEK 2	10MAY95	20	4	16	8.0	2	100.0	100.0
		WEEK 3	17MAY95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	24MAY95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	30MAY95	50	20	30	6.0	5	100.0	100.0
		WEEK 6	07JUN95	60	12	48	8.0	6	100.0	100.0
		WEEK 7	15JUN95	60	12	48	8.0	6	100.0	100.0
		WEEK 8	21JUN95	60	18	42	6.0	6	116.0	116.7
329.003.00080	96.1	WEEK 1	04DEC95	20	7	13	7.0	2	92.0	92.9
		WEEK 2	07DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	18DEC95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	29DEC95	40	4	36	11.0	4	80.0	81.8
		WEEK 5	04JAN96	40	14	26	6.0	4	108.0	108.3
		WEEK 6	10JAN96	50	19	31	6.0	5	103.0	103.3
		WEEK 7	17JAN96	60	18	42	7.0	6	100.0	100.0
		WEEK 8	24JAN96	60	21	39	7.0	6	93.0	92.9
329.003.00085	87.4	WEEK 1	14NOV94	20	8	12	7.0	2	86.0	85.7
		WEEK 2	21NOV94	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28NOV94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	05DEC94	40	11	29	7.0	4	100.0	103.6
		WEEK 5	12DEC94	50	29	21	7.0	5	60.0	60.0
		WEEK 6	19DEC94	60	18	42	7.0	6	100.0	100.0
		WEEK 7	27DEC94	60	17	43	8.0	6	90.0	89.6
		WEEK 8	03JAN95	60	27	33	7.0	6	78.0	78.6
329.003.00086	103.8	WEEK 1	05DEC94	20	4	16	7.0	2	100.0	114.3
		WEEK 2	12DEC94	20	7	13	7.0	2	93.0	92.9
		WEEK 3	19DEC94	30	9	21	7.0	3	100.0	100.0
		WEEK 4	27DEC94	40	8	32	8.0	4	100.0	100.0
		WEEK 5	03JAN95	50	15	35	7.0	5	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00086	103.8	WEEK 6	09JAN95	60	14	46	6.0	6	128.0	127.8
		WEEK 7	17JAN95	60	12	48	7.0	6	120.0	114.3
		WEEK 8	23JAN95	60	24	36	6.0	6	100.0	100.0
		WEEK 12	13FEB95	240	87	153	28.0	6	91.0	91.1
		WEEK 16	28MAR95	240	45	195	35.0	6	93.0	92.9
		WEEK 20	25APR95	240	87	153	28.0	6	91.0	91.1
		WEEK 24	30MAY95	240	39	201	35.0	6	96.0	95.7
		WEEK 28	11JUL95	240	18	222	41.0	6	90.0	90.2
		WEEK 32	17AUG95	240	78	162	36.0	6	75.0	75.0
		DOWN TITRATION	02SEP95	44	3	41	19.0	5	72.0	107.9
				44	3	41	19.0	4	72.0	107.9
				44	3	41	19.0	3	72.0	107.9
				44	3	41	19.0	2	72.0	107.9
				44	3	41	19.0	1	72.0	107.9
329.003.00094	95.5	WEEK 1	31OCT95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	07NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	14NOV95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	21NOV95	40	14	26	7.0	4	92.0	92.9
		WEEK 5	28NOV95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	05DEC95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	12DEC95	60	21	39	7.0	6	90.0	92.9
		WEEK 8	19DEC95	60	18	42	7.0	6	100.0	100.0
329.003.00251	.	WEEK 1	04APR96	20	.	.	.	2	.	.
		WEEK 2	09APR96	20	.	.	.	2	.	.
		WEEK 3	.	30	.	.	.	3	.	.
329.003.00252	97.3	WEEK 1	16APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	23APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	30APR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	09MAY96	40	6	34	9.0	4	94.0	94.4
		WEEK 5	14MAY96	40	20	20	5.0	4	100.0	100.0
		WEEK 6	21MAY96	50	20	30	7.0	5	85.0	85.7
		WEEK 7	28MAY96	40	0	40	8.0	4	125.0	125.0
		WEEK 8	04JUN96	40	0	40	8.0	4	125.0	125.0
329.003.00291	100.0	WEEK 1	15JUL96	20	.	.	.	2	.	.
		WEEK 2	24JUL96	20	.	.	15.0	2	.	.

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.003.00291	100.0	WEEK 3	31JUL96	30	9	21	8.0	3	87.5	87.5
		WEEK 4	07AUG96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	14AUG96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	21AUG96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	28AUG96	40	12	28	8.0	4	88.0	87.5
		WEEK 8	04SEP96	50	5	45	8.0	5	112.0	112.5
		WEEK 12	02OCT96	200	58	142	27.0	5	105.0	105.2
		WEEK 16	30OCT96	200	.	.	29.0	5	.	.
		WEEK 20	.	200	.	.	29.0	5	.	.
329.003.00315	94.2	WEEK 1	21NOV96	20	3	17	10.0	2	85.0	85.0
		WEEK 2	26NOV96	20	11	9	5.0	2	90.0	90.0
		WEEK 3	03DEC96	30	8	22	8.0	3	91.6	91.7
		WEEK 4	12DEC96	40	6	34	10.0	4	85.0	85.0
		WEEK 5	17DEC96	40	20	20	6.0	4	83.0	83.3
		WEEK 6	23DEC96	40	18	22	6.0	4	92.0	91.7
		WEEK 7	.	40	14	26	8.0	4	100.0	81.3
		WEEK 8	07JAN97	40	12	28	7.0	4	100.0	100.0
329.003.00316	110.0	WEEK 1	23DEC96	20	8	12	7.0	2	86.0	85.7
		WEEK 2	30DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	07JAN97	30	24	6	8.0	3	25.0	25.0
		WEEK 4	14JAN97	40	12	28	7.0	4	100.0	100.0
		WEEK 5	21JAN97	50	19	31	7.0	5	89.0	88.6
		WEEK 6	28JAN97	60	21	39	7.0	6	93.0	92.9
		WEEK 7	04FEB97	60	24	36	6.0	6	100.0	100.0
		WEEK 8	11FEB97	104	18	86	16.0	6	100.0	89.6
329.004.00016	98.2	WEEK 1	20MAR95	20	4	16	7.0	2	107.0	114.3
		WEEK 2	29MAR95	20	2	18	9.0	2	100.0	100.0
		WEEK 3	05APR95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	12APR95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	19APR95	40	12	28	7.0	4	100.0	100.0
329.004.00018	102.6	WEEK 1	11MAY95	20	7	13	7.0	2	98.0	92.9
		WEEK 2	18MAY95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	25MAY95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	01JUN95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	08JUN95	50	7	43	7.0	5	100.0	122.9
		WEEK 6	19JUN95	50	0	50	11.0	5	100.0	90.9

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.004.00018	102.6	WEEK 7	22JUN95	60	36	24	6.0	6	100.0	66.7
		WEEK 8	29JUN95	60	18	42	7.0	6	100.0	100.0
		DOWN TITRATION	13JUL95	44	1	42	15.0	5	100.0	56.0
329.004.00020	56.3	WEEK 1	16NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	24NOV95	20	16	4	8.0	2	10.0	25.0
329.004.00213	97.3	WEEK 1	08AUG96	20	9	11	7.0	2	79.0	78.6
		WEEK 2	15AUG96	20	8	12	7.0	2	86.0	85.7
		WEEK 3	21AUG96	30	12	18	7.0	3	100.0	85.7
		WEEK 4	29AUG96	40	10	30	8.0	4	100.0	93.8
		WEEK 5	03SEP96	40	20	20	5.0	4	91.0	100.0
		WEEK 6	10SEP96	40	12	28	7.0	4	93.0	100.0
		WEEK 7	17SEP96	40	12	28	7.0	4	93.0	100.0
		WEEK 8	24SEP96	40	8	32	9.0	4	89.0	88.9
		WEEK 12	22OCT96	160	56	104	28.0	4	93.0	92.9
		WEEK 16	19NOV96	160	48	112	29.0	4	97.0	96.6
		WEEK 20	20DEC96	160	40	120	32.0	4	94.0	93.8
		WEEK 24	21JAN97	160	36	124	32.0	4	97.0	96.9
		WEEK 28	18FEB97	160	50	110	28.0	4	98.0	98.2
		WEEK 32	19MAR97	160	44	116	29.0	4	100.0	100.0
		DOWN TITRATION	01APR97	44	18	26	15.0	3	100.0	100.0
				44	18	26	15.0	2	100.0	100.0
				44	18	26	15.0	2	100.0	100.0
329.005.00001	102.1	WEEK 1	27APR94	20	8	12	7.0	2	85.0	85.7
		WEEK 2	04MAY94	20	5	15	7.0	2	100.0	107.1
		WEEK 3	11MAY94	30	8	22	7.0	3	100.0	104.8
		WEEK 4	18MAY94	40	10	30	7.0	4	100.0	107.1
		WEEK 5	25MAY94	50	15	35	7.0	5	100.0	100.0
		WEEK 6	01JUN94	60	21	39	7.0	6	100.0	92.9
		WEEK 7	08JUN94	60	15	45	7.0	6	100.0	107.1
		WEEK 8	15JUN94	60	15	45	7.0	6	100.0	107.1
329.005.00005	83.3	WEEK 1	08NOV94	20	5	15	7.0	2	100.0	107.1
329.005.00010	99.6	WEEK 1	20DEC94	20	6	14	7.0	2	100.0	100.0
		WEEK 2	27DEC94	20	7	13	7.0	2	93.0	92.9

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00010	99.6	WEEK 3	04JAN95	30	6	24	8.0	3	100.0	100.0
		WEEK 4	11JAN95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	18JAN95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	25JAN95	60	18	42	7.0	6	100.0	100.0
		WEEK 7	02FEB95	60	12	48	8.0	6	100.0	100.0
		WEEK 8	08FEB95	60	24	36	6.0	6	100.0	100.0
		WEEK 12	10MAR95	240	.	.	30.0	6	100.0	.
		WEEK 16	13APR95	240	36	204	34.0	6	100.0	100.0
		WEEK 20	10MAY95	240	78	162	28.0	6	96.0	96.4
		WEEK 24	06JUN95	240	72	168	27.0	6	104.0	103.7
		WEEK 28	12JUL95	240	21	219	36.5	6	100.0	100.0
		WEEK 32	09AUG95	240	75	165	27.5	6	100.0	100.0
		DOWN TITRATION	06SEP95	44	0	44	28.0	5	100.0	100.0
				44	0	44	28.0	4	100.0	100.0
				44	0	44	28.0	3	100.0	100.0
				44	0	44	28.0	2	100.0	100.0
				44	0	44	28.0	2	100.0	100.0
329.005.00012	96.7	WEEK 1	27DEC94	20	5	15	7.5	2	100.0	100.0
		WEEK 2	05JAN95	20	3	17	9.0	2	94.0	94.4
		WEEK 3	12JAN95	30	10	20	7.0	3	95.0	95.2
		WEEK 4	18JAN95	40	16	24	7.0	4	86.0	85.7
		WEEK 5	25JAN95	50	20	30	7.0	5	85.0	85.7
		WEEK 6	31JAN95	60	24	36	6.0	6	100.0	100.0
		WEEK 7	08FEB95	60	12	48	8.0	6	100.0	100.0
		WEEK 8	16FEB95	60	12	48	8.0	6	100.0	100.0
		WEEK 12	27MAR95	240	27	213	37.0	6	96.0	95.9
		WEEK 16	04MAY95	240	18	222	37.0	6	100.0	100.0
		WEEK 20	31MAY95	240	18	222	37.0	6	100.0	100.0
		WEEK 24	.	240	.	.	.	6	.	.
329.005.00111	97.9	WEEK 1	18JAN95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	25JAN95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	01FEB95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	08FEB95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	15FEB95	40	14	26	7.0	4	93.0	92.9
		WEEK 6	22FEB95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	01MAR95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	08MAR95	40	14	26	7.0	4	93.0	92.9

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00111	97.9	WEEK 12	05APR95	160	50	110	28.0	4	98.0	98.2
		WEEK 16	19APR95	160	106	54	13.5	4	100.0	100.0
		DOWN TITRATION	03MAY95	26	2	24	11.5	3	100.0	126.3
				26	2	24	11.5	2	100.0	126.3
				26	2	24	11.5	1	100.0	126.3
329.005.00114	95.9	WEEK 1	07FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	21FEB95	30	11	19	7.0	3	90.0	90.5
		WEEK 4	28FEB95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	09MAR95	40	4	36	9.0	4	100.0	100.0
		WEEK 6	15MAR95	40	16	24	6.0	4	100.0	100.0
		WEEK 7	22MAR95	40	14	26	7.0	4	93.0	92.9
		WEEK 8	29MAR95	40	16	24	7.0	4	86.0	85.7
		WEEK 12	26APR95	160	62	98	24.5	4	100.0	100.0
		DOWN TITRATION	17MAY95	30	10	20	13.0	4	100.0	87.0
				30	10	20	13.0	3	100.0	87.0
				30	10	20	13.0	2	100.0	87.0
				30	10	20	13.0	1	100.0	87.0
329.005.00115	92.3	WEEK 1	13FEB95	20	7	13	7.0	2	92.0	92.9
		WEEK 2	20FEB95	20	8	12	7.0	2	86.0	85.7
		WEEK 3	02MAR95	30	0	30	10.0	3	100.0	100.0
		WEEK 4	10MAR95	40	10	30	8.0	4	94.0	93.8
		WEEK 5	17MAR95	40	10	30	7.5	4	100.0	100.0
		WEEK 6	28MAR95	40	0	40	10.0	4	100.0	100.0
		WEEK 7	10APR95	40	0	40	12.0	4	83.3	83.3
		WEEK 8	18APR95	40	8	32	8.0	4	100.0	100.0
		WEEK 12	27APR95	160	154	6	9.0	4	13.0	16.7
329.005.00120	92.5	WEEK 1	07SEP95	20	4	16	8.0	2	100.0	100.0
		WEEK 2	14SEP95	20	5	14	7.0	2	100.0	100.0
		WEEK 3	21SEP95	30	11	19	7.0	3	90.4	90.5
		WEEK 4	28SEP95	40	16	24	7.0	4	85.7	85.7
		WEEK 5	05OCT95	50	15	35	7.0	5	100.0	100.0
		WEEK 6	12OCT95	50	18	32	7.0	5	91.4	91.4
		WEEK 7	19OCT95	60	18	42	7.0	6	100.0	100.0
		WEEK 8	26OCT95	60	21	39	7.0	6	92.8	92.9

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00253	86.0	WEEK 1	14FEB96	20	10	10	6.0	2	83.3	83.3
		WEEK 2	21FEB96	20	8	12	7.0	2	85.7	85.7
		WEEK 3	28FEB96	30	11	19	7.0	3	90.4	90.5
		WEEK 4	06MAR96	40	16	24	7.0	4	85.7	85.7
		WEEK 5	14MAR96	50	15	35	8.0	5	87.5	87.5
		WEEK 6	20MAR96	60	30	30	6.0	6	83.3	83.3
		WEEK 7	28MAR96	60	24	36	8.0	6	75.0	75.0
		WEEK 8	03APR96	60	.	.	.	6	.	.
329.005.00254	96.8	WEEK 1	21FEB96	20	7	13	6.5	2	100.0	100.0
		WEEK 2	28FEB96	20	8	12	7.0	2	86.0	85.7
		WEEK 3	06MAR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	13MAR96	40	11	29	7.0	4	100.0	103.6
		WEEK 5	20MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	27MAR96	40	14	26	7.0	4	93.0	92.9
		WEEK 7	03APR96	40	11	28	7.0	4	100.0	100.0
		WEEK 8	10APR96	40	16	24	7.0	4	85.0	85.7
		WEEK 12	22MAY96	160	48	112	28.0	4	100.0	100.0
		WEEK 16	12JUN96	160	36	124	34.0	4	91.0	91.2
		WEEK 20	10JUL96	160	48	112	28.0	4	100.0	100.0
		WEEK 24	07AUG96	160	58	102	28.0	4	91.0	91.1
		WEEK 28	12SEP96	160	32	128	35.0	4	91.0	91.4
		WEEK 32	16OCT96	160	36	124	34.0	4	92.0	91.2
		DOWN TITRATION	30OCT96	44	12	32	14.0	4	100.0	94.1
				44	12	32	14.0	3	100.0	94.1
				44	12	32	14.0	2	100.0	94.1
				44	12	32	14.0	2	100.0	94.1
329.005.00293	91.0	WEEK 1	19MAR97	20	8	12	7.0	2	86.0	85.7
		WEEK 2	25MAR97	20	8	12	6.0	2	100.0	100.0
		WEEK 3	02APR97	30	5	25	8.0	3	100.0	104.2
		WEEK 4	09APR97	40	18	22	7.0	4	79.0	78.6
		WEEK 5	16APR97	50	15	35	7.0	5	100.0	100.0
		WEEK 6	23APR97	60	21	39	7.0	6	93.0	92.9
		WEEK 7	30APR97	60	18	42	7.0	6	100.0	100.0
		WEEK 8	07MAY97	60	24	36	7.0	6	86.0	85.7
329.005.00298	95.7	WEEK 1	30MAY96	20	4	16	8.0	2	100.0	100.0
		WEEK 2	06JUN96	20	6	14	7.0	2	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.005.00298	95.7	WEEK 3	12JUN96	30	14	16	6.0	3	89.0	88.9
		WEEK 4	19JUN96	40	14	26	7.0	4	95.0	92.9
		WEEK 5	26JUN96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	03JUL96	40	14	26	7.0	4	93.0	92.9
		WEEK 7	10JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	17JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	07AUG96	160	44	116	28.0	4	97.0	103.6
		WEEK 16	19SEP96	160	42	118	27.0	4	100.0	109.3
		WEEK 20	17OCT96	160	62	98	28.0	4	88.0	87.5
		WEEK 24	14NOV96	160	62	98	28.0	4	88.0	87.5
		WEEK 28	12DEC96	160	58	102	28.0	4	91.0	91.1
		WEEK 32	13JAN97	160	52	108	32.0	4	85.0	84.4
		DOWN TITRATION	27JAN97	26	1	25	14.0	3	95.0	96.2
				26	1	25	14.0	2	95.0	96.2
				26	1	25	14.0	2	95.0	96.2
329.005.00331	89.2	WEEK 1	27NOV96	20	9	11	6.0	2	92.0	91.7
		WEEK 2	04DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	12DEC96	30	8	22	8.0	3	92.0	91.7
		WEEK 4	19DEC96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	26DEC96	40	16	24	7.0	4	95.0	85.7
		WEEK 6	02JAN97	40	16	24	7.0	4	86.0	85.7
		WEEK 7	10JAN97	40	10	30	8.0	4	94.0	93.8
		WEEK 8	16JAN97	40	18	22	6.0	4	92.0	91.7
329.005.00334	96.7	WEEK 1	06FEB97	20	7	13	6.5	2	100.0	100.0
		WEEK 2	13FEB97	20	5	15	7.5	2	100.0	100.0
		WEEK 3	21FEB97	30	8	22	7.5	3	100.0	97.8
		WEEK 4	26FEB97	40	20	20	5.0	4	100.0	100.0
		WEEK 5	06MAR97	40	6	34	8.5	4	100.0	100.0
		WEEK 6	13MAR97	50	15	35	7.0	5	100.0	100.0
		WEEK 7	21MAR97	50	12	38	8.0	5	95.0	95.0
		WEEK 8	27MAR97	50	23	27	6.0	5	94.0	90.0
329.006.00037	98.3	WEEK 1	03FEB95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	13FEB95	20	0	20	10.0	2	100.0	100.0
		WEEK 3	22FEB95	30	6	24	8.0	3	100.0	100.0
329.006.00042	100.4	WEEK 1	13DEC95	20	7	13	7.0	2	100.0	92.9

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.006.00042	100.4	WEEK 2	20DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	27DEC95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	03JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	10JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	17JAN96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	23JAN96	50	20	30	6.0	5	100.0	100.0
		WEEK 8	02FEB96	60	0	60	10.0	6	100.0	100.0
		WEEK 12	29FEB96	240	78	162	27.0	6	100.0	100.0
		WEEK 16	26MAR96	240	84	156	26.5	6	100.0	98.1
		WEEK 20	23APR96	240	72	168	28.0	6	100.0	100.0
		WEEK 24	21MAY96	240	72	168	28.0	6	100.0	100.0
		WEEK 28	18JUN96	240	72	168	28.0	6	100.0	100.0
		WEEK 32	16JUL96	240	69	171	28.0	6	100.0	101.8
		DOWN TITRATION	31JUL96	44	3	41	15.0	5	100.0	113.9
				44	3	41	15.0	4	100.0	113.9
				44	3	41	15.0	3	100.0	113.9
				44	3	41	15.0	2	100.0	113.9
				44	3	41	15.0	1	100.0	113.9
329.006.00259	90.2	WEEK 1	30MAY96	20	.	2	4.0	2	50.0	25.0
		WEEK 2	06JUN96	16	1	15	7.0	2	100.0	107.1
		WEEK 3	13JUN96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	20JUN96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	27JUN96	50	15	35	8.0	5	90.0	87.5
		WEEK 6	03JUL96	60	12	48	8.0	6	100.0	100.0
		WEEK 7	10JUL96	30	0	30	5.0	6	100.0	100.0
		WEEK 8	17JUL96	60	27	33	6.0	6	100.0	91.7
329.007.00141	96.2	WEEK 1	28SEP95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	05OCT95	20	5	15	7.0	2	107.0	107.1
		WEEK 3	12OCT95	30	9	21	7.0	3	100.0	100.0
329.007.00144	96.7	WEEK 1	14DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	21DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28DEC95	30	11	19	7.0	3	90.0	90.5
		WEEK 4	04JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	11JAN96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	18JAN96	50	15	35	7.0	5	100.0	100.0
		WEEK 7	25JAN96	50	18	32	7.0	5	91.0	91.4

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.007.00144	96.7	WEEK 8	01FEB96	50	15	35	7.0	5	100.0	100.0
		WEEK 12	01FEB96	200	0	.	.	5	.	.
329.007.00266	89.4	WEEK 1	14MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	25MAR96	20	3	17	11.0	2	77.0	77.3
		WEEK 3	28MAR96	30	21	9	3.0	3	100.0	100.0
		WEEK 4	04APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	11APR96	50	17	33	7.0	5	94.0	94.3
		WEEK 6	18APR96	50	19	31	7.0	5	89.0	88.6
		WEEK 7	29APR96	50	0	50	11.0	5	91.0	90.9
		WEEK 8	02MAY96	50	37	13	3.0	5	87.0	86.7
329.007.00267	100.0	WEEK 1	14MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	21MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28MAR96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	04APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	11APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	18APR96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	25APR96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	02MAY96	50	15	35	7.0	5	100.0	100.0
329.007.00311	94.8	WEEK 1	10OCT96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	17OCT96	20	7	13	7.0	2	93.0	92.9
		WEEK 3	28OCT96	30	0	30	11.0	3	91.0	90.9
		WEEK 4	31OCT96	40	28	12	3.0	4	100.0	100.0
		WEEK 5	07NOV96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	14NOV96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	22NOV96	40	10	30	8.0	4	94.0	93.8
		WEEK 8	02DEC96	50	3	47	10.0	5	94.0	94.0
		WEEK 12	02JAN97	200	61	139	31.0	5	90.0	89.7
		WEEK 16	30JAN97	200	60	140	28.0	5	100.0	100.0
		WEEK 20	13MAR97	200	44	156	42.0	5	74.0	74.3
		WEEK 24	11APR97	200	.	.	.	5	.	.
		DOWN TITRATION	09MAY97	32	0	32	13.5	4	100.0	59.3
329.008.00158	85.6	WEEK 1	19SEP95	20	7	13	6.0	2	108.0	108.3
		WEEK 2	27SEP95	20	5	15	8.0	2	94.0	93.8
		WEEK 3	03OCT95	30	12	18	6.0	3	100.0	100.0
		WEEK 4	10OCT95	40	12	28	7.0	4	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.008.00158	85.6	WEEK 5	16OCT95	40	18	22	6.0	4	92.0	91.7
		WEEK 6	24OCT95	50	10	40	8.0	5	100.0	100.0
		WEEK 7	31OCT95	60	24	36	7.0	6	86.0	85.7
		WEEK 8	14NOV95	60	6	54	13.0	6	69.0	69.2
		WEEK 12	26DEC95	240	.	.	.	6	.	.
		WEEK 16	23JAN96	240	.	.	.	6	.	.
329.008.00162	107.0	WEEK 1	10NOV95	20	1	19	9.0	2	105.0	105.6
		WEEK 2	20NOV95	20	0	20	10.0	2	100.0	100.0
		WEEK 3	29NOV95	30	3	27	9.0	3	100.0	100.0
		WEEK 4	07DEC95	40	4	36	8.0	4	112.0	112.5
		WEEK 5	14DEC95	50	10	40	7.0	5	114.0	114.3
		WEEK 6	20DEC95	.	.	.	.	5	.	.
		WEEK 7	27DEC95	60	15	45	7.0	6	107.0	107.1
		WEEK 8	05JAN96	60	3	57	9.0	6	105.0	105.6
		WEEK 12	09FEB96	240	24	216	35.0	6	97.0	102.9
		WEEK 16	08MAR96	240	0	240	26.0	6	115.0	153.8
		WEEK 20	11APR96	240	6	234	33.0	6	118.0	118.2
		WEEK 24	01MAY96	60	.	.	.	6	.	.
		WEEK 28	05JUN96	240	6	234	35.0	6	111.0	111.4
		WEEK 32	02JUL96	240	60	180	26.0	6	115.0	115.4
		DOWN TITRATION	02JUL96	44	.	.	.	5	.	.
				44	.	.	.	4	.	.
				44	.	.	.	3	.	.
				44	.	.	.	2	.	.
				44	.	.	.	1	.	.
329.008.00191	98.0	WEEK 1	12FEB96	20	0	20	11.0	2	90.0	90.9
		WEEK 2	20FEB96	20	3	17	8.0	2	94.0	106.3
		WEEK 3	27FEB96	30	10	20	7.0	3	95.0	95.2
		WEEK 4	05MAR96	40	14	26	7.0	4	72.0	92.9
		WEEK 5	12MAR96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	18MAR96	40	8	32	6.0	4	130.0	133.3
		WEEK 7	26MAR96	40	16	24	7.0	4	85.0	85.7
		WEEK 8	02APR96	40	12	28	6.0	4	116.0	116.7
		WEEK 12	01MAY96	160	40	120	30.0	4	100.0	100.0
		WEEK 16	05JUN96	160	28	132	39.0	4	103.0	84.6
		WEEK 20	12JUN96	40	12	28	7.0	4	100.0	100.0

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.008.00191	98.0	DOWN TITRATION	.	44	.	.	.	4	.	.
329.009.00128	87.1	WEEK 1	18APR95	20	8	12	7.0	2	85.0	85.7
		WEEK 2	25APR95	20	9	11	7.0	2	79.0	78.6
		WEEK 3	26APR95	30	26	4	1.0	3	99.0	133.3
329.009.00129	90.6	WEEK 1	18APR95	20	9	11	7.0	2	79.0	78.6
		WEEK 2	25APR95	20	7	13	7.0	2	93.0	92.9
		WEEK 3	02MAY95	30	11	19	7.0	3	91.0	90.5
		WEEK 4	09MAY95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	16MAY95	50	15	35	7.0	5	100.0	100.0
329.009.00135	100.0	WEEK 1	09OCT95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	16OCT95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	23OCT95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	30OCT95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	06NOV95	50	15	35	7.0	5	100.0	100.0
329.009.00136	92.5	WEEK 1	10OCT95	20	14	6	7.0	2	43.0	42.9
		WEEK 2	17OCT95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	24OCT95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	03NOV95	40	0	40	10.0	4	100.0	100.0
		WEEK 5	07NOV95	50	30	20	4.0	5	100.0	100.0
		WEEK 6	14NOV95	50	17	33	7.0	5	94.0	94.3
		WEEK 7	21NOV95	50	18	32	7.0	5	91.0	91.4
		WEEK 8	28NOV95	50	18	32	7.0	5	91.0	91.4
329.009.00169	95.9	WEEK 1	07NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	14NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	21NOV95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	28NOV95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	05DEC95	40	16	24	7.0	4	86.0	85.7
		WEEK 6	12DEC95	40	12	28	7.0	4	100.0	100.0
		WEEK 7	19DEC95	40	12	28	7.0	4	100.0	100.0
		WEEK 8	27DEC95	40	8	32	8.0	4	100.0	100.0
		WEEK 12	23JAN96	160	86	74	19.0	4	97.0	97.4
		DOWN TITRATION	13FEB96	28	0	28	21.0	4	100.0	93.3
				28	0	28	21.0	3	100.0	93.3

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00169	95.9	DOWN TITRATION	13FEB96	28	0	28	21.0	2	100.0	93.3
				28	0	28	21.0	2	100.0	93.3
329.009.00174	97.7	WEEK 1	28NOV95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	05DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 3	12DEC95	30	9	21	7.0	3	100.0	100.0
		WEEK 4	19DEC95	40	12	28	7.0	4	100.0	100.0
		WEEK 5	27DEC95	50	10	40	8.0	5	100.0	100.0
		WEEK 6	02JAN96	50	20	30	6.0	5	100.0	100.0
		WEEK 7	09JAN96	50	15	35	7.0	5	100.0	100.0
		WEEK 8	17JAN96	50	15	35	8.0	5	88.0	87.5
		WEEK 12	31JAN96	200	128	72	15.0	5	103.0	96.0
		DOWN TITRATION	16FEB96	32	0	32	16.0	4	100.0	86.5
				32	0	32	16.0	3	100.0	86.5
				32	0	32	16.0	3	100.0	86.5
				32	0	32	16.0	2	100.0	86.5
329.009.00197	88.3	WEEK 1	02JAN96	20	12	8	4.0	2	100.0	100.0
		WEEK 2	08JAN96	20	9	11	6.0	2	92.0	91.7
		WEEK 3	16JAN96	30	10	20	8.0	3	83.0	83.3
		WEEK 4	23JAN96	40	15	25	7.0	4	89.0	89.3
		WEEK 5	30JAN96	40	14	26	7.0	4	93.0	92.9
		WEEK 6	06FEB96	40	18	22	7.0	4	79.0	78.6
		WEEK 7	13FEB96	40	14	26	7.0	4	93.0	92.9
		WEEK 8	20FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 12	19MAR96	184	94	90	28.0	4	80.0	80.4
		WEEK 16	23APR96	160	68	92	35.0	4	66.0	65.7
		WEEK 20	21MAY96	160	60	100	28.0	4	89.0	89.3
		WEEK 24	25JUN96	160	32	128	36.0	4	89.0	88.9
		WEEK 28	16JUL96	160	88	72	21.0	4	86.0	85.7
		WEEK 32	20AUG96	160	55	105	35.0	4	75.0	75.0
		DOWN TITRATION	03SEP96	44	23	21	14.0	4	75.0	70.0
				44	23	21	14.0	3	75.0	70.0
				44	23	21	14.0	2	75.0	70.0
				44	23	21	14.0	2	75.0	70.0
329.009.00198	96.3	WEEK 1	08JAN96	20	11	9	6.0	2	75.0	75.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00198	96.3	WEEK 2	16JAN96	20	7	13	8.0	2	81.0	81.3
		WEEK 3	23JAN96	30	10	20	7.0	3	95.0	95.2
		WEEK 4	30JAN96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	06FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	13FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	20FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	27FEB96	40	12	28	7.0	4	100.0	100.0
329.009.00200	91.0	WEEK 1	02FEB96	20	3	17	10.0	2	85.0	85.0
		WEEK 2	06FEB96	20	13	7	4.0	2	88.0	87.5
		WEEK 3	13FEB96	30	12	18	7.0	3	86.0	85.7
		WEEK 4	20FEB96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	28FEB96	40	8	32	8.0	4	100.0	100.0
		WEEK 6	08MAR96	40	10	30	9.0	4	83.0	83.3
		DOWN TITRATION	19MAR96	25	19	6	11.0	3	24.0	18.2
329.009.00202	87.9	WEEK 1	27FEB96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	08MAR96	20	1	19	10.0	2	95.0	95.0
		WEEK 3	19MAR96	30	4	26	11.0	3	79.0	78.8
		WEEK 4	26MAR96	40	12	28	7.0	4	100.0	100.0
329.009.00237	61.1	WEEK 1	18NOV96	20	9	11	8.0	2	69.0	68.8
329.009.00238	94.2	WEEK 1	19NOV96	20	8	12	7.0	2	86.0	85.7
		WEEK 2	26NOV96	20	5	15	7.0	2	101.0	107.1
		WEEK 3	03DEC96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	10DEC96	40	16	24	7.0	4	86.0	85.7
		WEEK 5	17DEC96	40	18	22	7.0	4	79.0	78.6
		WEEK 6	23DEC96	40	16	24	6.0	4	100.0	100.0
		WEEK 7	31DEC96	40	8	32	8.0	4	100.0	100.0
		WEEK 8	07JAN97	40	12	28	7.0	4	100.0	100.0
329.009.00276	88.7	WEEK 1	28JAN97	20	5	15	7.0	2	107.0	107.1
		WEEK 2	04FEB97	20	6	14	7.0	2	100.0	100.0
		WEEK 3	11FEB97	30	9	21	7.0	3	100.0	100.0
		WEEK 4	18FEB97	40	13	27	7.0	4	96.0	96.4
		WEEK 5	25FEB97	50	44	6	7.0	5	16.0	17.1
		WEEK 6	04MAR97	50	12	38	7.0	5	109.0	108.6
		WEEK 7	13MAR97	60	6	54	9.0	6	100.0	100.0

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.009.00276	88.7	WEEK 8	18MAR97	60	30	30	5.0	6	100.0	100.0
329.009.00302	90.0	WEEK 1	03APR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	10APR96	20	7	13	7.0	2	93.0	92.9
329.009.00306	100.0	WEEK 1	18JUN96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	25JUN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	02JUL96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	09JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	16JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	23JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 7	30JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 8	06AUG96	50	15	35	7.0	5	100.0	100.0
329.009.00312	84.2	WEEK 1	15NOV96	20	3	17	11.0	2	77.0	77.3
		WEEK 2	18NOV96	20	14	6	3.0	2	100.0	100.0
		WEEK 3	02DEC96	30	2	28	14.0	3	67.0	66.7
		WEEK 4	09DEC96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	16DEC96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	27DEC96	40	2	38	11.0	4	86.0	86.4
		WEEK 7	30DEC96	40	28	12	3.0	4	100.0	100.0
		WEEK 8	06JAN97	50	20	30	7.0	5	86.0	85.7
329.009.00327	100.0	WEEK 1	23SEP96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	30SEP96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	07OCT96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	14OCT96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	21OCT96	50	15	35	7.0	5	100.0	100.0
329.009.00330	46.7	WEEK 1	28OCT96	20	13	7	7.0	2	50.0	50.0
		WEEK 2	04NOV96	20	13	7	7.0	2	50.0	50.0
329.010.00183	66.7	WEEK 1	05DEC95	33	21	12	11.0	2	55.0	54.5
		WEEK 2	19DEC95	20	0	.	.	2	.	.
329.010.00263	98.0	WEEK 1	14AUG96	20	10	10	5.0	2	100.0	100.0
		WEEK 2	21AUG96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	28AUG96	30	10	20	7.0	3	95.0	95.2
		WEEK 4	04SEP96	40	16	24	7.0	4	86.0	85.7
		WEEK 5	11SEP96	50	18	32	7.0	5	91.0	91.4

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.010.00263	98.0	WEEK 6	18SEP96	60	24	36	7.0	6	86.0	85.7
		WEEK 7	25SEP96	60	24	36	7.0	6	86.0	85.7
		WEEK 8	09OCT96	104	35	69	15.0	6	80.0	76.7
329.010.00277	78.1	WEEK 1	08MAR96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	18MAR96	20	10	10	6.0	2	83.0	83.3
		WEEK 3	22MAR96	30	10	20	7.0	3	95.0	95.2
		WEEK 4	29MAR96	40	16	24	6.0	4	100.0	100.0
		WEEK 5	.	50	15	35	7.0	5	100.0	100.0
		WEEK 6	15APR96	50	20	30	10.0	5	60.0	60.0
		WEEK 7	19APR96	60	36	24	4.0	6	100.0	100.0
		WEEK 8	26APR96	60	39	21	7.0	6	50.0	50.0
		WEEK 12	24MAY96	240	113	127	28.0	6	76.0	75.6
		WEEK 16	21JUN96	240	240	0	28.0	6	0.0	0.0
329.010.00282	90.1	WEEK 1	02AUG96	20	5	15	7.0	2	107.0	107.1
		WEEK 2	09AUG96	20	7	13	7.0	2	93.0	92.9
		WEEK 3	16AUG96	30	10	20	7.0	3	95.0	95.2
		WEEK 4	26AUG96	40	8	32	9.0	4	89.0	88.9
		WEEK 5	03SEP96	50	13	37	8.0	5	93.0	92.5
		WEEK 6	13SEP96	60	12	48	9.0	6	89.0	88.9
		WEEK 7	19SEP96	60	27	33	6.0	6	92.0	91.7
		WEEK 8	27SEP96	60	12	48	8.0	6	100.0	100.0
329.011.00164	98.2	WEEK 1	28DEC95	20	6	14	7.0	2	100.0	100.0
		WEEK 2	04JAN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	11JAN96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	18JAN96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	25JAN96	50	15	35	7.0	5	100.0	100.0
329.011.00210	96.9	WEEK 1	03OCT96	20	9	11	6.0	2	92.0	91.7
		WEEK 2	09OCT96	20	8	12	6.0	2	100.0	100.0
		WEEK 3	17OCT96	30	6	24	8.0	3	100.0	100.0
		WEEK 4	24OCT96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	04NOV96	40	0	40	10.0	4	100.0	100.0
		WEEK 6	12NOV96	50	7	43	9.0	5	96.0	95.6
		WEEK 7	22NOV96	50	3	47	10.0	5	94.0	94.0
		WEEK 8	02DEC96	50	2	48	10.0	5	96.0	96.0
		WEEK 12	02DEC96	200	.	.	.	5	.	.

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Appendix B.15

Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.011.00285	97.9	WEEK 1	27MAY96	20	1	19	10.0	2	95.0	95.0
		WEEK 2	03JUN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	10JUN96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	21JUN96	40	0	40	10.0	4	100.0	100.0
		WEEK 5	28JUN96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	08JUL96	60	0	60	10.0	6	100.0	100.0
		WEEK 7	18JUL96	60	0	60	10.0	6	100.0	100.0
		WEEK 8	24JUL96	60	24	36	6.0	6	100.0	100.0
329.011.00287	96.6	WEEK 1	09JUL96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	17JUL96	20	4	16	8.0	2	100.0	100.0
		WEEK 3	23JUL96	30	12	18	6.0	3	100.0	100.0
		WEEK 4	30JUL96	40	14	26	7.0	4	93.0	92.9
		WEEK 5	06AUG96	50	15	35	7.0	5	100.0	100.0
		WEEK 6	13AUG96	60	18	42	7.0	6	100.0	100.0
		WEEK 7	20AUG96	60	24	36	7.0	6	86.0	85.7
		WEEK 8	27AUG96	60	18	42	7.0	6	100.0	100.0
329.012.00027	100.0	WEEK 1	12DEC95	20	7	13	6.5	2	100.0	100.0
		WEEK 2	19DEC95	20	5	15	7.0	2	107.0	107.1
		WEEK 3	27DEC95	30	6	24	8.0	3	100.0	100.0
		WEEK 4	02JAN96	40	14	26	6.5	4	100.0	100.0
329.012.00217	88.1	WEEK 1	31MAY96	20	4	16	9.5	2	84.0	84.2
		WEEK 2	19JUN96	20	5	15	7.0	2	107.0	107.1
		WEEK 3	14JUN96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	19JUN96	40	40	0	6.0	4	0.0	0.0
329.012.00218	100.5	WEEK 2	28JUN96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	05JUL96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	12JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	19JUL96	40	12	28	7.0	4	100.0	100.0
		WEEK 6	29JUL96	40	2	38	9.5	4	100.0	100.0
		WEEK 7	06AUG96	40	6	34	8.5	4	100.0	100.0
		WEEK 8	13AUG96	40	11	29	7.0	4	104.0	103.6
		WEEK 12	18SEP96	160	.	.	.	4	.	.
		DOWN TITRATION	.	44	0	.	13.0	4	.	.
				44	0	.	13.0	3	.	.
				44	0	.	13.0	2	.	.

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Listing of Drug Dispensing Data by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Overall Compliance (%)	Visit	Date Returned	# Capsules Dispensed	# Capsules Returned	# Capsules Taken	Days Since Last Visit	# Capsules Daily	Recorded Compliance (%)	Calculated Compliance (%)
329.012.00218	100.5	DOWN TITRATION	.	44	0	.	13.0	2	.	.
329.012.00224	96.9	WEEK 1	24SEP96	20	4	16	8.0	2	100.0	100.0
		WEEK 2	03OCT96	20	3	17	9.0	2	94.0	94.4
		WEEK 3	10OCT96	30	9	21	7.0	3	100.0	100.0
		WEEK 4	17OCT96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	25OCT96	40	10	30	8.0	4	94.0	93.8
		WEEK 6	04NOV96	40	4	36	9.5	4	95.0	94.7
		WEEK 7	12NOV96	40	9	31	8.0	4	97.0	96.9
		WEEK 8	20NOV96	40	3	37	9.0	4	103.0	102.8
		WEEK 12	19DEC96	160	66	94	28.0	4	84.0	83.9
		WEEK 16	20JAN97	160	60	100	32.0	4	78.0	78.1
		WEEK 20	18FEB97	160	88	72	29.0	4	62.0	62.1
		DOWN TITRATION	14MAR97	26	4	22	11.5	3	96.0	84.6
				26	4	22	11.5	2	96.0	84.6
				26	4	22	11.5	2	96.0	84.6
329.012.00225	97.2	WEEK 1	03DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 2	10DEC96	20	6	14	7.0	2	100.0	100.0
		WEEK 3	20DEC96	30	2	28	10.0	3	93.0	93.3
		WEEK 4	27DEC96	40	12	28	7.0	4	100.0	100.0
		WEEK 5	06JAN97	40	0	40	10.0	4	100.0	100.0
		WEEK 6	13JAN97	40	12	28	7.0	4	100.0	100.0
		WEEK 7	21JAN97	40	12	28	8.0	4	88.0	87.5
		WEEK 8	29JAN97	40	8	32	8.0	4	100.0	100.0
		WEEK 12	24FEB97	160	60	100	26.0	4	96.0	96.2
		WEEK 16	20MAR97	160	74	86	25.0	4	86.0	86.0
		WEEK 20	21APR97	160	50	110	32.0	4	86.0	85.9
		WEEK 24	26MAY97	160	34	126	35.0	4	90.0	90.0
		WEEK 28	30JUN97	160	42	118	34.0	4	87.0	86.8
		WEEK 32	30JUL97	160	78	82	30.0	4	68.0	68.3
		DOWN TITRATION	30SEP97	26	0	26	11.5	3	100.0	136.8
				26	0	26	11.5	2	100.0	136.8
				26	0	26	11.5	1	100.0	136.8

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.001.00063		Oral	1	20 MG	08NOV94	1	14NOV94	7	7
	00063	Oral	2	20 MG	15NOV94	8	21NOV94	14	7
	00063	Oral	3	20 MG	22NOV94	15	28NOV94	21	7
	00063	Oral	4	20 MG	29NOV94	22	05DEC94	28	7
	00063	Oral	4	20 MG	06DEC94	29	12DEC94	35	7
		Oral	4	20 MG	13DEC94	36	25DEC94	48	13
329.001.00065		Oral	1	20 MG	17NOV94	1	22NOV94	6	6
	00065	Oral	2	20 MG	23NOV94	7	30NOV94	14	8
329.001.00068		Oral	1	20 MG	08FEB95	1	14FEB95	7	7
	00068	Oral	2	20 MG	15FEB95	8	21FEB95	14	7
	00068	Oral	3	20 MG	22FEB95	15	28FEB95	21	7
	00068	Oral	4	20 MG	01MAR95	22	07MAR95	28	7
	00068	Oral	5	30 MG	08MAR95	29	14MAR95	35	7
	00068	Oral	6	40 MG	15MAR95	36	22MAR95	43	8
	00068	Oral	6	40 MG	23MAR95	44	28MAR95	49	6
	00068	Oral	6	40 MG	29MAR95	50	04APR95	56	7
		Oral	6	40 MG	05APR95	57	20APR95	72	16
329.001.00072		Oral	1	20 MG	20MAR95	1	26MAR95	7	7
	00072	Oral	2	20 MG	27MAR95	8	02APR95	14	7
	00072	Oral	3	20 MG	03APR95	15	09APR95	21	7
	00072	Oral	4	20 MG	10APR95	22	12APR95	24	3
		Oral	3	20 MG	13APR95	25	20APR95	32	8
329.001.00121		Oral	1	20 MG	04APR95	1	10APR95	7	7
	00121	Oral	2	20 MG	11APR95	8	17APR95	14	7
	00121	Oral	3	20 MG	18APR95	15	25APR95	22	8
	00121	Oral	4	20 MG	26APR95	23	01MAY95	28	6
	00121	Oral	5	30 MG	02MAY95	29	08MAY95	35	7
	00121	Oral	5	30 MG	09MAY95	36	15MAY95	42	7
	00121	Oral	5	30 MG	16MAY95	43	22MAY95	49	7
	00121	Oral	5	30 MG	23MAY95	50	29MAY95	56	7
	00051	Oral	5	30 MG	30MAY95	57	26JUN95	84	28
	00051	Oral	5	30 MG	27JUN95	85	23JUL95	111	27
	00051	Oral	5	30 MG	24JUL95	112	20AUG95	139	28
	00121	Oral	5	30 MG	21AUG95	140	04SEP95	154	15
329.001.00205		Oral	1	20 MG	07FEB96	1	14FEB96	8	8

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.001.00206		Oral	1	20 MG	21FEB96	1	27FEB96	7	7
	00206	Oral	2	20 MG	28FEB96	8	05MAR96	14	7
	00206	Oral	3	20 MG	06MAR96	15	12MAR96	21	7
	00206	Oral	4	20 MG	13MAR96	22	19MAR96	28	7
	00206	Oral	5	30 MG	20MAR96	29	25MAR96	34	6
	00206	Oral	6	40 MG	26MAR96	35	02APR96	42	8
	00206	Oral	6	40 MG	03APR96	43	09APR96	49	7
	00206	Oral	6	40 MG	10APR96	50	16APR96	56	7
		Oral	5	30 MG	17APR96	57	18APR96	58	2
329.002.00055		Oral	1	20 MG	24JUN94	1	29JUN94	6	6
	00055	Oral	2	20 MG	30JUN94	7	06JUL94	13	7
	00055	Oral	3	20 MG	07JUL94	14	13JUL94	20	7
	00055	Oral	4	20 MG	14JUL94	21	20JUL94	27	7
	00055	Oral	5	30 MG	21JUL94	28	27JUL94	34	7
	00055	Oral	6	40 MG	28JUL94	35	03AUG94	41	7
	00055	Oral	6	40 MG	04AUG94	42	10AUG94	48	7
	00055	Oral	6	40 MG	11AUG94	49	17AUG94	55	7
	00068	Oral	6	40 MG	18AUG94	56	14SEP94	83	28
	00068	Oral	6	40 MG	15SEP94	84	13OCT94	112	29
	00068	Oral	6	40 MG	14OCT94	113	10NOV94	140	28
	00055	Oral	5	30 MG	11NOV94	141	12NOV94	142	2
	00055	Oral	4	20 MG	13NOV94	143	14NOV94	144	2
	00055	Oral	3	20 MG	15NOV94	145	16NOV94	146	2
	00055	Oral	2	20 MG	17NOV94	147	19NOV94	149	3
	00055	Oral	1	20 MG	20NOV94	150	26NOV94	156	7
329.002.00058		Oral	1	20 MG	20SEP94	1	28SEP94	9	9
	00058	Oral	2	20 MG	29SEP94	10	06OCT94	17	8
	00058	Oral	3	20 MG	07OCT94	18	12OCT94	23	6
	00058	Oral	4	20 MG	13OCT94	24	19OCT94	30	7
	00058	Oral	5	30 MG	20OCT94	31	26OCT94	37	7
	00058	Oral	6	40 MG	27OCT94	38	02NOV94	44	7
	00058	Oral	6	40 MG	03NOV94	45	09NOV94	51	7
	00058	Oral	6	40 MG	10NOV94	52	16NOV94	58	7
	00070	Oral	6	40 MG	17NOV94	59	14DEC94	86	28
	00070	Oral	6	40 MG	15DEC94	87	12JAN95	115	29
	00070	Oral	6	40 MG	13JAN95	116	16JAN95	119	4
329.002.00099		Oral	1	20 MG	02MAR95	1	06MAR95	5	5

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00099	00099	Oral	2	20 MG	07MAR95	6	13MAR95	12	7
	00099	Oral	3	20 MG	14MAR95	13	20MAR95	19	7
	00099	Oral	4	20 MG	21MAR95	20	27MAR95	26	7
	00099	Oral	4	20 MG	28MAR95	27	03APR95	33	7
	00099	Oral	5	30 MG	04APR95	34	11APR95	41	8
	00099	Oral	6	40 MG	12APR95	42	18APR95	48	7
	00099	Oral	6	40 MG	19APR95	49	25APR95	55	7
	00025	Oral	6	40 MG	26APR95	56	22MAY95	82	27
	00025	Oral	6	40 MG	23MAY95	83	26JUN95	117	35
	00025	Oral	6	40 MG	27JUN95	118	31JUL95	152	35
	00025	Oral	6	40 MG	01AUG95	153	30AUG95	182	30
	00025	Oral	6	40 MG	31AUG95	183	27SEP95	210	28
	00025	Oral	6	40 MG	28SEP95	211	26OCT95	239	29
	00099	Oral	5	30 MG	27OCT95	240	28OCT95	241	2
	00099	Oral	4	20 MG	29OCT95	242	30OCT95	243	2
	00099	Oral	3	20 MG	31OCT95	244	01NOV95	245	2
	00099	Oral	2	20 MG	02NOV95	246	04NOV95	248	3
	00099	Oral	1	20 MG	05NOV95	249	11NOV95	255	7
329.002.00102		Oral	1	20 MG	13APR95	1	17APR95	5	5
	00102	Oral	2	20 MG	18APR95	6	24APR95	12	7
	00102	Oral	3	20 MG	25APR95	13	01MAY95	19	7
	00102	Oral	4	20 MG	02MAY95	20	08MAY95	26	7
	00102	Oral	5	30 MG	09MAY95	27	15MAY95	33	7
	00102	Oral	6	40 MG	16MAY95	34	22MAY95	40	7
	00102	Oral	6	40 MG	23MAY95	41	29MAY95	47	7
	00102	Oral	6	40 MG	30MAY95	48	05JUN95	54	7
	00071	Oral	6	40 MG	06JUN95	55	12JUL95	91	37
	00071	Oral	6	40 MG	13JUL95	92	09AUG95	119	28
	00071	Oral	6	40 MG	10AUG95	120	11SEP95	152	33
	00071	Oral	6	40 MG	12SEP95	153	09OCT95	180	28
	00071	Oral	6	40 MG	10OCT95	181	08NOV95	210	30
	00071	Oral	6	40 MG	09NOV95	211	04DEC95	236	26
	00102	Oral	5	30 MG	05DEC95	237	06DEC95	238	2
	00102	Oral	4	20 MG	07DEC95	239	08DEC95	240	2
	00102	Oral	3	20 MG	09DEC95	241	12DEC95	244	4
	00102	Oral	2	20 MG	13DEC95	245	16DEC95	248	4
	00102	Oral	1	20 MG	17DEC95	249	20DEC95	252	4
329.002.00105		Oral	1	20 MG	27JUL95	1	02AUG95	7	7

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00105	00105	Oral	2	20 MG	03AUG95	8	09AUG95	14	7
	00105	Oral	3	20 MG	10AUG95	15	16AUG95	21	7
	00105	Oral	4	20 MG	17AUG95	22	.	.	.
329.002.00106		Oral	1	20 MG	27JUL95	1	02AUG95	7	7
	00106	Oral	2	20 MG	03AUG95	8	07AUG95	12	5
	00106	Oral	3	20 MG	08AUG95	13	16AUG95	21	9
	00106	Oral	4	20 MG	17AUG95	22	23AUG95	28	7
	00106	Oral	4	20 MG	24AUG95	29	30AUG95	35	7
		Oral	5	30 MG	31AUG95	36	04SEP95	40	5
	00106	Oral	6	40 MG	05SEP95	41	11SEP95	47	7
	00106	Oral	6	40 MG	12SEP95	48	12SEP95	48	1
329.002.00242		Oral	1	20 MG	07FEB96	1	14FEB96	8	8
	00242	Oral	2	20 MG	15FEB96	9	21FEB96	15	7
	00242	Oral	3	20 MG	22FEB96	16	28FEB96	22	7
	00242	Oral	4	20 MG	29FEB96	23	05MAR96	28	6
	00242	Oral	5	30 MG	06MAR96	29	13MAR96	36	8
	00242	Oral	5	30 MG	14MAR96	37	20MAR96	43	7
	00242	Oral	6	40 MG	21MAR96	44	28MAR96	51	8
	00242	Oral	6	40 MG	29MAR96	52	04APR96	58	7
		Oral	6	40 MG	05APR96	59	07MAY96	91	33
	00136	Oral	6	40 MG	08MAY96	92	05JUN96	120	29
	00242	Oral	.		06JUN96	121	.	.	.
329.002.00245		Oral	1	20 MG	28MAR96	1	04APR96	8	8
	00245	Oral	1	20 MG	05APR96	9	09APR96	13	5
		Oral	1	20 MG	10APR96	14	14APR96	18	5
329.002.00319		Oral	1	20 MG	30APR96	1	06MAY96	7	7
	00319	Oral	2	20 MG	07MAY96	8	13MAY96	14	7
	00319	Oral	3	20 MG	14MAY96	15	20MAY96	21	7
	00319	Oral	4	20 MG	21MAY96	22	27MAY96	28	7
	00319	Oral	5	30 MG	28MAY96	29	03JUN96	35	7
	00319	Oral	5	30 MG	04JUN96	36	10JUN96	42	7
	00319	Oral	5	30 MG	11JUN96	43	17JUN96	49	7
	00319	Oral	5	30 MG	18JUN96	50	24JUN96	56	7
	00162	Oral	5	30 MG	25JUN96	57	22JUL96	84	28
	00162	Oral	5	30 MG	23JUL96	85	14AUG96	107	23
	00162	Oral	5	30 MG	15AUG96	108	23SEP96	147	40

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00319	00162	Oral	5	30 MG	24SEP96	148	21OCT96	175	28
	00162	Oral	5	30 MG	22OCT96	176	18NOV96	203	28
	00162	Oral	5	30 MG	19NOV96	204	16DEC96	231	28
	00319	Oral	5	30 MG	17DEC96	232	17DEC96	232	1
	00319	Oral	4	20 MG	18DEC96	233	19DEC96	234	2
	00319	Oral	3	20 MG	20DEC96	235	21DEC96	236	2
	00319	Oral	2	20 MG	22DEC96	237	24DEC96	239	3
	00319	Oral	1	20 MG	25DEC96	240	30DEC96	245	6
329.003.00075		Oral	1	20 MG	25JAN95	1	31JAN95	7	7
	00075	Oral	2	20 MG	01FEB95	8	07FEB95	14	7
	00075	Oral	3	20 MG	08FEB95	15	14FEB95	21	7
	00075	Oral	4	20 MG	15FEB95	22	20FEB95	27	6
	00075	Oral	5	30 MG	21FEB95	28	28FEB95	35	8
	00075	Oral	3	20 MG	01MAR95	36	07MAR95	42	7
	00075	Oral	2	20 MG	08MAR95	43	14MAR95	49	7
	00075	Oral	4	20 MG	15MAR95	50	21MAR95	56	7
	00041	Oral	4	20 MG	22MAR95	57	18APR95	84	28
	00041	Oral	4	20 MG	19APR95	85	16MAY95	112	28
	00041	Oral	4	20 MG	17MAY95	113	13JUN95	140	28
	00041	Oral	4	20 MG	14JUN95	141	11JUL95	168	28
	00041	Oral	4	20 MG	12JUL95	169	09AUG95	197	29
	00041	Oral	4	20 MG	10AUG95	198	12SEP95	231	34
	00075	Oral	3	20 MG	13SEP95	232	14SEP95	233	2
	00075	Oral	2	20 MG	15SEP95	234	17SEP95	236	3
	00075	Oral	1	20 MG	18SEP95	237	21SEP95	240	4
329.003.00077		Oral	1	20 MG	06MAR95	1	12MAR95	7	7
	00077	Oral	2	20 MG	13MAR95	8	19MAR95	14	7
	00077	Oral	3	20 MG	20MAR95	15	26MAR95	21	7
	00077	Oral	4	20 MG	27MAR95	22	04APR95	30	9
	00077	Oral	5	30 MG	05APR95	31	11APR95	37	7
	00077	Oral	5	30 MG	12APR95	38	18APR95	44	7
	00077	Oral	5	30 MG	19APR95	45	26APR95	52	8
	00077	Oral	5	30 MG	27APR95	53	03MAY95	59	7
	00042	Oral	5	30 MG	04MAY95	60	06JUN95	93	34
	00042	Oral	5	30 MG	07JUN95	94	.	.	.
329.003.00081		Oral	1	20 MG	11DEC95	1	17DEC95	7	7
	00081	Oral	2	20 MG	18DEC95	8	27DEC95	17	10

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00081	00081	Oral	3	20 MG	28DEC95	18	02JAN96	23	6
	00081	Oral	4	20 MG	03JAN96	24	09JAN96	30	7
	00081	Oral	5	30 MG	10JAN96	31	16JAN96	37	7
	00081	Oral	5	30 MG	17JAN96	38	23JAN96	44	7
	00081	Oral	5	30 MG	24JAN96	45	30JAN96	51	7
	00081	Oral	6	40 MG	31JAN96	52	06FEB96	58	7
		Oral	6	40 MG	07FEB96	59	.	.	.
329.003.00087		Oral	1	20 MG	31JAN95	1	03FEB95	4	4
329.003.00089		Oral	1	20 MG	07MAR95	1	13MAR95	7	7
	00089	Oral	2	20 MG	14MAR95	8	21MAR95	15	8
	00089	Oral	3	20 MG	22MAR95	16	27MAR95	21	6
	00089	Oral	4	20 MG	28MAR95	22	04APR95	29	8
	00089	Oral	4	20 MG	05APR95	30	11APR95	36	7
	00089	Oral	4	20 MG	12APR95	37	18APR95	43	7
	00089	Oral	4	20 MG	19APR95	44	25APR95	50	7
	00089	Oral	4	20 MG	26APR95	51	01MAY95	56	6
		Oral	3	20 MG	02MAY95	57	05MAY95	60	4
329.003.00091		Oral	1	20 MG	24MAR95	1	28MAR95	5	5
	00091	Oral	2	20 MG	29MAR95	6	04APR95	12	7
	00091	Oral	3	20 MG	05APR95	13	11APR95	19	7
	00091	Oral	4	20 MG	12APR95	20	18APR95	26	7
	00091	Oral	5	30 MG	19APR95	27	25APR95	33	7
	00091	Oral	6	40 MG	26APR95	34	01MAY95	39	6
	00091	Oral	6	40 MG	02MAY95	40	09MAY95	47	8
	00091	Oral	6	40 MG	10MAY95	48	16MAY95	54	7
	00033	Oral	6	40 MG	17MAY95	55	16JUN95	85	31
	00033	Oral	6	40 MG	17JUN95	86	14JUL95	113	28
	00033	Oral	6	40 MG	15JUL95	114	10AUG95	140	27
	00033	Oral	6	40 MG	11AUG95	141	05SEP95	166	26
	00033	Oral	6	40 MG	06SEP95	167	02OCT95	193	27
	00033	Oral	6	40 MG	03OCT95	194	07NOV95	229	36
	00091	Oral	5	30 MG	08NOV95	230	09NOV95	231	2
	00091	Oral	4	20 MG	10NOV95	232	11NOV95	233	2
	00091	Oral	3	20 MG	12NOV95	234	13NOV95	235	2
	00091	Oral	2	20 MG	14NOV95	236	16NOV95	238	3
	00091	Oral	1	20 MG	17NOV95	239	23NOV95	245	7

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00248		Oral	1	20 MG	01MAR96	1	05MAR96	5	5
	00248	Oral	2	20 MG	06MAR96	6	11MAR96	11	6
	00248	Oral	3	20 MG	12MAR96	12	18MAR96	18	7
	00248	Oral	4	20 MG	19MAR96	19	25MAR96	25	7
	00248	Oral	5	30 MG	26MAR96	26	01APR96	32	7
	00248	Oral	6	40 MG	02APR96	33	10APR96	41	9
	00248	Oral	6	40 MG	11APR96	42	15APR96	46	5
	00248	Oral	6	40 MG	16APR96	47	22APR96	53	7
		Oral	5	30 MG	23APR96	54	02MAY96	63	10
329.003.00250		Oral	1	20 MG	14MAR96	1	18MAR96	5	5
	00250	Oral	2	20 MG	19MAR96	6	25MAR96	12	7
	00250	Oral	3	20 MG	26MAR96	13	01APR96	19	7
	00250	Oral	4	20 MG	02APR96	20	11APR96	29	10
	00250	Oral	5	30 MG	12APR96	30	18APR96	36	7
	00250	Oral	6	40 MG	19APR96	37	22APR96	40	4
	00250	Oral	6	40 MG	23APR96	41	29APR96	47	7
	00250	Oral	5	30 MG	30APR96	48	09MAY96	57	10
	00250	Oral	6	40 MG	10MAY96	58	12MAY96	60	3
	00250	Oral	5	30 MG	13MAY96	61	27MAY96	75	15
329.003.00292		Oral	1	20 MG	07AUG96	1	16AUG96	10	10
	00292	Oral	2	20 MG	17AUG96	11	21AUG96	15	5
	00292	Oral	3	20 MG	22AUG96	16	30AUG96	24	9
	00292	Oral	4	20 MG	31AUG96	25	04SEP96	29	5
	00292	Oral	4	20 MG	05SEP96	30	17SEP96	42	13
	00292	Oral	4	20 MG	18SEP96	43	25SEP96	50	8
	00292	Oral	4	20 MG	26SEP96	51	03OCT96	58	8
	00179	Oral	4	20 MG	04OCT96	59	.	.	.
329.003.00313		Oral	1	20 MG	17MAY96	1	20MAY96	4	4
	00313	Oral	2	20 MG	21MAY96	5	28MAY96	12	8
329.004.00015		Oral	1	20 MG	08DEC94	1	13DEC94	6	6
	00015	Oral	2	20 MG	14DEC94	7	20DEC94	13	7
	00015	Oral	3	20 MG	21DEC94	14	27DEC94	20	7
	00015	Oral	4	20 MG	28DEC94	21	03JAN95	27	7
	00015	Oral	4	20 MG	04JAN95	28	10JAN95	34	7
	00015	Oral	4	20 MG	11JAN95	35	17JAN95	41	7
	00015	Oral	4	20 MG	18JAN95	42	24JAN95	48	7

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Listing of Study Medication Data
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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.004.00015	00015	Oral	4	20 MG	25JAN95	49	02FEB95	57	9
	00073	Oral	4	20 MG	03FEB95	58	27FEB95	82	25
	00073	Oral	4	20 MG	28FEB95	83	21MAR95	104	22
	00073	Oral	4	20 MG	22MAR95	105	18APR95	132	28
	00073	Oral	4	20 MG	19APR95	133	16MAY95	160	28
	00073	Oral	4	20 MG	17MAY95	161	13JUN95	188	28
	00015	Oral	4	20 MG	14JUN95	189	14JUN95	189	1
	00015	Oral	3	20 MG	15JUN95	190	15JUN95	190	1
	00015	Oral	2	20 MG	16JUN95	191	18JUN95	193	3
	00015	Oral	1	20 MG	19JUN95	194	28JUN95	203	10
329.004.00017		Oral	1	20 MG	22MAR95	1	26MAR95	5	5
	00017	Oral	0	0 MG	27MAR95	6	27MAR95	6	1
	00017	Oral	1	20 MG	28MAR95	7	29MAR95	8	2
	00017	Oral	2	20 MG	30MAR95	9	05APR95	15	7
	00017	Oral	3	20 MG	06APR95	16	12APR95	22	7
	00017	Oral	4	20 MG	13APR95	23	19APR95	29	7
	00017	Oral	4	20 MG	20APR95	30	25APR95	35	6
		Oral	5	30 MG	26APR95	36	02MAY95	42	7
	00017	Oral	5	30 MG	03MAY95	43	09MAY95	49	7
	00017	Oral	5	30 MG	10MAY95	50	16MAY95	56	7
	00075	Oral	5	30 MG	17MAY95	57	13JUN95	84	28
	00075	Oral	5	30 MG	14JUN95	85	12JUL95	113	29
	00075	Oral	5	30 MG	13JUL95	114	09AUG95	141	28
	00075	Oral	5	30 MG	10AUG95	142	05SEP95	168	27
	00075	Oral	5	30 MG	06SEP95	169	03OCT95	196	28
	00075	Oral	5	30 MG	04OCT95	197	31OCT95	224	28
	00017	Oral	4	20 MG	01NOV95	225	02NOV95	226	2
	00017	Oral	3	20 MG	03NOV95	227	04NOV95	228	2
	00017	Oral	2	20 MG	05NOV95	229	07NOV95	231	3
	00017	Oral	1	20 MG	08NOV95	232	14NOV95	238	7
329.004.00019		Oral	1	20 MG	31MAY95	1	06JUN95	7	7
	00019	Oral	2	20 MG	07JUN95	8	13JUN95	14	7
	00019	Oral	3	20 MG	14JUN95	15	.	.	.
329.004.00212		Oral	1	20 MG	03JUN96	1	09JUN96	7	7
	00212	Oral	2	20 MG	10JUN96	8	20JUN96	18	11
	00212	Oral	3	20 MG	21JUN96	19	25JUN96	23	5

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.004.00214		Oral	1	20 MG	04OCT96	1	08OCT96	5	5
	00214	Oral	2	20 MG	09OCT96	6	14OCT96	11	6
	00214	Oral	3	20 MG	15OCT96	12	20OCT96	17	6
	00214	Oral	4	20 MG	21OCT96	18	30OCT96	27	10
	00214	Oral	5	30 MG	01NOV96	29	10NOV96	38	10
	00214	Oral	5	30 MG	11NOV96	39	17NOV96	45	7
	00214	Oral	4	20 MG	18NOV96	46	24NOV96	52	7
	00214	Oral	4	20 MG	25NOV96	53	02DEC96	60	8
	00119	Oral	4	20 MG	03DEC96	61	30DEC96	88	28
329.005.00002		Oral	1	20 MG	25MAY94	1	31MAY94	7	7
	00002	Oral	2	20 MG	01JUN94	8	07JUN94	14	7
	00002	Oral	3	20 MG	08JUN94	15	14JUN94	21	7
	00002	Oral	4	20 MG	15JUN94	22	22JUN94	29	8
	00002	Oral	5	30 MG	23JUN94	30	29JUN94	36	7
	00002	Oral	6	40 MG	30JUN94	37	06JUL94	43	7
	00002	Oral	6	40 MG	07JUL94	44	12JUL94	49	6
	00002	Oral	6	40 MG	13JUL94	50	19JUL94	56	7
	00091	Oral	6	40 MG	20JUL94	57	16AUG94	84	28
	00091	Oral	6	40 MG	17AUG94	85	14SEP94	113	29
	00091	Oral	6	40 MG	15SEP94	114	17OCT94	146	33
	00091	Oral	6	40 MG	18OCT94	147	.	.	.
329.005.00004		Oral	1	20 MG	10OCT94	1	19OCT94	10	10
	00004	Oral	2	20 MG	20OCT94	11	26OCT94	17	7
	00004	Oral	3	20 MG	27OCT94	18	02NOV94	24	7
	00004	Oral	4	20 MG	03NOV94	25	09NOV94	31	7
	00004	Oral	5	30 MG	10NOV94	32	16NOV94	38	7
	00004	Oral	6	40 MG	17NOV94	39	22NOV94	44	6
	00004	Oral	6	40 MG	23NOV94	45	30NOV94	52	8
	00004	Oral	6	40 MG	01DEC94	53	07DEC94	59	7
	00093	Oral	6	40 MG	08DEC94	60	04JAN95	87	28
	00004	Oral	5	30 MG	05JAN95	88	20JAN95	103	16
329.005.00008		Oral	1	20 MG	16NOV94	1	22NOV94	7	7
	00008	Oral	2	20 MG	23NOV94	8	29NOV94	14	7
	00008	Oral	3	20 MG	30NOV94	15	06DEC94	21	7
	00008	Oral	4	20 MG	07DEC94	22	13DEC94	28	7
	00008	Oral	5	30 MG	14DEC94	29	20DEC94	35	7
	00008	Oral	6	40 MG	21DEC94	36	27DEC94	42	7

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00008	00008	Oral	6	40 MG	28DEC94	43	03JAN95	49	7
	00008	Oral	6	40 MG	04JAN95	50	09JAN95	55	6
	00095	Oral	5	30 MG	10JAN95	56	05FEB95	82	27
	00095	Oral	5	30 MG	06FEB95	83	07MAR95	112	30
	00095	Oral	5	30 MG	08MAR95	113	06APR95	142	30
329.005.00011		Oral	1	20 MG	13DEC94	1	19DEC94	7	7
	00011	Oral	2	20 MG	20DEC94	8	26DEC94	14	7
	00011	Oral	3	20 MG	27DEC94	15	02JAN95	21	7
	00011	Oral	4	20 MG	03JAN95	22	08JAN95	27	6
	00011	Oral	5	30 MG	09JAN95	28	16JAN95	35	8
	00011	Oral	6	40 MG	17JAN95	36	22JAN95	41	6
	00011	Oral	6	40 MG	23JAN95	42	30JAN95	49	8
	00011	Oral	6	40 MG	31JAN95	50	06FEB95	56	7
	00021	Oral	6	40 MG	07FEB95	57	08MAR95	86	30
	00021	Oral	6	40 MG	09MAR95	87	05APR95	114	28
	00021	Oral	6	40 MG	06APR95	115	02MAY95	141	27
	00021	Oral	5	30 MG	03MAY95	142	17MAY95	156	15
329.005.00109		Oral	1	20 MG	30DEC94	1	04JAN95	6	6
	00109	Oral	2	20 MG	05JAN95	7	11JAN95	13	7
	00109	Oral	3	20 MG	12JAN95	14	18JAN95	20	7
	00109	Oral	4	20 MG	19JAN95	21	25JAN95	27	7
	00109	Oral	4	20 MG	26JAN95	28	01FEB95	34	7
	00109	Oral	4	20 MG	02FEB95	35	07FEB95	40	6
	00109	Oral	4	20 MG	08FEB95	41	15FEB95	48	8
	00109	Oral	4	20 MG	16FEB95	49	20FEB95	53	5
	00023	Oral	4	20 MG	21FEB95	54	22MAR95	83	30
	00023	Oral	4	20 MG	23MAR95	84	23APR95	115	32
	00023	Oral	4	20 MG	24APR95	116	16MAY95	138	23
329.005.00112		Oral	1	20 MG	26JAN95	1	31JAN95	6	6
	00112	Oral	2	20 MG	01FEB95	7	07FEB95	13	7
	00112	Oral	3	20 MG	08FEB95	14	14FEB95	20	7
	00112	Oral	4	20 MG	15FEB95	21	22FEB95	28	8
	00112	Oral	4	20 MG	23FEB95	29	28FEB95	34	6
	00112	Oral	4	20 MG	01MAR95	35	07MAR95	41	7
	00112	Oral	4	20 MG	08MAR95	42	14MAR95	48	7
	00112	Oral	4	20 MG	15MAR95	49	21MAR95	55	7
	00024	Oral	4	20 MG	22MAR95	56	18APR95	83	28

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00112	00112	Oral	2	20 MG	19APR95	84	21APR95	86	3
	00112	Oral	1	20 MG	22APR95	87	28APR95	93	7
329.005.00116		Oral	1	20 MG	07FEB95	1	12FEB95	6	6
	00116	Oral	2	20 MG	13FEB95	7	19FEB95	13	7
	00116	Oral	3	20 MG	20FEB95	14	26FEB95	20	7
	00116	Oral	4	20 MG	27FEB95	21	08MAR95	30	10
		Oral	4	20 MG	09MAR95	31	15MAR95	37	7
	00116	Oral	4	20 MG	16MAR95	38	22MAR95	44	7
	00116	Oral	4	20 MG	23MAR95	45	29MAR95	51	7
	00116	Oral	4	20 MG	30MAR95	52	05APR95	58	7
	00002	Oral	4	20 MG	06APR95	59	03MAY95	86	28
	00002	Oral	4	20 MG	04MAY95	87	30MAY95	113	27
	00002	Oral	5	30 MG	31MAY95	114	27JUN95	141	28
	00116	Oral	4	20 MG	28JUN95	142	29JUN95	143	2
	00116	Oral	3	20 MG	30JUN95	144	01JUL95	145	2
	00116	Oral	2	20 MG	02JUL95	146	04JUL95	148	3
	00116	Oral	1	20 MG	05JUL95	149	11JUL95	155	7
329.005.00119		Oral	1	20 MG	11JUL95	1	17JUL95	7	7
	00119	Oral	2	20 MG	18JUL95	8	25JUL95	15	8
	00119	Oral	3	20 MG	26JUL95	16	01AUG95	22	7
	00119	Oral	4	20 MG	02AUG95	23	07AUG95	28	6
	00119	Oral	5	30 MG	08AUG95	29	14AUG95	35	7
	00119	Oral	6	40 MG	15AUG95	36	22AUG95	43	8
	00119	Oral	6	40 MG	23AUG95	44	28AUG95	49	6
	00119	Oral	6	40 MG	29AUG95	50	07SEP95	59	10
	00056	Oral	6	40 MG	08SEP95	60	02OCT95	84	25
	00056	Oral	6	40 MG	03OCT95	85	29OCT95	111	27
	00056	Oral	6	40 MG	30OCT95	112	27NOV95	140	29
	00119	Oral	5	30 MG	28NOV95	141	.	.	.
329.005.00151		Oral	1	20 MG	06SEP95	1	13SEP95	8	8
	00151	Oral	2	20 MG	14SEP95	9	19SEP95	14	6
	00151	Oral	3	20 MG	20SEP95	15	27SEP95	22	8
	00151	Oral	4	20 MG	28SEP95	23	02OCT95	27	5
	00151	Oral	4	20 MG	03OCT95	28	10OCT95	35	8
	00151	Oral	4	20 MG	11OCT95	36	18OCT95	43	8
	00151	Oral	4	20 MG	19OCT95	44	25OCT95	50	7
	00151	Oral	4	20 MG	26OCT95	51	01NOV95	57	7

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00151	00030	Oral	4	20 MG	02NOV95	58	27NOV95	83	26
	00030	Oral	4	20 MG	28NOV95	84	03JAN96	120	37
	00030	Oral	5	30 MG	04JAN96	121	30JAN96	147	27
	00030	Oral	5	30 MG	31JAN96	148	26FEB96	174	27
	00192	Oral	5	30 MG	27FEB96	175	26MAR96	203	29
	00192	Oral	5	30 MG	27MAR96	204	30APR96	238	35
	00350	Oral	4	20 MG	01MAY96	239	.	.	.
329.005.00152		Oral	1	20 MG	26OCT95	1	30OCT95	5	5
329.005.00257		Oral	1	20 MG	11MAR96	1	17MAR96	7	7
	00257	Oral	2	20 MG	18MAR96	8	24MAR96	14	7
	00257	Oral	3	20 MG	25MAR96	15	31MAR96	21	7
	00257	Oral	4	20 MG	01APR96	22	07APR96	28	7
	00257	Oral	4	20 MG	08APR96	29	14APR96	35	7
	00257	Oral	4	20 MG	15APR96	36	21APR96	42	7
	00257	Oral	5	30 MG	22APR96	43	28APR96	49	7
	00257	Oral	5	30 MG	29APR96	50	05MAY96	56	7
	00144	Oral	5	30 MG	06MAY96	57	02JUN96	84	28
	00144	Oral	5	30 MG	03JUN96	85	07JUL96	119	35
	00144	Oral	5	30 MG	08JUL96	120	06AUG96	149	30
	00144	Oral	5	30 MG	07AUG96	150	26AUG96	169	20
	00144	Oral	5	30 MG	27AUG96	170	30SEP96	204	35
	00144	Oral	5	30 MG	01OCT96	205	21OCT96	225	21
	00257	Oral	4	20 MG	22OCT96	226	23OCT96	227	2
	00257	Oral	3	20 MG	24OCT96	228	25OCT96	229	2
	00257	Oral	2	20 MG	26OCT96	230	28OCT96	232	3
	00257	Oral	1	20 MG	29OCT96	233	04NOV96	239	7
329.005.00258		Oral	1	20 MG	12MAR96	1	18MAR96	7	7
	00258	Oral	2	20 MG	19MAR96	8	25MAR96	14	7
	00258	Oral	3	20 MG	26MAR96	15	01APR96	21	7
	00258	Oral	4	20 MG	02APR96	22	08APR96	28	7
	00258	Oral	5	30 MG	09APR96	29	17APR96	37	9
	00258	Oral	6	40 MG	18APR96	38	22APR96	42	5
	00258	Oral	6	40 MG	23APR96	43	29APR96	49	7
	00258	Oral	6	40 MG	30APR96	50	06MAY96	56	7
		Oral	5	30 MG	07MAY96	57	.	.	.
329.005.00299		Oral	1	20 MG	08JUN96	1	17JUN96	10	10

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00299	00299	Oral	2	20 MG	18JUN96	11	24JUN96	17	7
	00299	Oral	3	20 MG	25JUN96	18	01JUL96	24	7
	00299	Oral	4	20 MG	02JUL96	25	09JUL96	32	8
	00299	Oral	4	20 MG	10JUL96	33	21JUL96	44	12
		Oral	4	20 MG	22JUL96	45	30JUL96	53	9
	00299	Oral	4	20 MG	31JUL96	54	06AUG96	60	7
	00169	Oral	4	20 MG	07AUG96	61	02SEP96	87	27
	00169	Oral	4	20 MG	03SEP96	88	01OCT96	116	29
	00169	Oral	5	30 MG	02OCT96	117	28OCT96	143	27
	00169	Oral	5	30 MG	29OCT96	144	04NOV96	150	7
	00299	Oral	4	20 MG	05NOV96	151	06NOV96	152	2
	00299	Oral	3	20 MG	07NOV96	153	08NOV96	154	2
	00299	Oral	2	20 MG	09NOV96	155	11NOV96	157	3
	00299	Oral	1	20 MG	12NOV96	158	18NOV96	164	7
329.005.00300		Oral	1	20 MG	19SEP96	1	25SEP96	7	7
	00300	Oral	2	20 MG	26SEP96	8	02OCT96	14	7
	00300	Oral	3	20 MG	03OCT96	15	09OCT96	21	7
	00300	Oral	4	20 MG	10OCT96	22	16OCT96	28	7
	00300	Oral	4	20 MG	17OCT96	29	23OCT96	35	7
	00300	Oral	4	20 MG	24OCT96	36	30OCT96	42	7
	00300	Oral	4	20 MG	31OCT96	43	06NOV96	49	7
	00300	Oral	4	20 MG	07NOV96	50	13NOV96	56	7
		Oral	3	20 MG	14NOV96	57	.	.	.
329.005.00333		Oral	1	20 MG	23JAN97	1	30JAN97	8	8
	00333	Oral	2	20 MG	31JAN97	9	05FEB97	14	6
	00333	Oral	3	20 MG	06FEB97	15	12FEB97	21	7
	00333	Oral	4	20 MG	13FEB97	22	19FEB97	28	7
	00333	Oral	4	20 MG	20FEB97	29	24FEB97	33	5
329.005.00336		Oral	1	20 MG	04MAR97	1	11MAR97	8	8
	00336	Oral	2	20 MG	12MAR97	9	18MAR97	15	7
	00336	Oral	3	20 MG	19MAR97	16	24MAR97	21	6
	00336	Oral	4	20 MG	25MAR97	22	01APR97	29	8
	00336	Oral	4	20 MG	02APR97	30	08APR97	36	7
	00336	Oral	4	20 MG	09APR97	37	15APR97	43	7
	00336	Oral	4	20 MG	16APR97	44	22APR97	50	7
	00336	Oral	4	20 MG	23APR97	51	30APR97	58	8

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.006.00038		Oral	1	20 MG	15FEB95	1	21FEB95	7	7
	00038	Oral	2	20 MG	22FEB95	8	02MAR95	16	9
	00038	Oral	3	20 MG	03MAR95	17	07MAR95	21	5
	00038	Oral	4	20 MG	08MAR95	22	15MAR95	29	8
	00038	Oral	4	20 MG	16MAR95	30	22MAR95	36	7
	00038	Oral	4	20 MG	23MAR95	37	29MAR95	43	7
	00038	Oral	4	20 MG	30MAR95	44	04APR95	49	6
	00038	Oral	4	20 MG	05APR95	50	12APR95	57	8
329.006.00039		Oral	1	20 MG	08FEB95	1	13FEB95	6	6
	00039	Oral	2	20 MG	14FEB95	7	21FEB95	14	8
	00039	Oral	3	20 MG	22FEB95	15	01MAR95	22	8
	00039	Oral	4	20 MG	02MAR95	23	07MAR95	28	6
	00039	Oral	4	20 MG	08MAR95	29	17MAR95	38	10
	00039	Oral	4	20 MG	18MAR95	39	23MAR95	44	6
	00039	Oral	5	30 MG	24MAR95	45	28MAR95	49	5
	00039	Oral	5	30 MG	29MAR95	50	09APR95	61	12
	00057	Oral	5	30 MG	10APR95	62	30APR95	82	21
	00039	Oral	4	20 MG	01MAY95	83	05MAY95	87	5
	00039	Oral	3	20 MG	06MAY95	88	07MAY95	89	2
	00039	Oral	2	20 MG	08MAY95	90	08MAY95	90	1
	00039	Oral	1	20 MG	09MAY95	91	10MAY95	92	2
329.006.00260		Oral	1	20 MG	18JUL96	1	26JUL96	9	9
	00260	Oral	2	20 MG	27JUL96	10	31JUL96	14	5
	00260	Oral	3	20 MG	01AUG96	15	06AUG96	20	6
	00260	Oral	4	20 MG	07AUG96	21	13AUG96	27	7
	00260	Oral	5	30 MG	14AUG96	28	20AUG96	34	7
	00260	Oral	5	30 MG	21AUG96	35	27AUG96	41	7
	00260	Oral	5	30 MG	28AUG96	42	03SEP96	48	7
	00260	Oral	5	30 MG	04SEP96	49	13SEP96	58	10
	00172	Oral	5	30 MG	14SEP96	59	08OCT96	83	25
	00172	Oral	5	30 MG	09OCT96	84	08NOV96	114	31
	00172	Oral	5	30 MG	09NOV96	115	04DEC96	140	26
	00260	Oral	4	20 MG	05DEC96	141	08DEC96	144	4
	00260	Oral	3	20 MG	09DEC96	145	11DEC96	147	3
	00260	Oral	2	20 MG	12DEC96	148	13DEC96	149	2
	00260	Oral	1	20 MG	14DEC96	150	18DEC96	154	5
329.006.00261		Oral	1	20 MG	26NOV96	1	02DEC96	7	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.006.00261	00261	Oral	2	20 MG	03DEC96	8	09DEC96	14	7
	00261	Oral	3	20 MG	10DEC96	15	16DEC96	21	7
	00261	Oral	4	20 MG	17DEC96	22	23DEC96	28	7
	00261	Oral	5	30 MG	24DEC96	29	01JAN97	37	9
	00261	Oral	5	30 MG	02JAN97	38	08JAN97	44	7
	00261	Oral	5	30 MG	09JAN97	45	14JAN97	50	6
	00261	Oral	5	30 MG	15JAN97	51	22JAN97	58	8
	00187	Oral	5	30 MG	23JAN97	59	19FEB97	86	28
	00187	Oral	5	30 MG	20FEB97	87	02APR97	128	42
	00261	Oral	5	30 MG	02APR97	128	03APR97	129	2
	00261	Oral	4	20 MG	04APR97	130	05APR97	131	2
	00261	Oral	3	20 MG	06APR97	132	07APR97	133	2
	00261	Oral	2	20 MG	08APR97	134	10APR97	136	3
	00261	Oral	1	20 MG	11APR97	137	29APR97	155	19
329.007.00140		Oral	1	20 MG	15SEP95	1	20SEP95	6	6
	00140	Oral	2	20 MG	21SEP95	7	27SEP95	13	7
	00140	Oral	3	20 MG	28SEP95	14	04OCT95	20	7
	00140	Oral	4	20 MG	05OCT95	21	11OCT95	27	7
	00140	Oral	4	20 MG	12OCT95	28	17OCT95	33	6
	00140	Oral	4	20 MG	18OCT95	34	25OCT95	41	8
	00140	Oral	4	20 MG	26OCT95	42	01NOV95	48	7
	00140	Oral	4	20 MG	02NOV95	49	08NOV95	55	7
	00005	Oral	4	20 MG	09NOV95	56	21NOV95	68	13
	00140	Oral	4	20 MG	22NOV95	69	.	.	.
329.007.00142		Oral	1	20 MG	18OCT95	1	25OCT95	8	8
	00142	Oral	2	20 MG	26OCT95	9	01NOV95	15	7
	00142	Oral	3	20 MG	02NOV95	16	08NOV95	22	7
	00142	Oral	4	20 MG	09NOV95	23	15NOV95	29	7
	00142	Oral	5	30 MG	16NOV95	30	21NOV95	35	6
	00142	Oral	5	30 MG	22NOV95	36	29NOV95	43	8
	00142	Oral	6	40 MG	30NOV95	44	04DEC95	48	5
329.007.00145		Oral	1	20 MG	11JAN96	1	17JAN96	7	7
	00145	Oral	2	20 MG	18JAN96	8	24JAN96	14	7
	00145	Oral	3	20 MG	25JAN96	15	31JAN96	21	7
		Oral	4	20 MG	01FEB96	22	07FEB96	28	7
	00348	Oral	5	30 MG	08FEB96	29	11FEB96	32	4
	00348	Oral	5	30 MG	12FEB96	33	20FEB96	41	9

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.007.00145	00348	Oral	5	30 MG	21FEB96	42	25FEB96	46	5
	00348	Oral	6	40 MG	26FEB96	47	06MAR96	56	10
	00190	Oral	6	40 MG	07MAR96	57	03APR96	84	28
	00190	Oral	6	40 MG	04APR96	85	01MAY96	112	28
	00190	Oral	5	30 MG	02MAY96	113	13MAY96	124	12
	00190	Oral	4	20 MG	14MAY96	125	29MAY96	140	16
	00190	Oral	4	20 MG	30MAY96	141	26JUN96	168	28
	00190	Oral	4	20 MG	27JUN96	169	24JUL96	196	28
	00190	Oral	4	20 MG	25JUL96	197	22AUG96	225	29
	00348	Oral	3	20 MG	23AUG96	226	.	.	.
329.007.00265		Oral	1	20 MG	01FEB96	1	14FEB96	14	14
	00265	Oral	2	20 MG	15FEB96	15	.	.	.
329.007.00268		Oral	1	20 MG	01APR96	1	10APR96	10	10
	00268	Oral	2	20 MG	11APR96	11	17APR96	17	7
	00268	Oral	3	20 MG	18APR96	18	24APR96	24	7
	00268	Oral	4	20 MG	25APR96	25	01MAY96	31	7
	00268	Oral	4	20 MG	02MAY96	32	08MAY96	38	7
	00268	Oral	4	20 MG	09MAY96	39	15MAY96	45	7
	00268	Oral	5	30 MG	16MAY96	46	23MAY96	53	8
	00268	Oral	5	30 MG	24MAY96	54	29MAY96	59	6
	00157	Oral	5	30 MG	30MAY96	60	26JUN96	87	28
	00157	Oral	5	30 MG	27JUN96	88	31JUL96	122	35
	00157	Oral	6	40 MG	01AUG96	123	29AUG96	151	29
	00157	Oral	6	40 MG	30AUG96	152	29SEP96	182	31
	00157	Oral	5	30 MG	30SEP96	183	06NOV96	220	38
	00157	Oral	5	30 MG	07NOV96	221	04DEC96	248	28
	00268	Oral	4	20 MG	05DEC96	249	18DEC96	262	14
329.007.00294		Oral	1	20 MG	28FEB97	1	09MAR97	10	10
	00294	Oral	2	20 MG	10MAR97	11	16MAR97	17	7
	00294	Oral	3	20 MG	17MAR97	18	27MAR97	28	11
	00294	Oral	4	20 MG	28MAR97	29	02APR97	34	6
	00294	Oral	5	30 MG	03APR97	35	09APR97	41	7
	00294	Oral	4	20 MG	10APR97	42	.	.	.
329.007.00309		Oral	1	20 MG	15JUL96	1	17JUL96	3	3
	00309	Oral	2	20 MG	18JUL96	4	24JUL96	10	7
	00309	Oral	3	20 MG	25JUL96	11	31JUL96	17	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.007.00309	00309	Oral	4	20 MG	01AUG96	18	07AUG96	24	7
	00309	Oral	4	20 MG	08AUG96	25	14AUG96	31	7
	00309	Oral	4	20 MG	15AUG96	32	22AUG96	39	8
	00309	Oral	4	20 MG	23AUG96	40	29AUG96	46	7
	00309	Oral	4	20 MG	30AUG96	47	04SEP96	52	6
	00170	Oral	4	20 MG	05SEP96	53	02OCT96	80	28
	00170	Oral	4	20 MG	03OCT96	81	30OCT96	108	28
	00170	Oral	4	20 MG	31OCT96	109	12DEC96	151	43
	00170	Oral	4	20 MG	13DEC96	152	08JAN97	178	27
	00170	Oral	4	20 MG	09JAN97	179	09FEB97	210	32
	00170	Oral	5	30 MG	10FEB97	211	12MAR97	241	31
	00309	Oral	4	20 MG	13MAR97	242	26MAR97	255	14
329.007.00310		Oral	1	20 MG	26SEP96	1	02OCT96	7	7
	00310	Oral	2	20 MG	03OCT96	8	09OCT96	14	7
	00310	Oral	3	20 MG	10OCT96	15	16OCT96	21	7
	00310	Oral	4	20 MG	17OCT96	22	27OCT96	32	11
	00310	Oral	4	20 MG	28OCT96	33	30OCT96	35	3
	00310	Oral	4	20 MG	31OCT96	36	07NOV96	43	8
	00310	Oral	4	20 MG	08NOV96	44	17NOV96	53	10
	00310	Oral	4	20 MG	18NOV96	54	24NOV96	60	7
	00180	Oral	4	20 MG	25NOV96	61	01JAN97	98	38
	00180	Oral	4	20 MG	02JAN97	99	13FEB97	141	43
	00180	Oral	4	20 MG	14FEB97	142	12MAR97	168	27
	00180	Oral	4	20 MG	13MAR97	169	16APR97	203	35
	00180	Oral	4	20 MG	17APR97	204	14MAY97	231	28
	00180	Oral	4	20 MG	15MAY97	232	11JUN97	259	28
	00310	Oral	3	20 MG	12JUN97	260	23JUN97	271	12
329.007.00318		Oral	1	20 MG	02DEC96	1	.	.	.
329.008.00157		Oral	1	20 MG	30AUG95	1	04SEP95	6	6
	00157	Oral	2	20 MG	05SEP95	7	12SEP95	14	8
	00157	Oral	3	20 MG	13SEP95	15	19SEP95	21	7
	00157	Oral	4	20 MG	20SEP95	22	26SEP95	28	7
	00157	Oral	4	20 MG	27SEP95	29	03OCT95	35	7
	00157	Oral	4	20 MG	04OCT95	36	09OCT95	41	6
	00157	Oral	4	20 MG	10OCT95	42	15OCT95	47	6
	00157	Oral	4	20 MG	16OCT95	48	23OCT95	55	8
		Oral	4	20 MG	24OCT95	56	22NOV95	85	30

* DAYS RELATIVE TO START OF STUDY MEDICATION

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.008.00157	00100	Oral	4	20 MG	23NOV95	86	14DEC95	107	22
	00100	Oral	4	20 MG	15DEC95	108	22JAN96	146	39
	00100	Oral	4	20 MG	23JAN96	147	19FEB96	174	28
329.008.00160		Oral	1	20 MG	01NOV95	1	09NOV95	9	9
	00160	Oral	2	20 MG	10NOV95	10	19NOV95	19	10
	00160	Oral	3	20 MG	20NOV95	20	26NOV95	26	7
	00160	Oral	4	20 MG	27NOV95	27	04DEC95	34	8
	00160	Oral	4	20 MG	05DEC95	35	12DEC95	42	8
	00160	Oral	5	30 MG	13DEC95	43	19DEC95	49	7
	00160	Oral	5	30 MG	20DEC95	50	26DEC95	56	7
	00160	Oral	5	30 MG	27DEC95	57	05JAN96	66	10
	00104	Oral	5	30 MG	06JAN96	67	30JAN96	91	25
	00104	Oral	5	30 MG	31JAN96	92	04MAR96	125	34
	00104	Oral	5	30 MG	05MAR96	126	08APR96	160	35
	00104	Oral	5	30 MG	09APR96	161	15MAY96	197	37
	00104	Oral	5	30 MG	16MAY96	198	17JUN96	230	33
	00104	Oral	5	30 MG	18JUN96	231	22JUL96	265	35
	00160	Oral	5	30 MG	23JUL96	266	24JUL96	267	2
	00160	Oral	4	20 MG	25JUL96	268	26JUL96	269	2
	00160	Oral	3	20 MG	27JUL96	270	28JUL96	271	2
	00160	Oral	2	20 MG	29JUL96	272	31JUL96	274	3
	00160	Oral	1	20 MG	01AUG96	275	07AUG96	281	7
329.008.00188		Oral	1	20 MG	04JAN96	1	09JAN96	6	6
	00188	Oral	2	20 MG	10JAN96	7	16JAN96	13	7
	00188	Oral	3	20 MG	17JAN96	14	23JAN96	20	7
	00188	Oral	4	20 MG	24JAN96	21	30JAN96	27	7
	00188	Oral	5	30 MG	31JAN96	28	06FEB96	34	7
	00188	Oral	6	40 MG	07FEB96	35	13FEB96	41	7
	00188	Oral	6	40 MG	14FEB96	42	20FEB96	48	7
	00188	Oral	6	40 MG	21FEB96	49	27FEB96	55	7
329.008.00271		Oral	1	20 MG	11MAR96	1	17MAR96	7	7
	00271	Oral	2	20 MG	18MAR96	8	24MAR96	14	7
	00271	Oral	3	20 MG	25MAR96	15	31MAR96	21	7
	00271	Oral	4	20 MG	01APR96	22	07APR96	28	7
	00271	Oral	4	20 MG	08APR96	29	14APR96	35	7
	00271	Oral	5	30 MG	15APR96	36	21APR96	42	7
	00271	Oral	6	40 MG	22APR96	43	01MAY96	52	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.008.00271	00271	Oral	6	40 MG	02MAY96	53	13MAY96	64	12
	00137	Oral	6	40 MG	14MAY96	65	09JUN96	91	27
	00137	Oral	6	40 MG	10JUN96	92	11JUL96	123	32
	00137	Oral	6	40 MG	12JUL96	124	08AUG96	151	28
	00137	Oral	6	40 MG	09AUG96	152	09SEP96	183	32
	00137	Oral	6	40 MG	10SEP96	184	06OCT96	210	27
	00137	Oral	6	40 MG	07OCT96	211	04NOV96	239	29
	00271	Oral	5	30 MG	05NOV96	240	06NOV96	241	2
	00271	Oral	4	20 MG	07NOV96	242	08NOV96	243	2
	00271	Oral	3	20 MG	09NOV96	244	10NOV96	245	2
	00271	Oral	2	20 MG	11NOV96	246	13NOV96	248	3
	00271	Oral	1	20 MG	14NOV96	249	20NOV96	255	7
329.008.00275		Oral	1	20 MG	08MAY96	1	14MAY96	7	7
	00275	Oral	2	20 MG	15MAY96	8	20MAY96	13	6
	00275	Oral	3	20 MG	21MAY96	14	27MAY96	20	7
	00275	Oral	4	20 MG	28MAY96	21	03JUN96	27	7
	00275	Oral	5	30 MG	04JUN96	28	10JUN96	34	7
	00275	Oral	5	30 MG	11JUN96	35	24JUN96	48	14
	00275	Oral	6	40 MG	25JUN96	49	01JUL96	55	7
	00163	Oral	5	30 MG	02JUL96	56	22JUL96	76	21
	00163	Oral	5	30 MG	23JUL96	77	19AUG96	104	28
	00163	Oral	5	30 MG	20AUG96	105	15SEP96	131	27
	00163	Oral	5	30 MG	16SEP96	132	20OCT96	166	35
		Oral	5	30 MG	21OCT96	167	24NOV96	201	35
	00163	Oral	5	30 MG	25NOV96	202	16DEC96	223	22
329.009.00130		Oral	1	20 MG	18APR95	1	24APR95	7	7
	00130	Oral	2	20 MG	25APR95	8	01MAY95	14	7
	00130	Oral	3	20 MG	02MAY95	15	08MAY95	21	7
	00130	Oral	4	20 MG	09MAY95	22	15MAY95	28	7
	00130	Oral	4	20 MG	16MAY95	29	22MAY95	35	7
	00130	Oral	4	20 MG	23MAY95	36	29MAY95	42	7
	00130	Oral	4	20 MG	30MAY95	43	05JUN95	49	7
	00130	Oral	4	20 MG	06JUN95	50	12JUN95	56	7
	00010	Oral	4	20 MG	13JUN95	57	06AUG95	111	55
	00010	Oral	4	20 MG	07AUG95	112	18SEP95	154	43
	00010	Oral	4	20 MG	19SEP95	155	02OCT95	168	14
	00130	Oral	4	20 MG	03OCT95	169	04OCT95	170	2
	00130	Oral	3	20 MG	05OCT95	171	06OCT95	172	2

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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00130	00130	Oral	2	20 MG	07OCT95	173	09OCT95	175	3
	00130	Oral	1	20 MG	10OCT95	176	16OCT95	182	7
329.009.00131		Oral	1	20 MG	02MAY95	1	08MAY95	7	7
	00131	Oral	2	20 MG	09MAY95	8	15MAY95	14	7
	00131	Oral	3	20 MG	16MAY95	15	22MAY95	21	7
	00131	Oral	4	20 MG	23MAY95	22	29MAY95	28	7
	00131	Oral	4	20 MG	30MAY95	29	05JUN95	35	7
	00131	Oral	4	20 MG	06JUN95	36	12JUN95	42	7
	00131	Oral	4	20 MG	13JUN95	43	19JUN95	49	7
	00131	Oral	4	20 MG	20JUN95	50	26JUN95	56	7
	00011	Oral	4	20 MG	27JUN95	57	24JUL95	84	28
	00011	Oral	4	20 MG	25JUL95	85	23AUG95	114	30
	00011	Oral	4	20 MG	24AUG95	115	27AUG95	118	4
329.009.00133		Oral	1	20 MG	13JUN95	1	19JUN95	7	7
	00133	Oral	2	20 MG	20JUN95	8	26JUN95	14	7
	00133	Oral	3	20 MG	27JUN95	15	04JUL95	22	8
	00133	Oral	4	20 MG	05JUL95	23	10JUL95	28	6
	00133	Oral	5	30 MG	11JUL95	29	17JUL95	35	7
	00133	Oral	6	40 MG	18JUL95	36	27JUL95	45	10
329.009.00138		Oral	1	20 MG	10OCT95	1	13OCT95	4	4
329.009.00170		Oral	1	20 MG	07NOV95	1	13NOV95	7	7
	00170	Oral	2	20 MG	14NOV95	8	20NOV95	14	7
	00170	Oral	3	20 MG	21NOV95	15	27NOV95	21	7
	00170	Oral	4	20 MG	28NOV95	22	04DEC95	28	7
	00170	Oral	5	30 MG	05DEC95	29	11DEC95	35	7
	00170	Oral	6	40 MG	12DEC95	36	20DEC95	44	9
	00170	Oral	6	40 MG	21DEC95	45	28DEC95	52	8
	00170	Oral	5	30 MG	29DEC95	53	02JAN96	57	5
	00102	Oral	5	30 MG	03JAN96	58	28JAN96	83	26
	00102	Oral	5	30 MG	29JAN96	84	25FEB96	111	28
	00102	Oral	5	30 MG	26FEB96	112	31MAR96	146	35
	00102	Oral	5	30 MG	01APR96	147	21APR96	167	21
	00102	Oral	5	30 MG	22APR96	168	22MAY96	198	31
	00102	Oral	5	30 MG	23MAY96	199	24JUN96	231	33
	00358	Oral	4	20 MG	25JUN96	232	26JUN96	233	2
	00358	Oral	3	20 MG	27JUN96	234	28JUN96	235	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00170	00358	Oral	2	20 MG	29JUN96	236	01JUL96	238	3
	00358	Oral	1	20 MG	02JUL96	239	08JUL96	245	7
329.009.00173		Oral	1	20 MG	20NOV95	1	26NOV95	7	7
	00173	Oral	2	20 MG	27NOV95	8	03DEC95	14	7
	00173	Oral	3	20 MG	04DEC95	15	10DEC95	21	7
	00173	Oral	4	20 MG	11DEC95	22	17DEC95	28	7
	00173	Oral	5	30 MG	18DEC95	29	28DEC95	39	11
	00173	Oral	5	30 MG	29DEC95	40	07JAN96	49	10
	00173	Oral	4	20 MG	08JAN96	50	14JAN96	56	7
	00173	Oral	4	20 MG	15JAN96	57	21JAN96	63	7
	00108	Oral	4	20 MG	22JAN96	64	26FEB96	99	36
	00173	Oral	4	20 MG	27FEB96	100	.	.	.
329.009.00193		Oral	1	20 MG	28NOV95	1	04DEC95	7	7
	00193	Oral	2	20 MG	05DEC95	8	11DEC95	14	7
	00193	Oral	3	20 MG	12DEC95	15	18DEC95	21	7
	00193	Oral	4	20 MG	19DEC95	22	26DEC95	29	8
	00193	Oral	5	30 MG	27DEC95	30	04JAN96	38	9
	00193	Oral	5	30 MG	05JAN96	39	08JAN96	42	4
	00193	Oral	5	30 MG	09JAN96	43	15JAN96	49	7
	00193	Oral	5	30 MG	16JAN96	50	23JAN96	57	8
		Oral	1	20 MG	24JAN96	58	06FEB96	71	14
329.009.00196		Oral	1	20 MG	18DEC95	1	26DEC95	9	9
	00196	Oral	2	20 MG	27DEC95	10	01JAN96	15	6
	00196	Oral	3	20 MG	02JAN96	16	07JAN96	21	6
	00196	Oral	4	20 MG	08JAN96	22	14JAN96	28	7
	00196	Oral	5	30 MG	15JAN96	29	21JAN96	35	7
	00196	Oral	5	30 MG	22JAN96	36	28JAN96	42	7
	00196	Oral	5	30 MG	29JAN96	43	04FEB96	49	7
	00196	Oral	5	30 MG	05FEB96	50	11FEB96	56	7
	00196	Oral	4	20 MG	12FEB96	57	25FEB96	70	14
329.009.00201		Oral	1	20 MG	06FEB96	1	12FEB96	7	7
	00201	Oral	2	20 MG	13FEB96	8	19FEB96	14	7
	00201	Oral	3	20 MG	20FEB96	15	27FEB96	22	8
	00201	Oral	4	20 MG	28FEB96	23	04MAR96	28	6
	00201	Oral	4	20 MG	05MAR96	29	11MAR96	35	7
	00201	Oral	4	20 MG	12MAR96	36	18MAR96	42	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00201	00201	Oral	4	20 MG	19MAR96	43	25MAR96	49	7
	00201	Oral	5	30 MG	26MAR96	50	01APR96	56	7
		Oral	4	20 MG	02APR96	57	04APR96	59	3
329.009.00204		Oral	1	20 MG	19MAR96	1	25MAR96	7	7
	00204	Oral	2	20 MG	26MAR96	8	01APR96	14	7
	00204	Oral	3	20 MG	02APR96	15	08APR96	21	7
	00204	Oral	4	20 MG	09APR96	22	15APR96	28	7
	00204	Oral	4	20 MG	16APR96	29	22APR96	35	7
	00204	Oral	4	20 MG	23APR96	36	29APR96	42	7
	00204	Oral	4	20 MG	30APR96	43	06MAY96	49	7
	00204	Oral	4	20 MG	07MAY96	50	13MAY96	56	7
	00149	Oral	4	20 MG	14MAY96	57	10JUN96	84	28
	00149	Oral	4	20 MG	11JUN96	85	08JUL96	112	28
	00149	Oral	4	20 MG	09JUL96	113	12AUG96	147	35
	00149	Oral	4	20 MG	13AUG96	148	09SEP96	175	28
	00149	Oral	4	20 MG	10SEP96	176	14OCT96	210	35
	00149	Oral	4	20 MG	15OCT96	211	.	.	.
329.009.00235		Oral	1	20 MG	18DEC96	1	22DEC96	5	5
	00235	Oral	2	20 MG	23DEC96	6	29DEC96	12	7
	00235	Oral	3	20 MG	30DEC96	13	05JAN97	19	7
	00235	Oral	4	20 MG	06JAN97	20	14JAN97	28	9
	00235	Oral	4	20 MG	15JAN97	29	19JAN97	33	5
	00235	Oral	4	20 MG	20JAN97	34	26JAN97	40	7
	00235	Oral	4	20 MG	27JAN97	41	02FEB97	47	7
	00235	Oral	4	20 MG	03FEB97	48	09FEB97	54	7
	00109	Oral	4	20 MG	10FEB97	55	17MAR97	90	36
	00109	Oral	4	20 MG	17MAR97	90	13APR97	117	28
	00235	Oral	4	20 MG	14APR97	118	14APR97	118	1
	00235	Oral	3	20 MG	15APR97	119	16APR97	120	2
	00235	Oral	2	20 MG	17APR97	121	19APR97	123	3
	00235	Oral	1	20 MG	20APR97	124	26APR97	130	7
329.009.00240		Oral	1	20 MG	14JAN97	1	20JAN97	7	7
	00240	Oral	2	20 MG	21JAN97	8	27JAN97	14	7
	00240	Oral	3	20 MG	28JAN97	15	03FEB97	21	7
	00240	Oral	4	20 MG	04FEB97	22	10FEB97	28	7
	00240	Oral	4	20 MG	11FEB97	29	17FEB97	35	7
	00240	Oral	5	30 MG	18FEB97	36	25FEB97	43	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00240	00240	Oral	5	30 MG	25FEB97	43	04MAR97	50	8
		Oral	5	30 MG	04MAR97	50	05MAR97	51	2
329.009.00303		Oral	1	20 MG	02APR96	1	08APR96	7	7
	00303	Oral	2	20 MG	09APR96	8	15APR96	14	7
	00303	Oral	3	20 MG	16APR96	15	22APR96	21	7
	00303	Oral	4	20 MG	23APR96	22	29APR96	28	7
	00303	Oral	4	20 MG	30APR96	29	06MAY96	35	7
	00303	Oral	4	20 MG	07MAY96	36	13MAY96	42	7
	00303	Oral	4	20 MG	14MAY96	43	21MAY96	50	8
	00303	Oral	4	20 MG	22MAY96	51	27MAY96	56	6
	00155	Oral	4	20 MG	28MAY96	57	24JUN96	84	28
	00155	Oral	4	20 MG	25JUN96	85	29JUL96	119	35
	00155	Oral	4	20 MG	30JUL96	120	26AUG96	147	28
	00155	Oral	4	20 MG	27AUG96	148	24SEP96	176	29
	00155	Oral	4	20 MG	25SEP96	177	29OCT96	211	35
	00155	Oral	4	20 MG	30OCT96	212	09DEC96	252	41
	00303	Oral	4	20 MG	10DEC96	253	10DEC96	253	1
	00303	Oral	3	20 MG	11DEC96	254	12DEC96	255	2
	00303	Oral	2	20 MG	13DEC96	256	15DEC96	258	3
	00303	Oral	1	20 MG	16DEC96	259	22DEC96	265	7
329.009.00304		Oral	1	20 MG	09APR96	1	15APR96	7	7
	00304	Oral	2	20 MG	16APR96	8	22APR96	14	7
	00304	Oral	3	20 MG	23APR96	15	29APR96	21	7
	00304	Oral	4	20 MG	30APR96	22	06MAY96	28	7
	00304	Oral	5	30 MG	07MAY96	29	13MAY96	35	7
	00304	Oral	5	30 MG	14MAY96	36	20MAY96	42	7
	00304	Oral	5	30 MG	21MAY96	43	27MAY96	49	7
	00304	Oral	5	30 MG	28MAY96	50	03JUN96	56	7
	00159	Oral	5	30 MG	04JUN96	57	01JUL96	84	28
	00159	Oral	5	30 MG	02JUL96	85	29JUL96	112	28
	00159	Oral	5	30 MG	30JUL96	113	26AUG96	140	28
	00159	Oral	5	30 MG	27AUG96	141	22SEP96	167	27
	00159	Oral	5	30 MG	23SEP96	168	21OCT96	196	29
	00304	Oral	4	20 MG	22OCT96	197	23OCT96	198	2
	00304	Oral	3	20 MG	24OCT96	199	24OCT96	199	1
	00304	Oral	2	20 MG	25OCT96	200	28OCT96	203	4
	00304	Oral	1	20 MG	29OCT96	204	04NOV96	210	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00324		Oral	1	20 MG	28OCT96	1	03NOV96	7	7
	00324	Oral	2	20 MG	04NOV96	8	10NOV96	14	7
	00324	Oral	3	20 MG	11NOV96	15	17NOV96	21	7
	00324	Oral	4	20 MG	18NOV96	22	24NOV96	28	7
	00324	Oral	4	20 MG	25NOV96	29	01DEC96	35	7
	00324	Oral	4	20 MG	02DEC96	36	08DEC96	42	7
	00324	Oral	4	20 MG	09DEC96	43	15DEC96	49	7
	00324	Oral	4	20 MG	16DEC96	50	26DEC96	60	11
		Oral	4	20 MG	27DEC96	61	08JAN97	73	13
329.009.00328		Oral	1	20 MG	07OCT96	1	.	.	.
329.009.00329		Oral	1	20 MG	09OCT96	1	15OCT96	7	7
	00329	Oral	2	20 MG	16OCT96	8	22OCT96	14	7
	00329	Oral	3	20 MG	23OCT96	15	28OCT96	20	6
	00329	Oral	4	20 MG	29OCT96	21	04NOV96	27	7
	00329	Oral	4	20 MG	05NOV96	28	11NOV96	34	7
	00329	Oral	4	20 MG	12NOV96	35	18NOV96	41	7
	00329	Oral	5	30 MG	19NOV96	42	25NOV96	48	7
	00329	Oral	5	30 MG	26NOV96	49	02DEC96	55	7
		Oral	5	30 MG	03DEC96	56	17DEC96	70	15
329.010.00182	00182	Oral	3	20 MG	19DEC95	1	11JAN96	24	24
	00182	Oral	4	20 MG	12JAN96	25	18JAN96	31	7
	00182	Oral	4	20 MG	19JAN96	32	.	.	.
329.010.00278		Oral	1	20 MG	09FEB96	1	15FEB96	7	7
	00278	Oral	2	20 MG	16FEB96	8	22FEB96	14	7
	00278	Oral	3	20 MG	23FEB96	15	29FEB96	21	7
	00278	Oral	4	20 MG	01MAR96	22	07MAR96	28	7
	00278	Oral	4	20 MG	08MAR96	29	14MAR96	35	7
	00278	Oral	5	30 MG	15MAR96	36	21MAR96	42	7
	00278	Oral	6	40 MG	22MAR96	43	28MAR96	49	7
	00278	Oral	6	40 MG	29MAR96	50	04APR96	56	7
	00132	Oral	6	40 MG	05APR96	57	02MAY96	84	28
	00132	Oral	6	40 MG	03MAY96	85	30MAY96	112	28
	00132	Oral	6	40 MG	31MAY96	113	26JUN96	139	27
	00132	Oral	6	40 MG	27JUN96	140	24JUL96	167	28
	00132	Oral	6	40 MG	25JUL96	168	21AUG96	195	28
	00132	Oral	6	40 MG	22AUG96	196	19SEP96	224	29

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.010.00278	00278	Oral	5	30 MG	20SEP96	225	21SEP96	226	2
	00278	Oral	4	20 MG	22SEP96	227	23SEP96	228	2
	00278	Oral	3	20 MG	24SEP96	229	25SEP96	230	2
	00278	Oral	2	20 MG	26SEP96	231	28SEP96	233	3
	00278	Oral	1	20 MG	29SEP96	234	05OCT96	240	7
329.010.00280		Oral	1	20 MG	17MAY96	1	23MAY96	7	7
	00280	Oral	2	20 MG	24MAY96	8	30MAY96	14	7
	00280	Oral	3	20 MG	31MAY96	15	06JUN96	21	7
	00280	Oral	4	20 MG	07JUN96	22	13JUN96	28	7
	00280	Oral	4	20 MG	14JUN96	29	20JUN96	35	7
	00280	Oral	5	30 MG	21JUN96	36	26JUN96	41	6
	00280	Oral	6	40 MG	27JUN96	42	02JUL96	47	6
	00280	Oral	6	40 MG	03JUL96	48	10JUL96	55	8
		Oral	6	40 MG	11JUL96	56	29JUL96	74	19
329.011.00283		Oral	1	20 MG	08FEB96	1	14FEB96	7	7
	00283	Oral	2	20 MG	15FEB96	8	21FEB96	14	7
	00283	Oral	3	20 MG	22FEB96	15	29FEB96	22	8
	00283	Oral	4	20 MG	01MAR96	23	07MAR96	29	7
	00283	Oral	4	20 MG	08MAR96	30	15MAR96	37	8
	00283	Oral	4	20 MG	16MAR96	38	22MAR96	44	7
	00283	Oral	4	20 MG	23MAR96	45	28MAR96	50	6
	00283	Oral	4	20 MG	29MAR96	51	04APR96	57	7
	00130	Oral	4	20 MG	05APR96	58	.	.	.
329.011.00288		Oral	1	20 MG	25JUL96	1	31JUL96	7	7
	00288	Oral	2	20 MG	01AUG96	8	08AUG96	15	8
	00288	Oral	3	20 MG	09AUG96	16	18AUG96	25	10
	00288	Oral	4	20 MG	19AUG96	26	29AUG96	36	11
	00288	Oral	4	20 MG	30AUG96	37	05SEP96	43	7
329.012.00025		Oral	1	20 MG	24OCT95	1	30OCT95	7	7
	00025	Oral	2	20 MG	31OCT95	8	06NOV95	14	7
	00025	Oral	3	20 MG	07NOV95	15	13NOV95	21	7
	00025	Oral	4	20 MG	14NOV95	22	20NOV95	28	7
	00025	Oral	4	20 MG	21NOV95	29	27NOV95	35	7
	00025	Oral	5	30 MG	28NOV95	36	04DEC95	42	7
	00025	Oral	6	40 MG	05DEC95	43	11DEC95	49	7
	00025	Oral	6	40 MG	12DEC95	50	19DEC95	57	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.012.00025		Oral	5	30 MG	20DEC95	58	04JAN96	73	16
329.012.00220		Oral	1	20 MG	17JUN96	1	21JUN96	5	5
	00220	Oral	2	20 MG	22JUN96	6	27JUN96	11	6
	00220	Oral	3	20 MG	28JUN96	12	04JUL96	18	7
	00220	Oral	4	20 MG	05JUL96	19	11JUL96	25	7
	00220	Oral	5	30 MG	12JUL96	26	18JUL96	32	7
	00220	Oral	5	30 MG	19JUL96	33	28JUL96	42	10
	00220	Oral	5	30 MG	29JUL96	43	05AUG96	50	8
	00220	Oral	5	30 MG	06AUG96	51	15AUG96	60	10
	00110	Oral	5	30 MG	16AUG96	61	12SEP96	88	28
	00110	Oral	5	30 MG	13SEP96	89	10OCT96	116	28
	00110	Oral	5	30 MG	11OCT96	117	07NOV96	144	28
	00110	Oral	5	30 MG	08NOV96	145	21NOV96	158	14
	00220	Oral	5	30 MG	22NOV96	159	.	.	.
329.012.00222		Oral	1	20 MG	28JUN96	1	04JUL96	7	7
	00222	Oral	2	20 MG	05JUL96	8	11JUL96	14	7
	00222	Oral	3	20 MG	12JUL96	15	18JUL96	21	7
	00222	Oral	4	20 MG	19JUL96	22	28JUL96	31	10
	00222	Oral	4	20 MG	29JUL96	32	05AUG96	39	8
	00222	Oral	5	30 MG	06AUG96	40	12AUG96	46	7
	00222	Oral	5	30 MG	13AUG96	47	19AUG96	53	7
	00222	Oral	5	30 MG	20AUG96	54	29AUG96	63	10
	00113	Oral	5	30 MG	30AUG96	64	21SEP96	86	23
329.012.00226		Oral	1	20 MG	03DEC96	1	09DEC96	7	7
	00226	Oral	2	20 MG	10DEC96	8	19DEC96	17	10
	00226	Oral	3	20 MG	20DEC96	18	20DEC96	18	1
329.012.00228		Oral	1	20 MG	19MAR97	1	22MAR97	4	4
329.012.00231		Oral	1	20 MG	07MAR97	1	16MAR97	10	10
	00231	Oral	2	20 MG	17MAR97	11	23MAR97	17	7
	00231	Oral	3	20 MG	24MAR97	18	01APR97	26	9
	00231	Oral	4	20 MG	02APR97	27	08APR97	33	7
	00231	Oral	4	20 MG	09APR97	34	16APR97	41	8
	00231	Oral	4	20 MG	17APR97	42	24APR97	49	8
	00231	Oral	5	30 MG	25APR97	50	30APR97	55	6
	00231	Oral	5	30 MG	01MAY97	56	06MAY97	61	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
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TREATMENT GROUP: PAROXETINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.012.00231	00118	Oral	5	30 MG	07MAY97	62	03JUN97	89	28
	00118	Oral	5	30 MG	04JUN97	90	29JUN97	115	26
	00118	Oral	5	30 MG	30JUN97	116	05AUG97	152	37
	00231	Oral	4	20 MG	05AUG97	152	06AUG97	153	2
	00231	Oral	3	20 MG	07AUG97	154	08AUG97	155	2
	00231	Oral	2	20 MG	09AUG97	156	11AUG97	158	3
	00231	Oral	1	20 MG	12AUG97	159	18AUG97	165	7

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.001.00061		Oral	1	50 MG	29JUL94	1	03AUG94	6	6
	00061	Oral	2	100 MG	04AUG94	7	10AUG94	13	7
	00061	Oral	3	150 MG	11AUG94	14	17AUG94	20	7
	00061	Oral	4	200 MG	18AUG94	21	24AUG94	27	7
	00061	Oral	4	200 MG	25AUG94	28	31AUG94	34	7
		Oral	4	200 MG	01SEP94	35	14SEP94	48	14
329.001.00066		Oral	1	50 MG	22NOV94	1	27NOV94	6	6
	00066	Oral	2	100 MG	28NOV94	7	04DEC94	13	7
		Oral	2	100 MG	05DEC94	14	13DEC94	22	9
329.001.00067		Oral	1	50 MG	22NOV94	1	28NOV94	7	7
	00067	Oral	2	100 MG	29NOV94	8	05DEC94	14	7
		Oral	2	100 MG	06DEC94	15	13DEC94	22	8
329.001.00070		Oral	1	50 MG	22FEB95	1	27FEB95	6	6
	00070	Oral	2	100 MG	28FEB95	7	07MAR95	14	8
	00070	Oral	3	150 MG	08MAR95	15	14MAR95	21	7
	00070	Oral	3	150 MG	15MAR95	22	24MAR95	31	10
329.001.00122		Oral	1	50 MG	20JUN95	1	26JUN95	7	7
	00122	Oral	2	100 MG	27JUN95	8	04JUL95	15	8
	00122	Oral	3	150 MG	05JUL95	16	10JUL95	21	6
	00122	Oral	4	200 MG	11JUL95	22	17JUL95	28	7
	00122	Oral	4	200 MG	18JUL95	29	24JUL95	35	7
	00122	Oral	4	200 MG	25JUL95	36	31JUL95	42	7
	00122	Oral	4	200 MG	01AUG95	43	08AUG95	50	8
	00122	Oral	4	200 MG	09AUG95	51	15AUG95	57	7
	00052	Oral	4	200 MG	16AUG95	58	11SEP95	84	27
	00052	Oral	4	200 MG	12SEP95	85	09OCT95	112	28
	00052	Oral	4	200 MG	10OCT95	113	06NOV95	140	28
	00052	Oral	4	200 MG	07NOV95	141	04DEC95	168	28
		Oral	4	200 MG	05DEC95	169	18DEC95	182	14
329.002.00050		Oral	1	50 MG	23MAR95	1	29MAR95	7	7
	00050	Oral	2	100 MG	30MAR95	8	05APR95	14	7
	00050	Oral	3	150 MG	06APR95	15	12APR95	21	7
		Oral	3	150 MG	14APR95	23	26APR95	35	13
329.002.00056		Oral	1	50 MG	19JUL94	1	25JUL94	7	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00056	00056	Oral	2	100 MG	26JUL94	8	01AUG94	14	7
	00056	Oral	3	150 MG	02AUG94	15	08AUG94	21	7
	00056	Oral	4	200 MG	09AUG94	22	16AUG94	29	8
		Oral	3	150 MG	17AUG94	30	23AUG94	36	7
329.002.00057		Oral	1	50 MG	08SEP94	1	14SEP94	7	7
	00057	Oral	2	100 MG	15SEP94	8	21SEP94	14	7
	00057	Oral	3	150 MG	22SEP94	15	28SEP94	21	7
	00057	Oral	4	200 MG	29SEP94	22	05OCT94	28	7
	00057	Oral	5	250 MG	06OCT94	29	12OCT94	35	7
	00057	Oral	6	300 MG	13OCT94	36	19OCT94	42	7
	00057	Oral	6	300 MG	20OCT94	43	26OCT94	49	7
	00057	Oral	6	300 MG	27OCT94	50	03NOV94	57	8
	00067	Oral	6	300 MG	04NOV94	58	30NOV94	84	27
	00067	Oral	6	300 MG	01DEC94	85	29DEC94	113	29
	00057	Oral	5	250 MG	30DEC94	114	31DEC94	115	2
	00057	Oral	4	200 MG	01JAN95	116	02JAN95	117	2
	00057	Oral	3	150 MG	03JAN95	118	04JAN95	119	2
	00057	Oral	2	100 MG	05JAN95	120	07JAN95	122	3
	00057	Oral	1	50 MG	08JAN95	123	14JAN95	129	7
329.002.00098		Oral	1	50 MG	03JAN95	1	09JAN95	7	7
	00098	Oral	2	100 MG	10JAN95	8	17JAN95	15	8
	00098	Oral	3	150 MG	18JAN95	16	23JAN95	21	6
	00098	Oral	4	200 MG	24JAN95	22	30JAN95	28	7
	00098	Oral	5	250 MG	31JAN95	29	06FEB95	35	7
	00098	Oral	6	300 MG	07FEB95	36	13FEB95	42	7
	00098	Oral	5	250 MG	14FEB95	43	20FEB95	49	7
	00098	Oral	5	250 MG	21FEB95	50	22FEB95	51	2
	00098	Oral	4	200 MG	23FEB95	52	01MAR95	58	7
		Oral	5	250 MG	02MAR95	59	16MAR95	73	15
329.002.00100		Oral	1	50 MG	07MAR95	1	13MAR95	7	7
	00100	Oral	2	100 MG	14MAR95	8	20MAR95	14	7
	00100	Oral	3	150 MG	21MAR95	15	27MAR95	21	7
	00100	Oral	4	200 MG	28MAR95	22	03APR95	28	7
	00100	Oral	4	200 MG	04APR95	29	10APR95	35	7
	00100	Oral	5	250 MG	11APR95	36	17APR95	42	7
	00100	Oral	5	250 MG	18APR95	43	24APR95	49	7
	00100	Oral	5	250 MG	25APR95	50	03MAY95	58	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00100	00069	Oral	5	250 MG	04MAY95	59	29MAY95	84	26
	00069	Oral	5	250 MG	30MAY95	85	.	.	.
329.002.00103		Oral	1	50 MG	20APR95	1	26APR95	7	7
	00103	Oral	2	100 MG	27APR95	8	01MAY95	12	5
	00103	Oral	3	150 MG	02MAY95	13	08MAY95	19	7
	00103	Oral	4	200 MG	09MAY95	20	15MAY95	26	7
	00103	Oral	4	200 MG	16MAY95	27	24MAY95	35	9
	00103	Oral	4	200 MG	25MAY95	36	29MAY95	40	5
	00103	Oral	5	250 MG	30MAY95	41	05JUN95	47	7
	00103	Oral	5	250 MG	06JUN95	48	14JUN95	56	9
	00072	Oral	5	250 MG	15JUN95	57	12JUL95	84	28
	00072	Oral	5	250 MG	13JUL95	85	09AUG95	112	28
	00103	Oral	5	250 MG	10AUG95	113	11AUG95	114	2
	00103	Oral	4	200 MG	12AUG95	115	13AUG95	116	2
	00103	Oral	3	150 MG	14AUG95	117	15AUG95	118	2
	00103	Oral	2	100 MG	16AUG95	119	18AUG95	121	3
	00103	Oral	1	50 MG	19AUG95	122	25AUG95	128	7
329.002.00104		Oral	1	50 MG	04MAY95	1	10MAY95	7	7
	00104	Oral	2	100 MG	11MAY95	8	17MAY95	14	7
	00104	Oral	3	150 MG	18MAY95	15	24MAY95	21	7
	00104	Oral	4	200 MG	25MAY95	22	31MAY95	28	7
	00104	Oral	5	250 MG	01JUN95	29	08JUN95	36	8
	00104	Oral	6	300 MG	09JUN95	37	15JUN95	43	7
	00104	Oral	6	300 MG	16JUN95	44	21JUN95	49	6
	00104	Oral	6	300 MG	22JUN95	50	28JUN95	56	7
	00027	Oral	6	300 MG	29JUN95	57	24JUL95	82	26
	00027	Oral	6	300 MG	25JUL95	83	28AUG95	117	35
	00027	Oral	6	300 MG	29AUG95	118	02OCT95	152	35
	00027	Oral	6	300 MG	03OCT95	153	05NOV95	186	34
	00027	Oral	6	300 MG	06NOV95	187	05DEC95	216	30
	00027	Oral	6	300 MG	06DEC95	217	01JAN96	243	27
	00104	Oral	5	250 MG	02JAN96	244	03JAN96	245	2
	00104	Oral	4	200 MG	04JAN96	246	05JAN96	247	2
	00104	Oral	3	150 MG	06JAN96	248	07JAN96	249	2
	00104	Oral	2	100 MG	08JAN96	250	10JAN96	252	3
	00104	Oral	1	50 MG	11JAN96	253	17JAN96	259	7
329.002.00243		Oral	1	50 MG	14MAR96	1	20MAR96	7	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00243	00243	Oral	2	100 MG	21MAR96	8	27MAR96	14	7
	00243	Oral	3	150 MG	28MAR96	15	04APR96	22	8
	00243	Oral	3	150 MG	05APR96	23	.	.	.
329.002.00244		Oral	1	50 MG	21MAR96	1	27MAR96	7	7
	00244	Oral	2	100 MG	28MAR96	8	03APR96	14	7
	00244	Oral	3	150 MG	04APR96	15	10APR96	21	7
	00244	Oral	4	200 MG	11APR96	22	17APR96	28	7
	00244	Oral	5	250 MG	18APR96	29	24APR96	35	7
	00244	Oral	4	200 MG	25APR96	36	01MAY96	42	7
	00244	Oral	5	250 MG	02MAY96	43	08MAY96	49	7
	00244	Oral	6	300 MG	09MAY96	50	16MAY96	57	8
	00138	Oral	6	300 MG	17MAY96	58	23MAY96	64	7
	00138	Oral	5	250 MG	24MAY96	65	28MAY96	69	5
	00244	Oral	4	200 MG	29MAY96	70	31MAY96	72	3
	00244	Oral	3	150 MG	01JUN96	73	02JUN96	74	2
	00244	Oral	2	100 MG	03JUN96	75	05JUN96	77	3
	00244	Oral	1	50 MG	06JUN96	78	12JUN96	84	7
329.002.00321		Oral	1	50 MG	23MAY96	1	03JUN96	12	12
329.002.00322		Oral	1	50 MG	09JAN97	1	15JAN97	7	7
	00322	Oral	2	100 MG	16JAN97	8	22JAN97	14	7
	00322	Oral	3	150 MG	23JAN97	15	29JAN97	21	7
	00322	Oral	4	200 MG	30JAN97	22	03FEB97	26	5
	00322	Oral	4	200 MG	04FEB97	27	13FEB97	36	10
		Oral	4	200 MG	14FEB97	37	23FEB97	46	10
329.003.00073		Oral	1	50 MG	19JAN95	1	24JAN95	6	6
	00073	Oral	2	100 MG	25JAN95	7	02FEB95	15	9
	00073	Oral	3	150 MG	03FEB95	16	06FEB95	19	4
	00073	Oral	4	200 MG	07FEB95	20	13FEB95	26	7
	00073	Oral	4	200 MG	14FEB95	27	21FEB95	34	8
	00073	Oral	5	250 MG	22FEB95	35	28FEB95	41	7
	00073	Oral	5	250 MG	01MAR95	42	04MAR95	45	4
329.003.00076		Oral	1	50 MG	31JAN95	1	06FEB95	7	7
	00076	Oral	2	100 MG	07FEB95	8	13FEB95	14	7
	00076	Oral	3	150 MG	14FEB95	15	20FEB95	21	7
	00076	Oral	4	200 MG	21FEB95	22	26FEB95	27	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00076	00076	Oral	4	200 MG	27FEB95	28	05MAR95	34	7
	00076	Oral	4	200 MG	06MAR95	35	12MAR95	41	7
	00076	Oral	4	200 MG	13MAR95	42	19MAR95	48	7
	00076	Oral	4	200 MG	20MAR95	49	26MAR95	55	7
	00045	Oral	4	200 MG	27MAR95	56	02MAY95	92	37
	00045	Oral	4	200 MG	03MAY95	93	30MAY95	120	28
	00045	Oral	4	200 MG	31MAY95	121	27JUN95	148	28
	00045	Oral	4	200 MG	28JUN95	149	01AUG95	183	35
	00045	Oral	4	200 MG	02AUG95	184	05SEP95	218	35
	00045	Oral	4	200 MG	06SEP95	219	27SEP95	240	22
329.003.00079		Oral	1	50 MG	03MAY95	1	09MAY95	7	7
	00079	Oral	2	100 MG	10MAY95	8	18MAY95	16	9
	00079	Oral	3	150 MG	19MAY95	17	19MAY95	17	1
329.003.00082		Oral	1	50 MG	11DEC95	1	27DEC95	17	17
	00082	Oral	2	100 MG	28DEC95	18	02JAN96	23	6
	00082	Oral	3	150 MG	03JAN96	24	10JAN96	31	8
	00082	Oral	4	200 MG	11JAN96	32	16JAN96	37	6
	00082	Oral	5	250 MG	17JAN96	38	.	.	.
329.003.00088		Oral	1	50 MG	28FEB95	1	08MAR95	9	9
	00088	Oral	2	100 MG	09MAR95	10	14MAR95	15	6
	00088	Oral	3	150 MG	15MAR95	16	20MAR95	21	6
	00088	Oral	4	200 MG	21MAR95	22	29MAR95	30	9
		Oral	4	200 MG	30MAR95	31	03APR95	35	5
	00088	Oral	4	200 MG	04APR95	36	09APR95	41	6
329.003.00090		Oral	1	50 MG	14MAR95	1	18MAR95	5	5
	00090	Oral	1	50 MG	19MAR95	6	23MAR95	10	5
	00090	Oral	1	50 MG	24MAR95	11	27MAR95	14	4
	00090	Oral	2	100 MG	28MAR95	15	03APR95	21	7
	00090	Oral	3	150 MG	04APR95	22	10APR95	28	7
	00090	Oral	4	200 MG	11APR95	29	17APR95	35	7
	00090	Oral	4	200 MG	18APR95	36	25APR95	43	8
	00090	Oral	5	250 MG	26APR95	44	01MAY95	49	6
	00090	Oral	4	200 MG	02MAY95	50	08MAY95	56	7
	00090	Oral	4	200 MG	09MAY95	57	15MAY95	63	7
		Oral	3	150 MG	16MAY95	64	21MAY95	69	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00092		Oral	1	50 MG	03MAY95	1	11MAY95	9	9
	00092	Oral	2	100 MG	12MAY95	10	16MAY95	14	5
	00092	Oral	3	150 MG	17MAY95	15	25MAY95	23	9
	00092	Oral	4	200 MG	26MAY95	24	02JUN95	31	8
	00092	Oral	4	200 MG	03JUN95	32	05JUN95	34	3
	00092	Oral	4	200 MG	06JUN95	35	13JUN95	42	8
	00092	Oral	4	200 MG	14JUN95	43	20JUN95	49	7
	00092	Oral	4	200 MG	21JUN95	50	29JUN95	58	9
	00035	Oral	4	200 MG	30JUN95	59	08AUG95	98	40
	00035	Oral	4	200 MG	09AUG95	99	05SEP95	126	28
	00035	Oral	4	200 MG	06SEP95	127	26SEP95	147	21
	00035	Oral	4	200 MG	27SEP95	148	21OCT95	172	25
	00035	Oral	0	0 MG	22OCT95	173	23OCT95	174	2
	00035	Oral	4	200 MG	24OCT95	175	07NOV95	189	15
	00035	Oral	4	200 MG	08NOV95	190	05DEC95	217	28
	00035	Oral	4	200 MG	06DEC95	218	02JAN96	245	28
	00092	Oral	5	250 MG	03JAN96	246	04JAN96	247	2
	00092	Oral	4	200 MG	05JAN96	248	06JAN96	249	2
	00092	Oral	3	150 MG	07JAN96	250	08JAN96	251	2
	00092	Oral	2	100 MG	09JAN96	252	11JAN96	254	3
	00092	Oral	1	50 MG	12JAN96	255	18JAN96	261	7
329.003.00093		Oral	1	50 MG	21JUN95	1	26JUN95	6	6
	00093	Oral	2	100 MG	27JUN95	7	06JUL95	16	10
	00093	Oral	3	150 MG	07JUL95	17	21JUL95	31	15
	00093	Oral	4	200 MG	22JUL95	32	25JUL95	35	4
	00093	Oral	5	250 MG	26JUL95	36	01AUG95	42	7
	00093	Oral	6	300 MG	02AUG95	43	10AUG95	51	9
	00093	Oral	6	300 MG	11AUG95	52	16AUG95	57	6
	00093	Oral	6	300 MG	17AUG95	58	22AUG95	63	6
	00053	Oral	6	300 MG	23AUG95	64	08SEP95	80	17
329.003.00247		Oral	1	50 MG	01FEB96	1	06FEB96	6	6
	00247	Oral	2	100 MG	07FEB96	7	12FEB96	12	6
	00247	Oral	3	150 MG	13FEB96	13	20FEB96	20	8
	00247	Oral	4	200 MG	21FEB96	21	27FEB96	27	7
	00247	Oral	4	200 MG	28FEB96	28	07MAR96	36	9
	00247	Oral	4	200 MG	08MAR96	37	11MAR96	40	4
	00247	Oral	4	200 MG	12MAR96	41	21MAR96	50	10
	00247	Oral	4	200 MG	22MAR96	51	25MAR96	54	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00247	00128	Oral	4	200 MG	26MAR96	55	29APR96	89	35
	00128	Oral	4	200 MG	30APR96	90	20MAY96	110	21
	00128	Oral	4	200 MG	21MAY96	111	.	.	.
329.003.00249		Oral	1	50 MG	07MAR96	1	11MAR96	5	5
	00249	Oral	2	100 MG	12MAR96	6	18MAR96	12	7
	00249	Oral	3	150 MG	19MAR96	13	25MAR96	19	7
	00249	Oral	4	200 MG	26MAR96	20	01APR96	26	7
	00249	Oral	5	250 MG	02APR96	27	08APR96	33	7
	00249	Oral	6	300 MG	09APR96	34	15APR96	40	7
	00249	Oral	6	300 MG	16APR96	41	22APR96	47	7
	00249	Oral	6	300 MG	23APR96	48	29APR96	54	7
		Oral	5	250 MG	30APR96	55	07MAY96	62	8
329.003.00289		Oral	1	50 MG	28FEB96	1	05MAR96	7	7
	00289	Oral	2	100 MG	06MAR96	8	12MAR96	14	7
	00289	Oral	3	150 MG	13MAR96	15	19MAR96	21	7
	00289	Oral	4	200 MG	20MAR96	22	26MAR96	28	7
	00289	Oral	4	200 MG	27MAR96	29	02APR96	35	7
	00289	Oral	4	200 MG	03APR96	36	09APR96	42	7
	00289	Oral	4	200 MG	10APR96	43	16APR96	49	7
	00289	Oral	4	200 MG	17APR96	50	23APR96	56	7
	00131	Oral	4	200 MG	24APR96	57	21MAY96	84	28
	00131	Oral	4	200 MG	22MAY96	85	19JUN96	113	29
	00131	Oral	4	200 MG	20JUN96	114	18JUL96	142	29
	00131	Oral	4	200 MG	19JUL96	143	15AUG96	170	28
	00131	Oral	4	200 MG	16AUG96	171	12SEP96	198	28
	00131	Oral	4	200 MG	13SEP96	199	10OCT96	226	28
	00289	Oral	3	150 MG	11OCT96	227	12OCT96	228	2
	00289	Oral	2	100 MG	13OCT96	229	15OCT96	231	3
	00289	Oral	1	50 MG	16OCT96	232	22OCT96	238	7
329.003.00290		Oral	1	50 MG	11MAR96	1	19MAR96	9	9
	00290	Oral	2	100 MG	20MAR96	10	22MAR96	12	3
329.003.00314		Oral	1	50 MG	22OCT96	1	28OCT96	7	7
	00314	Oral	2	100 MG	29OCT96	8	04NOV96	14	7
	00314	Oral	3	150 MG	05NOV96	15	13NOV96	23	9
	00314	Oral	4	200 MG	14NOV96	24	25NOV96	35	12
	00314	Oral	4	200 MG	26NOV96	36	02DEC96	42	7

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TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00314	00314	Oral	4	200 MG	03DEC96	43	09DEC96	49	7
	00314	Oral	4	200 MG	10DEC96	50	17DEC96	57	8
	00314	Oral	5	250 MG	18DEC96	58	22DEC96	62	5
	00314	Oral	5	250 MG	23DEC96	63	06JAN97	77	15
329.003.00317		Oral	1	50 MG	19DEC96	1	23DEC96	5	5
	00317	Oral	2	100 MG	24DEC96	6	30DEC96	12	7
	00317	Oral	3	150 MG	31DEC96	13	07JAN97	20	8
	00317	Oral	4	200 MG	08JAN97	21	14JAN97	27	7
	00317	Oral	4	200 MG	15JAN97	28	21JAN97	34	7
	00317	Oral	5	250 MG	22JAN97	35	28JAN97	41	7
	00317	Oral	6	300 MG	29JAN97	42	04FEB97	48	7
	00317	Oral	6	300 MG	05FEB97	49	11FEB97	55	7
		Oral	5	250 MG	11FEB97	55	26FEB97	70	16
329.004.00013		Oral	1	50 MG	19JUL94	1	25JUL94	7	7
	00013	Oral	2	100 MG	26JUL94	8	01AUG94	14	7
	00013	Oral	3	150 MG	02AUG94	15	08AUG94	21	7
	00013	Oral	4	200 MG	09AUG94	22	14AUG94	27	6
	00013	Oral	4	200 MG	15AUG94	28	22AUG94	35	8
	00013	Oral	4	200 MG	23AUG94	36	30AUG94	43	8
	00013	Oral	4	200 MG	31AUG94	44	07SEP94	51	8
	00013	Oral	4	200 MG	08SEP94	52	15SEP94	59	8
	00074	Oral	4	200 MG	16SEP94	60	10OCT94	84	25
	00074	Oral	4	200 MG	11OCT94	85	26OCT94	100	16
	00074	Oral	5	250 MG	27OCT94	101	07NOV94	112	12
	00074	Oral	5	250 MG	08NOV94	113	05DEC94	140	28
	00074	Oral	5	250 MG	06DEC94	141	09JAN95	175	35
	00074	Oral	5	250 MG	10JAN95	176	06FEB95	203	28
	00074	Oral	5	250 MG	07FEB95	204	09MAR95	234	31
	00013	Oral	4	200 MG	10MAR95	235	11MAR95	236	2
	00013	Oral	3	150 MG	12MAR95	237	13MAR95	238	2
	00013	Oral	2	100 MG	14MAR95	239	16MAR95	241	3
	00013	Oral	1	50 MG	17MAR95	242	23MAR95	248	7
329.004.00014		Oral	1	50 MG	29NOV94	1	04DEC94	6	6
	00014	Oral	2	100 MG	05DEC94	7	13DEC94	15	9
329.004.00211		Oral	1	50 MG	02FEB96	1	08FEB96	7	7
	00211	Oral	2	100 MG	09FEB96	8	15FEB96	14	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.004.00211	00211	Oral	3	150 MG	16FEB96	15	22FEB96	21	7
	00211	Oral	4	200 MG	23FEB96	22	28FEB96	27	6
	00211	Oral	4	200 MG	29FEB96	28	06MAR96	34	7
	00211	Oral	4	200 MG	07MAR96	35	13MAR96	41	7
	00211	Oral	4	200 MG	14MAR96	42	21MAR96	49	8
329.004.00215		Oral	1	50 MG	20MAR97	1	26MAR97	7	7
	00215	Oral	2	100 MG	27MAR97	8	02APR97	14	7
	00215	Oral	3	150 MG	03APR97	15	09APR97	21	7
	00215	Oral	4	200 MG	10APR97	22	14APR97	26	5
	00215	Oral	4	200 MG	15APR97	27	23APR97	35	9
	00215	Oral	4	200 MG	24APR97	36	28APR97	40	5
329.005.00003		Oral	1	50 MG	20SEP94	1	26SEP94	7	7
	00003	Oral	2	100 MG	27SEP94	8	30SEP94	11	4
	00003	Oral	2	100 MG	01OCT94	12	04OCT94	15	4
329.005.00006		Oral	1	50 MG	04NOV94	1	13NOV94	10	10
	00006	Oral	2	100 MG	14NOV94	11	20NOV94	17	7
	00006	Oral	3	150 MG	21NOV94	18	27NOV94	24	7
	00006	Oral	4	200 MG	28NOV94	25	04DEC94	31	7
	00006	Oral	5	250 MG	05DEC94	32	11DEC94	38	7
	00006	Oral	6	300 MG	12DEC94	39	18DEC94	45	7
	00006	Oral	6	300 MG	19DEC94	46	26DEC94	53	8
	00006	Oral	6	300 MG	27DEC94	54	02JAN95	60	7
	00089	Oral	6	300 MG	03JAN95	61	01FEB95	90	30
	00089	Oral	6	300 MG	02FEB95	91	26FEB95	115	25
	00089	Oral	6	300 MG	27FEB95	116	04APR95	152	37
	00089	Oral	6	300 MG	05APR95	153	11APR95	159	7
	00006	Oral	5	250 MG	12APR95	160	13APR95	161	2
	00006	Oral	4	200 MG	14APR95	162	15APR95	163	2
	00006	Oral	3	150 MG	16APR95	164	17APR95	165	2
	00006	Oral	2	100 MG	18APR95	166	20APR95	168	3
	00006	Oral	1	50 MG	21APR95	169	27APR95	175	7
329.005.00007		Oral	1	50 MG	09NOV94	1	09NOV94	1	1
	00007	Oral	1	50 MG	10NOV94	2	15NOV94	7	6
	00007	Oral	1	50 MG	16NOV94	8	22NOV94	14	7
	00007	Oral	2	100 MG	23NOV94	15	29NOV94	21	7
	00007	Oral	3	150 MG	30NOV94	22	06DEC94	28	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
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TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00007	00007	Oral	4	200 MG	07DEC94	29	13DEC94	35	7
	00007	Oral	5	250 MG	14DEC94	36	20DEC94	42	7
	00007	Oral	6	300 MG	21DEC94	43	27DEC94	49	7
	00007	Oral	5	250 MG	28DEC94	50	03JAN95	56	7
	00007	Oral	5	250 MG	04JAN95	57	10JAN95	63	7
	00092	Oral	5	250 MG	11JAN95	64	14FEB95	98	35
	00092	Oral	5	250 MG	15FEB95	99	21MAR95	133	35
	00092	Oral	5	250 MG	22MAR95	134	18APR95	161	28
	00092	Oral	5	250 MG	19APR95	162	16MAY95	189	28
	00092	Oral	5	250 MG	17MAY95	190	19MAY95	192	3
329.005.00009		Oral	1	50 MG	12DEC94	1	18DEC94	7	7
	00009	Oral	2	100 MG	19DEC94	8	26DEC94	15	8
	00009	Oral	3	150 MG	27DEC94	16	02JAN95	22	7
	00009	Oral	4	200 MG	03JAN95	23	10JAN95	30	8
	00009	Oral	5	250 MG	11JAN95	31	17JAN95	37	7
	00009	Oral	6	300 MG	18JAN95	38	24JAN95	44	7
	00009	Oral	5	250 MG	25JAN95	45	30JAN95	50	6
	00009	Oral	5	250 MG	31JAN95	51	06FEB95	57	7
		Oral	5	250 MG	07FEB95	58	22FEB95	73	16
329.005.00110		Oral	1	50 MG	11JAN95	1	17JAN95	7	7
	00110	Oral	2	100 MG	18JAN95	8	19JAN95	9	2
329.005.00113		Oral	1	50 MG	30JAN95	1	07FEB95	9	9
	00113	Oral	2	100 MG	08FEB95	10	15FEB95	17	8
	00113	Oral	3	150 MG	16FEB95	18	22FEB95	24	7
	00113	Oral	4	200 MG	23FEB95	25	02MAR95	32	8
329.005.00117		Oral	1	50 MG	18MAR95	1	26MAR95	9	9
	00117	Oral	2	100 MG	27MAR95	10	02APR95	16	7
	00117	Oral	3	150 MG	03APR95	17	09APR95	23	7
	00117	Oral	4	200 MG	10APR95	24	16APR95	30	7
	00117	Oral	4	200 MG	17APR95	31	23APR95	37	7
	00117	Oral	4	200 MG	24APR95	38	30APR95	44	7
	00117	Oral	4	200 MG	01MAY95	45	07MAY95	51	7
	00117	Oral	4	200 MG	08MAY95	52	14MAY95	58	7
		Oral	4	200 MG	15MAY95	59	26MAY95	70	12
329.005.00118		Oral	1	50 MG	17MAY95	1	23MAY95	7	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
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TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00118	00118	Oral	2	100 MG	24MAY95	8	29MAY95	13	6
	00118	Oral	3	150 MG	30MAY95	14	05JUN95	20	7
	00118	Oral	4	200 MG	06JUN95	21	13JUN95	28	8
	00118	Oral	5	250 MG	14JUN95	29	19JUN95	34	6
	00118	Oral	6	300 MG	20JUN95	35	26JUN95	41	7
		Oral	5	250 MG	27JUN95	42	05JUL95	50	9
329.005.00153		Oral	1	50 MG	25JAN96	1	31JAN96	7	7
	00153	Oral	2	100 MG	01FEB96	8	07FEB96	14	7
	00153	Oral	3	150 MG	08FEB96	15	14FEB96	21	7
	00153	Oral	4	200 MG	15FEB96	22	21FEB96	28	7
	00153	Oral	5	250 MG	22FEB96	29	28FEB96	35	7
	00153	Oral	5	250 MG	29FEB96	36	05MAR96	41	6
	00153	Oral	5	250 MG	06MAR96	42	13MAR96	49	8
	00153	Oral	5	250 MG	14MAR96	50	20MAR96	56	7
	00125	Oral	5	250 MG	21MAR96	57	16APR96	83	27
	00125	Oral	6	300 MG	17APR96	84	14MAY96	111	28
	00125	Oral	6	300 MG	15MAY96	112	11JUN96	139	28
	00125	Oral	6	300 MG	12JUN96	140	09JUL96	167	28
	00125	Oral	6	300 MG	10JUL96	168	04AUG96	193	26
	00125	Oral	6	300 MG	05AUG96	194	03SEP96	223	30
	00153	Oral	5	250 MG	04SEP96	224	05SEP96	225	2
	00153	Oral	4	200 MG	06SEP96	226	07SEP96	227	2
	00153	Oral	3	150 MG	08SEP96	228	09SEP96	229	2
	00153	Oral	2	100 MG	10SEP96	230	13SEP96	233	4
	00153	Oral	1	50 MG	14SEP96	234	16SEP96	236	3
329.005.00255		Oral	1	50 MG	04MAR96	1	10MAR96	7	7
	00255	Oral	2	100 MG	11MAR96	8	17MAR96	14	7
	00255	Oral	3	150 MG	18MAR96	15	24MAR96	21	7
	00255	Oral	4	200 MG	25MAR96	22	31MAR96	28	7
	00255	Oral	5	250 MG	01APR96	29	07APR96	35	7
	00255	Oral	6	300 MG	08APR96	36	14APR96	42	7
	00255	Oral	5	250 MG	15APR96	43	22APR96	50	8
	00255	Oral	5	250 MG	23APR96	51	28APR96	56	6
		Oral	4	200 MG	29APR96	57	13MAY96	71	15
329.005.00256		Oral	1	50 MG	05MAR96	1	11MAR96	7	7
	00256	Oral	2	100 MG	12MAR96	8	20MAR96	16	9
	00256	Oral	3	150 MG	21MAR96	17	25MAR96	21	5

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TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00256	00256	Oral	4	200 MG	26MAR96	22	01APR96	28	7
	00256	Oral	5	250 MG	02APR96	29	10APR96	37	9
	00256	Oral	5	250 MG	11APR96	38	15APR96	42	5
	00256	Oral	5	250 MG	16APR96	43	22APR96	49	7
	00256	Oral	6	300 MG	23APR96	50	29APR96	56	7
	00133	Oral	6	300 MG	30APR96	57	27MAY96	84	28
	00133	Oral	6	300 MG	28MAY96	85	01JUL96	119	35
	00256	Oral	5	250 MG	02JUL96	120	03JUL96	121	2
	00256	Oral	4	200 MG	04JUL96	122	05JUL96	123	2
	00256	Oral	3	150 MG	06JUL96	124	07JUL96	125	2
	00256	Oral	2	100 MG	08JUL96	126	10JUL96	128	3
	00256	Oral	1	50 MG	11JUL96	129	17JUL96	135	7
329.005.00295		Oral	1	50 MG	28MAR96	1	03APR96	7	7
	00295	Oral	2	100 MG	04APR96	8	10APR96	14	7
	00295	Oral	3	150 MG	11APR96	15	17APR96	21	7
	00295	Oral	4	200 MG	18APR96	22	23APR96	27	6
	00295	Oral	4	200 MG	24APR96	28	05MAY96	39	12
	00295	Oral	4	200 MG	06MAY96	40	08MAY96	42	3
	00295	Oral	5	250 MG	09MAY96	43	15MAY96	49	7
	00295	Oral	5	250 MG	16MAY96	50	19MAY96	53	4
	00295	Oral	5	250 MG	20MAY96	54	04JUN96	69	16
329.005.00297		Oral	1	50 MG	19APR96	1	25APR96	7	7
	00297	Oral	2	100 MG	26APR96	8	01MAY96	13	6
	00297	Oral	3	150 MG	02MAY96	14	13MAY96	25	12
	00297	Oral	4	200 MG	14MAY96	26	.	.	.
329.005.00332		Oral	1	50 MG	12DEC96	1	18DEC96	7	7
	00332	Oral	2	100 MG	19DEC96	8	25DEC96	14	7
	00332	Oral	3	150 MG	26DEC96	15	01JAN97	21	7
	00332	Oral	4	200 MG	02JAN97	22	08JAN97	28	7
	00332	Oral	5	250 MG	09JAN97	29	15JAN97	35	7
	00332	Oral	6	300 MG	16JAN97	36	22JAN97	42	7
	00332	Oral	6	300 MG	23JAN97	43	29JAN97	49	7
	00332	Oral	6	300 MG	30JAN97	50	05FEB97	56	7
		Oral	5	250 MG	06FEB97	57	21FEB97	72	16
329.005.00335		Oral	1	50 MG	28FEB97	1	06MAR97	7	7
	00335	Oral	2	100 MG	07MAR97	8	13MAR97	14	7

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Listing of Study Medication Data
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TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00335	00335	Oral	3	150 MG	14MAR97	15	20MAR97	21	7
	00335	Oral	4	200 MG	21MAR97	22	26MAR97	27	6
	00335	Oral	5	250 MG	27MAR97	28	02APR97	34	7
	00335	Oral	4	200 MG	03APR97	35	09APR97	41	7
	00335	Oral	4	200 MG	10APR97	42	16APR97	48	7
	00335	Oral	4	200 MG	17APR97	49	24APR97	56	8
		Oral	3	150 MG	25APR97	57	06MAY97	68	12
329.006.00040		Oral	1	50 MG	16FEB95	1	22FEB95	7	7
	00040	Oral	2	100 MG	23FEB95	8	28FEB95	13	6
	00040	Oral	1	50 MG	01MAR95	14	.	.	.
329.006.00041		Oral	1	50 MG	05APR95	1	09APR95	5	5
	00041	Oral	2	100 MG	10APR95	6	18APR95	14	9
	00041	Oral	3	150 MG	19APR95	15	23APR95	19	5
	00041	Oral	4	200 MG	24APR95	20	30APR95	26	7
	00041	Oral	4	200 MG	01MAY95	27	07MAY95	33	7
	00041	Oral	4	200 MG	08MAY95	34	14MAY95	40	7
	00041	Oral	4	200 MG	15MAY95	41	23MAY95	49	9
	00041	Oral	5	250 MG	24MAY95	50	02JUN95	59	10
	00041	Oral	6	300 MG	03JUN95	60	07JUN95	64	5
	00059	Oral	6	300 MG	08JUN95	65	04JUL95	91	27
	00059	Oral	6	300 MG	05JUL95	92	30JUL95	117	26
	00059	Oral	6	300 MG	31JUL95	118	23AUG95	141	24
	00059	Oral	6	300 MG	24AUG95	142	20SEP95	169	28
	00059	Oral	6	300 MG	21SEP95	170	23OCT95	202	33
	00059	Oral	6	300 MG	24OCT95	203	20NOV95	230	28
	00041	Oral	5	250 MG	21NOV95	231	22NOV95	232	2
	00041	Oral	4	200 MG	23NOV95	233	24NOV95	234	2
	00041	Oral	3	150 MG	25NOV95	235	26NOV95	236	2
	00041	Oral	2	100 MG	27NOV95	237	29NOV95	239	3
	00041	Oral	1	50 MG	30NOV95	240	05DEC95	245	6
329.007.00139		Oral	1	50 MG	08MAY95	1	17MAY95	10	10
	00139	Oral	2	100 MG	18MAY95	11	25MAY95	18	8
329.007.00143		Oral	1	50 MG	09NOV95	1	15NOV95	7	7
	00143	Oral	2	100 MG	16NOV95	8	21NOV95	13	6
		Oral	2	100 MG	22NOV95	14	01DEC95	23	10

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TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.007.00146		Oral	1	50 MG	25JAN96	1	31JAN96	7	7
	00347	Oral	2	100 MG	01FEB96	8	04FEB96	11	4
	00347	Oral	3	150 MG	05FEB96	12	11FEB96	18	7
	00347	Oral	4	200 MG	12FEB96	19	18FEB96	25	7
	00347	Oral	5	250 MG	19FEB96	26	25FEB96	32	7
	00347	Oral	5	250 MG	26FEB96	33	03MAR96	39	7
	00347	Oral	5	250 MG	04MAR96	40	10MAR96	46	7
	00347	Oral	4	200 MG	11MAR96	47	17MAR96	53	7
	00188	Oral	4	200 MG	18MAR96	54	14APR96	81	28
	00188	Oral	5	250 MG	15APR96	82	24APR96	91	10
	00188	Oral	4	200 MG	25APR96	92	12MAY96	109	18
	00188	Oral	4	200 MG	13MAY96	110	05JUN96	133	24
	00188	Oral	4	200 MG	06JUN96	134	07JUL96	165	32
	00188	Oral	4	200 MG	08JUL96	166	04AUG96	193	28
	00188	Oral	4	200 MG	05AUG96	194	08SEP96	228	35
	00347	Oral	4	200 MG	09SEP96	229	09SEP96	229	1
	00347	Oral	3	150 MG	10SEP96	230	11SEP96	231	2
	00347	Oral	2	100 MG	12SEP96	232	14SEP96	234	3
	00347	Oral	1	50 MG	15SEP96	235	21SEP96	241	7
329.007.00269		Oral	1	50 MG	11APR96	1	17APR96	7	7
	00269	Oral	2	100 MG	18APR96	8	25APR96	15	8
329.007.00270		Oral	1	50 MG	09MAY96	1	15MAY96	7	7
	00270	Oral	2	100 MG	16MAY96	8	22MAY96	14	7
	00270	Oral	3	150 MG	23MAY96	15	29MAY96	21	7
	00270	Oral	4	200 MG	30MAY96	22	05JUN96	28	7
	00270	Oral	4	200 MG	06JUN96	29	13JUN96	36	8
	00270	Oral	4	200 MG	14JUN96	37	20JUN96	43	7
329.007.00307		Oral	1	50 MG	16MAY96	1	22MAY96	7	7
	00307	Oral	2	100 MG	23MAY96	8	29MAY96	14	7
	00307	Oral	3	150 MG	30MAY96	15	05JUN96	21	7
	00307	Oral	4	200 MG	06JUN96	22	12JUN96	28	7
	00307	Oral	4	200 MG	13JUN96	29	20JUN96	36	8
329.007.00308		Oral	1	50 MG	02JUL96	1	11JUL96	10	10
329.008.00159		Oral	1	50 MG	13SEP95	1	18SEP95	6	6
	00159	Oral	2	100 MG	19SEP95	7	26SEP95	14	8

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.008.00159	00159	Oral	3	150 MG	27SEP95	15	02OCT95	20	6
	00159	Oral	4	200 MG	03OCT95	21	09OCT95	27	7
	00159	Oral	5	250 MG	10OCT95	28	15OCT95	33	6
	00159	Oral	5	250 MG	16OCT95	34	23OCT95	41	8
	00159	Oral	5	250 MG	24OCT95	42	30OCT95	48	7
	00159	Oral	4	200 MG	31OCT95	49	13NOV95	62	14
	00022	Oral	4	200 MG	14NOV95	63	25DEC95	104	42
	00022	Oral	4	200 MG	26DEC95	105	23JAN96	133	29
	00191	Oral	4	200 MG	24JAN96	134	.	.	.
329.008.00161		Oral	1	50 MG	16NOV95	1	21NOV95	6	6
	00161	Oral	2	100 MG	22NOV95	7	28NOV95	13	7
	00161	Oral	3	150 MG	29NOV95	14	06DEC95	21	8
	00161	Oral	4	200 MG	07DEC95	22	14DEC95	29	8
	00161	Oral	4	200 MG	15DEC95	30	26DEC95	41	12
	00161	Oral	4	200 MG	27DEC95	42	02JAN96	48	7
	00161	Oral	4	200 MG	03JAN96	49	09JAN96	55	7
	00099	Oral	4	200 MG	10JAN96	56	.	.	.
329.008.00187		Oral	1	50 MG	29NOV95	1	06DEC95	8	8
	00187	Oral	2	100 MG	07DEC95	9	14DEC95	16	8
	00187	Oral	3	150 MG	15DEC95	17	20DEC95	22	6
	00187	Oral	4	200 MG	21DEC95	23	26DEC95	28	6
	00187	Oral	4	200 MG	27DEC95	29	03JAN96	36	8
	00187	Oral	4	200 MG	04JAN96	37	10JAN96	43	7
	00187	Oral	5	250 MG	11JAN96	44	17JAN96	50	7
	00187	Oral	4	200 MG	18JAN96	51	25JAN96	58	8
		Oral	4	200 MG	26JAN96	59	09FEB96	73	15
329.008.00192		Oral	1	50 MG	05MAR96	1	11MAR96	7	7
	00192	Oral	2	100 MG	12MAR96	8	18MAR96	14	7
	00192	Oral	3	150 MG	19MAR96	15	24MAR96	20	6
	00192	Oral	4	200 MG	25MAR96	21	03APR96	30	10
	00192	Oral	4	200 MG	04APR96	31	11APR96	38	8
329.008.00272		Oral	1	50 MG	03APR96	1	10APR96	8	8
	00272	Oral	2	100 MG	11APR96	9	17APR96	15	7
	00272	Oral	3	150 MG	18APR96	16	26APR96	24	9
	00272	Oral	4	200 MG	27APR96	25	30APR96	28	4
	00272	Oral	4	200 MG	01MAY96	29	06MAY96	34	6

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Listing of Study Medication Data
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TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.008.00272	00272	Oral	4	200 MG	07MAY96	35	14MAY96	42	8
	00272	Oral	4	200 MG	15MAY96	43	21MAY96	49	7
	00272	Oral	4	200 MG	22MAY96	50	28MAY96	56	7
	00142	Oral	4	200 MG	29MAY96	57	25JUN96	84	28
	00142	Oral	4	200 MG	26JUN96	85	23JUL96	112	28
	00142	Oral	4	200 MG	24JUL96	113	20AUG96	140	28
	00142	Oral	4	200 MG	21AUG96	141	18SEP96	169	29
329.008.00273		Oral	1	50 MG	17MAY96	1	23MAY96	7	7
	00273	Oral	2	100 MG	24MAY96	8	29MAY96	13	6
	00273	Oral	3	150 MG	30MAY96	14	09JUN96	24	11
	00273	Oral	4	200 MG	10JUN96	25	16JUN96	31	7
	00273	Oral	4	200 MG	17JUN96	32	23JUN96	38	7
	00273	Oral	5	250 MG	24JUN96	39	30JUN96	45	7
	00273	Oral	6	300 MG	01JUL96	46	10JUL96	55	10
	00273	Oral	6	300 MG	11JUL96	56	18JUL96	63	8
	00153	Oral	6	300 MG	19JUL96	64	03SEP96	110	47
	00153	Oral	6	300 MG	04SEP96	111	09SEP96	116	6
329.009.00127		Oral	1	50 MG	10APR95	1	16APR95	7	7
	00127	Oral	2	100 MG	17APR95	8	23APR95	14	7
	00127	Oral	3	150 MG	24APR95	15	30APR95	21	7
	00127	Oral	4	200 MG	01MAY95	22	08MAY95	29	8
	00127	Oral	4	200 MG	09MAY95	30	14MAY95	35	6
	00127	Oral	4	200 MG	15MAY95	36	26MAY95	47	12
329.009.00132		Oral	1	50 MG	23MAY95	1	29MAY95	7	7
	00132	Oral	2	100 MG	30MAY95	8	05JUN95	14	7
	00132	Oral	3	150 MG	06JUN95	15	12JUN95	21	7
	00132	Oral	4	200 MG	13JUN95	22	19JUN95	28	7
	00132	Oral	4	200 MG	20JUN95	29	26JUN95	35	7
	00132	Oral	4	200 MG	27JUN95	36	04JUL95	43	8
	00132	Oral	4	200 MG	05JUL95	44	10JUL95	49	6
	00132	Oral	4	200 MG	11JUL95	50	18JUL95	57	8
	00001	Oral	4	200 MG	19JUL95	58	23AUG95	93	36
	00001	Oral	4	200 MG	24AUG95	94	14SEP95	115	22
	00001	Oral	4	200 MG	15SEP95	116	23OCT95	154	39
	00132	Oral	4	200 MG	24OCT95	155	24OCT95	155	1
	00132	Oral	3	150 MG	25OCT95	156	26OCT95	157	2
	00132	Oral	2	100 MG	27OCT95	158	29OCT95	160	3

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00132	00132	Oral	1	50 MG	30OCT95	161	05NOV95	167	7
329.009.00134		Oral	1	50 MG	06JUL95	1	13JUL95	8	8
	00134	Oral	2	100 MG	14JUL95	9	18JUL95	13	5
	00134	Oral	3	150 MG	19JUL95	14	25JUL95	20	7
	00134	Oral	4	200 MG	26JUL95	21	02AUG95	28	8
	00134	Oral	4	200 MG	03AUG95	29	07AUG95	33	5
	00134	Oral	4	200 MG	08AUG95	34	14AUG95	40	7
	00134	Oral	4	200 MG	15AUG95	41	23AUG95	49	9
	00134	Oral	4	200 MG	24AUG95	50	28AUG95	54	5
	00134	Oral	3	150 MG	29AUG95	55	09SEP95	66	12
329.009.00137		Oral	1	50 MG	10OCT95	1	16OCT95	7	7
	00137	Oral	2	100 MG	17OCT95	8	23OCT95	14	7
	00137	Oral	3	150 MG	24OCT95	15	30OCT95	21	7
	00137	Oral	4	200 MG	31OCT95	22	06NOV95	28	7
	00137	Oral	4	200 MG	07NOV95	29	13NOV95	35	7
	00137	Oral	4	200 MG	14NOV95	36	20NOV95	42	7
	00137	Oral	4	200 MG	21NOV95	43	27NOV95	49	7
	00137	Oral	4	200 MG	28NOV95	50	04DEC95	56	7
		Oral	3	150 MG	05DEC95	57	16DEC95	68	12
329.009.00171		Oral	1	50 MG	07NOV95	1	14NOV95	8	8
329.009.00172		Oral	1	50 MG	13NOV95	1	19NOV95	7	7
	00172	Oral	2	100 MG	20NOV95	8	26NOV95	14	7
	00172	Oral	3	150 MG	27NOV95	15	03DEC95	21	7
	00172	Oral	4	200 MG	04DEC95	22	10DEC95	28	7
	00172	Oral	4	200 MG	11DEC95	29	20DEC95	38	10
	00172	Oral	4	200 MG	21DEC95	39	26DEC95	44	6
	00172	Oral	4	200 MG	27DEC95	45	02JAN96	51	7
	00172	Oral	4	200 MG	03JAN96	52	08JAN96	57	6
	00097	Oral	4	200 MG	09JAN96	58	06FEB96	86	29
	00097	Oral	4	200 MG	07FEB96	87	03MAR96	112	26
	00097	Oral	4	200 MG	04MAR96	113	31MAR96	140	28
	00097	Oral	4	200 MG	01APR96	141	28APR96	168	28
	00097	Oral	4	200 MG	29APR96	169	09JUN96	210	42
	00097	Oral	4	200 MG	10JUN96	211	07JUL96	238	28
	00360	Oral	4	200 MG	08JUL96	239	08JUL96	239	1
	00360	Oral	3	150 MG	09JUL96	240	10JUL96	241	2

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00172	00360	Oral	2	100 MG	11JUL96	242	13JUL96	244	3
	00360	Oral	1	50 MG	14JUL96	245	20JUL96	251	7
329.009.00194		Oral	1	50 MG	05DEC95	1	11DEC95	7	7
	00194	Oral	2	100 MG	12DEC95	8	18DEC95	14	7
	00194	Oral	3	150 MG	19DEC95	15	26DEC95	22	8
	00194	Oral	4	200 MG	27DEC95	23	01JAN96	28	6
	00194	Oral	4	200 MG	02JAN96	29	08JAN96	35	7
	00194	Oral	4	200 MG	09JAN96	36	15JAN96	42	7
	00194	Oral	4	200 MG	16JAN96	43	22JAN96	49	7
	00194	Oral	4	200 MG	23JAN96	50	29JAN96	56	7
	00105	Oral	4	200 MG	30JAN96	57	26FEB96	84	28
	00105	Oral	4	200 MG	27FEB96	85	01APR96	119	35
	00105	Oral	4	200 MG	02APR96	120	29APR96	147	28
	00105	Oral	4	200 MG	30APR96	148	04JUN96	183	36
	00194	Oral	4	200 MG	05JUN96	184	.	.	.
329.009.00195		Oral	1	50 MG	15DEC95	1	18DEC95	4	4
	00195	Oral	2	100 MG	19DEC95	5	26DEC95	12	8
	00195	Oral	3	150 MG	27DEC95	13	01JAN96	18	6
	00195	Oral	4	200 MG	02JAN96	19	07JAN96	24	6
		Oral	3	150 MG	08JAN96	25	19JAN96	36	12
329.009.00199		Oral	1	50 MG	16JAN96	1	22JAN96	7	7
	00199	Oral	2	100 MG	23JAN96	8	28JAN96	13	6
	00199	Oral	3	150 MG	29JAN96	14	06FEB96	22	9
	00199	Oral	4	200 MG	07FEB96	23	13FEB96	29	7
	00199	Oral	4	200 MG	14FEB96	30	20FEB96	36	7
	00199	Oral	5	250 MG	21FEB96	37	27FEB96	43	7
	00199	Oral	5	250 MG	28FEB96	44	05MAR96	50	7
	00199	Oral	5	250 MG	06MAR96	51	12MAR96	57	7
		Oral	4	200 MG	13MAR96	58	26MAR96	71	14
329.009.00203		Oral	1	50 MG	04MAR96	1	10MAR96	7	7
	00203	Oral	2	100 MG	11MAR96	8	18MAR96	15	8
	00203	Oral	3	150 MG	19MAR96	16	26MAR96	23	8
		Oral	2	100 MG	27MAR96	24	05APR96	33	10
329.009.00236		Oral	1	50 MG	30DEC96	1	05JAN97	7	7
	00236	Oral	2	100 MG	06JAN97	8	14JAN97	16	9

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00236	00236	Oral	3	150 MG	15JAN97	17	19JAN97	21	5
	00236	Oral	4	200 MG	20JAN97	22	26JAN97	28	7
		Oral	4	200 MG	27JAN97	29	08FEB97	41	13
329.009.00239		Oral	1	50 MG	19NOV96	1	24NOV96	6	6
	00239	Oral	2	100 MG	25NOV96	7	01DEC96	13	7
	00239	Oral	3	150 MG	02DEC96	14	08DEC96	20	7
	00239	Oral	4	200 MG	09DEC96	21	15DEC96	27	7
	00239	Oral	4	200 MG	16DEC96	28	22DEC96	34	7
	00239	Oral	4	200 MG	23DEC96	35	29DEC96	41	7
	00239	Oral	4	200 MG	30DEC96	42	05JAN97	48	7
	00239	Oral	4	200 MG	06JAN97	49	14JAN97	57	9
	00183	Oral	4	200 MG	15JAN97	58	17FEB97	91	34
	00183	Oral	4	200 MG	18FEB97	92	16MAR97	118	27
	00183	Oral	4	200 MG	17MAR97	119	13APR97	146	28
	00183	Oral	4	200 MG	14APR97	147	.	.	.
329.009.00262		Oral	1	50 MG	17FEB97	1	23FEB97	7	7
	00262	Oral	2	100 MG	24FEB97	8	02MAR97	14	7
	00262	Oral	3	150 MG	03MAR97	15	06MAR97	18	4
	00262	Oral	4	200 MG	07MAR97	19	16MAR97	28	10
	00262	Oral	4	200 MG	17MAR97	29	23MAR97	35	7
	00262	Oral	4	200 MG	24MAR97	36	30MAR97	42	7
	00262	Oral	4	200 MG	31MAR97	43	06APR97	49	7
	00262	Oral	4	200 MG	07APR97	50	14APR97	57	8
		Oral	4	200 MG	14APR97	57	26APR97	69	13
329.009.00264		Oral	1	50 MG	01NOV96	1	07NOV96	7	7
	00264	Oral	2	100 MG	08NOV96	8	10NOV96	10	3
	00264	Oral	3	150 MG	11NOV96	11	17NOV96	17	7
	00264	Oral	4	200 MG	18NOV96	18	24NOV96	24	7
	00264	Oral	4	200 MG	25NOV96	25	01DEC96	31	7
	00264	Oral	4	200 MG	02DEC96	32	10DEC96	40	9
	00264	Oral	4	200 MG	11DEC96	41	15DEC96	45	5
	00264	Oral	4	200 MG	16DEC96	46	22DEC96	52	7
		Oral	4	200 MG	23DEC96	53	04JAN97	65	13
329.009.00301		Oral	1	50 MG	19MAR96	1	25MAR96	7	7
	00301	Oral	2	100 MG	26MAR96	8	04APR96	17	10
	00301	Oral	3	150 MG	05APR96	18	11APR96	24	7

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00301	00301	Oral	4	200 MG	12APR96	25	15APR96	28	4
	00301	Oral	4	200 MG	16APR96	29	22APR96	35	7
	00301	Oral	4	200 MG	23APR96	36	29APR96	42	7
	00301	Oral	4	200 MG	30APR96	43	06MAY96	49	7
	00301	Oral	4	200 MG	07MAY96	50	13MAY96	56	7
	00140	Oral	4	200 MG	14MAY96	57	10JUN96	84	28
	00301	Oral	4	200 MG	11JUN96	85	11JUN96	85	1
	00301	Oral	3	150 MG	12JUN96	86	13JUN96	87	2
	00301	Oral	2	100 MG	14JUN96	88	16JUN96	90	3
	00301	Oral	1	50 MG	17JUN96	91	23JUN96	97	7
329.009.00305		Oral	1	50 MG	07MAY96	1	13MAY96	7	7
	00305	Oral	2	100 MG	14MAY96	8	20MAY96	14	7
	00305	Oral	3	150 MG	21MAY96	15	27MAY96	21	7
	00305	Oral	4	200 MG	28MAY96	22	03JUN96	28	7
	00305	Oral	4	200 MG	04JUN96	29	10JUN96	35	7
	00305	Oral	4	200 MG	11JUN96	36	18JUN96	43	8
	00305	Oral	4	200 MG	19JUN96	44	24JUN96	49	6
	00305	Oral	4	200 MG	25JUN96	50	02JUL96	57	8
	00151	Oral	4	200 MG	03JUL96	58	05AUG96	91	34
	00151	Oral	4	200 MG	06AUG96	92	26AUG96	112	21
	00151	Oral	4	200 MG	27AUG96	113	23SEP96	140	28
	00151	Oral	4	200 MG	24SEP96	141	28OCT96	175	35
	00151	Oral	4	200 MG	29OCT96	176	02DEC96	210	35
	00151	Oral	4	200 MG	03DEC96	211	09JAN97	248	38
	00305	Oral	4	200 MG	10JAN97	249	10JAN97	249	1
	00305	Oral	3	150 MG	11JAN97	250	12JAN97	251	2
	00305	Oral	2	100 MG	13JAN97	252	15JAN97	254	3
	00305	Oral	1	50 MG	16JAN97	255	22JAN97	261	7
329.009.00325		Oral	1	50 MG	27AUG96	1	02SEP96	7	7
	00325	Oral	2	100 MG	03SEP96	8	08SEP96	13	6
	00325	Oral	3	150 MG	09SEP96	14	15SEP96	20	7
	00325	Oral	4	200 MG	16SEP96	21	22SEP96	27	7
	00325	Oral	4	200 MG	23SEP96	28	29SEP96	34	7
	00325	Oral	4	200 MG	30SEP96	35	09OCT96	44	10
	00325	Oral	4	200 MG	10OCT96	45	13OCT96	48	4
	00325	Oral	4	200 MG	14OCT96	49	20OCT96	55	7
	00166	Oral	4	200 MG	21OCT96	56	17NOV96	83	28
	00166	Oral	4	200 MG	18NOV96	84	15DEC96	111	28

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00325	00325	Oral	4	200 MG	16DEC96	112	16DEC96	112	1
	00325	Oral	3	150 MG	17DEC96	113	18DEC96	114	2
	00325	Oral	2	100 MG	19DEC96	115	21DEC96	117	3
	00325	Oral	1	50 MG	22DEC96	118	28DEC96	124	7
329.009.00326		Oral	1	50 MG	05SEP96	1	08SEP96	4	4
	00326	Oral	2	100 MG	09SEP96	5	15SEP96	11	7
	00326	Oral	3	150 MG	16SEP96	12	22SEP96	18	7
	00326	Oral	4	200 MG	23SEP96	19	29SEP96	25	7
	00326	Oral	4	200 MG	30SEP96	26	06OCT96	32	7
	00326	Oral	4	200 MG	07OCT96	33	16OCT96	42	10
	00326	Oral	4	200 MG	17OCT96	43	23OCT96	49	7
	00326	Oral	4	200 MG	24OCT96	50	27OCT96	53	4
	00167	Oral	4	200 MG	28OCT96	54	24NOV96	81	28
	00167	Oral	4	200 MG	25NOV96	82	15DEC96	102	21
	00326	Oral	4	200 MG	16DEC96	103	16DEC96	103	1
	00326	Oral	3	150 MG	17DEC96	104	18DEC96	105	2
	00326	Oral	2	100 MG	19DEC96	106	21DEC96	108	3
	00326	Oral	1	50 MG	22DEC96	109	28DEC96	115	7
329.010.00279		Oral	1	50 MG	22MAR96	1	28MAR96	7	7
	00279	Oral	2	100 MG	29MAR96	8	04APR96	14	7
	00279	Oral	3	150 MG	05APR96	15	11APR96	21	7
	00279	Oral	4	200 MG	12APR96	22	18APR96	28	7
	00279	Oral	5	250 MG	19APR96	29	24APR96	34	6
	00279	Oral	6	300 MG	25APR96	35	02MAY96	42	8
	00279	Oral	6	300 MG	03MAY96	43	09MAY96	49	7
	00279	Oral	6	300 MG	10MAY96	50	16MAY96	56	7
	00147	Oral	6	300 MG	17MAY96	57	13JUN96	84	28
	00147	Oral	6	300 MG	14JUN96	85	10JUL96	111	27
	00147	Oral	6	300 MG	11JUL96	112	07AUG96	139	28
	00147	Oral	6	300 MG	08AUG96	140	04SEP96	167	28
	00147	Oral	6	300 MG	05SEP96	168	01OCT96	194	27
	00147	Oral	6	300 MG	02OCT96	195	04OCT96	197	3
	00147	Oral	5	250 MG	05OCT96	198	06NOV96	230	33
	00279	Oral	5	250 MG	07NOV96	231	08NOV96	232	2
	00279	Oral	4	200 MG	09NOV96	233	10NOV96	234	2
	00279	Oral	3	150 MG	11NOV96	235	12NOV96	236	2
	00279	Oral	2	100 MG	13NOV96	237	15NOV96	239	3
	00279	Oral	1	50 MG	16NOV96	240	22NOV96	246	7

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.010.00281		Oral	1	50 MG	26JUL96	1	01AUG96	7	7
	00281	Oral	2	100 MG	02AUG96	8	08AUG96	14	7
	00281	Oral	3	150 MG	09AUG96	15	18AUG96	24	10
	00281	Oral	4	200 MG	19AUG96	25	25AUG96	31	7
	00281	Oral	5	250 MG	26AUG96	32	03SEP96	40	9
	00281	Oral	6	300 MG	04SEP96	41	08SEP96	45	5
	00281	Oral	6	300 MG	09SEP96	46	17SEP96	54	9
	00281	Oral	6	300 MG	18SEP96	55	24SEP96	61	7
	00158	Oral	6	300 MG	25SEP96	62	24OCT96	91	30
	00158	Oral	6	300 MG	25OCT96	92	19NOV96	117	26
	00158	Oral	6	300 MG	20NOV96	118	19DEC96	147	30
	00158	Oral	6	300 MG	20DEC96	148	03JAN97	162	15
	00281	Oral	5	250 MG	04JAN97	163	05JAN97	164	2
	00281	Oral	4	200 MG	06JAN97	165	07JAN97	166	2
	00281	Oral	3	150 MG	08JAN97	167	09JAN97	168	2
	00281	Oral	2	100 MG	10JAN97	169	12JAN97	171	3
	00281	Oral	1	50 MG	13JAN97	172	19JAN97	178	7
329.011.00163		Oral	1	50 MG	25NOV95	1	01DEC95	7	7
	00163	Oral	2	100 MG	02DEC95	8	11DEC95	17	10
	00163	Oral	3	150 MG	12DEC95	18	18DEC95	24	7
	00163	Oral	4	200 MG	19DEC95	25	22DEC95	28	4
329.011.00208		Oral	1	50 MG	06SEP96	1	11SEP96	6	6
	00208	Oral	2	100 MG	12SEP96	7	17SEP96	12	6
	00208	Oral	3	150 MG	18SEP96	13	26SEP96	21	9
	00208	Oral	4	200 MG	27SEP96	22	03OCT96	28	7
	00208	Oral	5	250 MG	04OCT96	29	10OCT96	35	7
	00208	Oral	6	300 MG	11OCT96	36	17OCT96	42	7
	00208	Oral	6	300 MG	18OCT96	43	24OCT96	49	7
	00208	Oral	6	300 MG	25OCT96	50	03NOV96	59	10
	00171	Oral	6	300 MG	04NOV96	60	07NOV96	63	4
	00208	Oral	5	250 MG	08NOV96	64	09NOV96	65	2
	00208	Oral	4	200 MG	10NOV96	66	11NOV96	67	2
	00208	Oral	3	150 MG	12NOV96	68	13NOV96	69	2
	00208	Oral	2	100 MG	14NOV96	70	16NOV96	72	3
	00208	Oral	1	50 MG	17NOV96	73	23NOV96	79	7
329.011.00209		Oral	1	50 MG	11SEP96	1	19SEP96	9	9
	00209	Oral	2	100 MG	20SEP96	10	26SEP96	16	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.011.00209	00209	Oral	3	150 MG	27SEP96	17	03OCT96	23	7
	00209	Oral	4	200 MG	04OCT96	24	11OCT96	31	8
	00209	Oral	4	200 MG	12OCT96	32	17OCT96	37	6
	00209	Oral	4	200 MG	18OCT96	38	24OCT96	44	7
	00209	Oral	4	200 MG	25OCT96	45	01NOV96	52	8
	00209	Oral	5	250 MG	02NOV96	53	11NOV96	62	10
	00173	Oral	5	250 MG	12NOV96	63	18DEC96	99	37
	00209	Oral	5	250 MG	19DEC96	100	.	.	.
329.011.00284		Oral	1	50 MG	22MAR96	1	28MAR96	7	7
	00284	Oral	2	100 MG	29MAR96	8	05APR96	15	8
	00284	Oral	3	150 MG	06APR96	16	11APR96	21	6
	00284	Oral	4	200 MG	12APR96	22	19APR96	29	8
	00284	Oral	4	200 MG	20APR96	30	25APR96	35	6
	00284	Oral	5	250 MG	26APR96	36	02MAY96	42	7
	00284	Oral	5	250 MG	03MAY96	43	09MAY96	49	7
	00284	Oral	5	250 MG	10MAY96	50	16MAY96	56	7
	00134	Oral	5	250 MG	17MAY96	57	10JUN96	81	25
	00134	Oral	5	250 MG	11JUN96	82	08JUL96	109	28
	00134	Oral	5	250 MG	09JUL96	110	05AUG96	137	28
	00134	Oral	5	250 MG	06AUG96	138	.	.	.
329.011.00286		Oral	1	50 MG	06JUN96	1	14JUN96	9	9
	00286	Oral	2	100 MG	15JUN96	10	21JUN96	16	7
	00286	Oral	3	150 MG	22JUN96	17	28JUN96	23	7
	00286	Oral	4	200 MG	29JUN96	24	08JUL96	33	10
	00286	Oral	5	250 MG	09JUL96	34	17JUL96	42	9
	00286	Oral	5	250 MG	18JUL96	43	24JUL96	49	7
	00286	Oral	6	300 MG	25JUL96	50	02AUG96	58	9
	00286	Oral	6	300 MG	03AUG96	59	12AUG96	68	10
	00154	Oral	6	300 MG	13AUG96	69	17SEP96	104	36
	00154	Oral	6	300 MG	18SEP96	105	24OCT96	141	37
	00154	Oral	6	300 MG	25OCT96	142	24NOV96	172	31
	00154	Oral	6	300 MG	25NOV96	173	30DEC96	208	36
	00154	Oral	6	300 MG	31DEC96	209	.	.	.
329.012.00026		Oral	1	50 MG	28NOV95	1	04DEC95	7	7
	00026	Oral	2	100 MG	05DEC95	8	.	.	.
329.012.00219		Oral	1	50 MG	31MAY96	1	06JUN96	7	7

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.012.00219	00219	Oral	2	100 MG	07JUN96	8	13JUN96	14	7
	00219	Oral	3	150 MG	14JUN96	15	23JUN96	24	10
	00219	Oral	4	200 MG	24JUN96	25	01JUL96	32	8
	00219	Oral	4	200 MG	02JUL96	33	08JUL96	39	7
	00219	Oral	4	200 MG	09JUL96	40	15JUL96	46	7
	00219	Oral	4	200 MG	16JUL96	47	22JUL96	53	7
	00219	Oral	4	200 MG	23JUL96	54	29JUL96	60	7
	00106	Oral	4	200 MG	30JUL96	61	29AUG96	91	31
	00106	Oral	4	200 MG	30AUG96	92	25SEP96	118	27
	00106	Oral	4	200 MG	26SEP96	119	24OCT96	147	29
	00106	Oral	4	200 MG	25OCT96	148	21NOV96	175	28
	00106	Oral	4	200 MG	22NOV96	176	19DEC96	203	28
	00106	Oral	4	200 MG	20DEC96	204	18JAN97	233	30
329.012.00221		Oral	1	50 MG	25JUN96	1	01JUL96	7	7
	00221	Oral	2	100 MG	02JUL96	8	08JUL96	14	7
	00221	Oral	3	150 MG	09JUL96	15	15JUL96	21	7
	00221	Oral	4	200 MG	16JUL96	22	22JUL96	28	7
	00221	Oral	5	250 MG	23JUL96	29	31JUL96	37	9
	00221	Oral	4	200 MG	01AUG96	38	08AUG96	45	8
	00221	Oral	4	200 MG	09AUG96	46	18AUG96	55	10
	00221	Oral	4	200 MG	19AUG96	56	26AUG96	63	8
	00112	Oral	4	200 MG	27AUG96	64	22SEP96	90	27
	00112	Oral	4	200 MG	23SEP96	91	20OCT96	118	28
	00112	Oral	4	200 MG	21OCT96	119	03NOV96	132	14
329.012.00223		Oral	1	50 MG	30AUG96	1	05SEP96	7	7
	00223	Oral	2	100 MG	06SEP96	8	15SEP96	17	10
	00223	Oral	3	150 MG	16SEP96	18	22SEP96	24	7
	00223	Oral	4	200 MG	23SEP96	25	30SEP96	32	8
		Oral	3	150 MG	01OCT96	33	12OCT96	44	12
329.012.00227		Oral	1	50 MG	18DEC96	1	26DEC96	9	9
	00227	Oral	2	100 MG	27DEC96	10	05JAN97	19	10
	00227	Oral	3	150 MG	06JAN97	20	14JAN97	28	9
	00227	Oral	4	200 MG	15JAN97	29	23JAN97	37	9
	00227	Oral	4	200 MG	24JAN97	38	03FEB97	48	11
	00227	Oral	4	200 MG	04FEB97	49	13FEB97	58	10
	00227	Oral	5	250 MG	14FEB97	59	19FEB97	64	6
	00227	Oral	5	250 MG	20FEB97	65	24FEB97	69	5

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.012.00227	00114	Oral	6	300 MG	25FEB97	70	26MAR97	99	30
	00114	Oral	6	300 MG	27MAR97	100	24APR97	128	29
	00114	Oral	6	300 MG	25APR97	129	25MAY97	159	31
	00114	Oral	6	300 MG	26MAY97	160	24JUN97	189	30
	00114	Oral	6	300 MG	25JUN97	190	20JUL97	215	26
	00114	Oral	6	300 MG	21JUL97	216	18AUG97	244	29
	00227	Oral	5	250 MG	19AUG97	245	20AUG97	246	2
	00227	Oral	4	200 MG	21AUG97	247	22AUG97	248	2
	00227	Oral	3	150 MG	23AUG97	249	24AUG97	250	2
	00227	Oral	2	100 MG	25AUG97	251	27AUG97	253	3
	00227	Oral	1	50 MG	28AUG97	254	03SEP97	260	7
329.012.00230		Oral	1	50 MG	28FEB97	1	06MAR97	7	7
	00230	Oral	2	100 MG	07MAR97	8	13MAR97	14	7
	00230	Oral	3	150 MG	14MAR97	15	23MAR97	24	10
	00230	Oral	4	200 MG	24MAR97	25	02APR97	34	10
	00230	Oral	4	200 MG	03APR97	35	10APR97	42	8
	00230	Oral	4	200 MG	11APR97	43	20APR97	52	10
	00230	Oral	4	200 MG	21APR97	53	01MAY97	63	11
	00230	Oral	5	250 MG	02MAY97	64	07MAY97	69	6
	00116	Oral	5	250 MG	08MAY97	70	12MAY97	74	5
	00230	Oral	4	200 MG	13MAY97	75	13MAY97	75	1
	00230	Oral	3	150 MG	14MAY97	76	14MAY97	76	1
	00230	Oral	2	100 MG	15MAY97	77	16MAY97	78	2
	00230	Oral	1	50 MG	17MAY97	79	26MAY97	88	10

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.001.00062		Oral	1	0 MG	20OCT94	1	26OCT94	7	7
	00062	Oral	2	0 MG	27OCT94	8	02NOV94	14	7
	00062	Oral	3	0 MG	03NOV94	15	09NOV94	21	7
	00062	Oral	4	0 MG	10NOV94	22	15NOV94	27	6
329.001.00064		Oral	1	0 MG	10NOV94	1	15NOV94	6	6
	00064	Oral	2	0 MG	16NOV94	7	21NOV94	12	6
	00064	Oral	3	0 MG	22NOV94	13	28NOV94	19	7
	00064	Oral	4	0 MG	29NOV94	20	05DEC94	26	7
	00064	Oral	4	0 MG	06DEC94	27	12DEC94	33	7
	00064	Oral	4	0 MG	13DEC94	34	19DEC94	40	7
	00064	Oral	4	0 MG	20DEC94	41	26DEC94	47	7
	00064	Oral	4	0 MG	27DEC94	48	02JAN95	54	7
	00050	Oral	4	0 MG	03JAN95	55	30JAN95	82	28
	00050	Oral	4	0 MG	31JAN95	83	27FEB95	110	28
	00050	Oral	4	0 MG	28FEB95	111	27MAR95	138	28
	00064	Oral	4	0 MG	28MAR95	139	10APR95	152	14
329.001.00069		Oral	1	0 MG	16FEB95	1	22FEB95	7	7
	00069	Oral	2	0 MG	23FEB95	8	01MAR95	14	7
	00069	Oral	3	0 MG	02MAR95	15	08MAR95	21	7
	00069	Oral	4	0 MG	09MAR95	22	15MAR95	28	7
	00069	Oral	4	0 MG	16MAR95	29	22MAR95	35	7
	00069	Oral	4	0 MG	23MAR95	36	29MAR95	42	7
	00069	Oral	5	0 MG	30MAR95	43	05APR95	49	7
	00069	Oral	6	0 MG	06APR95	50	12APR95	56	7
		Oral	5	0 MG	13APR95	57	18APR95	62	6
329.001.00071		Oral	1	0 MG	23FEB95	1	01MAR95	7	7
	00071	Oral	2	0 MG	02MAR95	8	08MAR95	14	7
	00071	Oral	3	0 MG	09MAR95	15	15MAR95	21	7
	00071	Oral	4	0 MG	16MAR95	22	22MAR95	28	7
	00071	Oral	5	0 MG	23MAR95	29	29MAR95	35	7
	00071	Oral	6	0 MG	30MAR95	36	05APR95	42	7
	00071	Oral	6	0 MG	06APR95	43	12APR95	49	7
	00071	Oral	6	0 MG	13APR95	50	19APR95	56	7
		Oral	6	0 MG	20APR95	57	04MAY95	71	15
329.001.00123		Oral	1	0 MG	04JAN96	1	11JAN96	8	8
	00123	Oral	2	0 MG	12JAN96	9	17JAN96	14	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.001.00123	00123	Oral	3	0 MG	18JAN96	15	24JAN96	21	7
	00123	Oral	4	0 MG	25JAN96	22	31JAN96	28	7
	00123	Oral	4	0 MG	01FEB96	29	07FEB96	35	7
	00123	Oral	4	0 MG	08FEB96	36	14FEB96	42	7
	00123	Oral	4	0 MG	15FEB96	43	21FEB96	49	7
329.001.00207		Oral	1	0 MG	28FEB96	1	05MAR96	7	7
	00207	Oral	2	0 MG	06MAR96	8	12MAR96	14	7
	00207	Oral	3	0 MG	13MAR96	15	19MAR96	21	7
	00207	Oral	4	0 MG	20MAR96	22	25MAR96	27	6
	00207	Oral	4	0 MG	26MAR96	28	02APR96	35	8
	00207	Oral	4	0 MG	03APR96	36	09APR96	42	7
	00207	Oral	4	0 MG	10APR96	43	16APR96	49	7
	00207	Oral	4	0 MG	17APR96	50	23APR96	56	7
		Oral	3	0 MG	24APR96	57	25APR96	58	2
329.002.00049		Oral	1	0 MG	09MAR95	1	15MAR95	7	7
	00049	Oral	2	0 MG	16MAR95	8	22MAR95	14	7
	00049	Oral	3	0 MG	23MAR95	15	29MAR95	21	7
	00049	Oral	4	0 MG	30MAR95	22	05APR95	28	7
	00049	Oral	5	0 MG	06APR95	29	12APR95	35	7
	00049	Oral	6	0 MG	13APR95	36	19APR95	42	7
	00049	Oral	6	0 MG	20APR95	43	27APR95	50	8
	00049	Oral	6	0 MG	28APR95	51	05MAY95	58	8
		Oral	6	0 MG	06MAY95	59	21MAY95	74	16
329.002.00059		Oral	1	0 MG	10NOV94	1	16NOV94	7	7
	00059	Oral	2	0 MG	17NOV94	8	22NOV94	13	6
	00059	Oral	3	0 MG	23NOV94	14	30NOV94	21	8
	00059	Oral	4	0 MG	01DEC94	22	07DEC94	28	7
	00059	Oral	5	0 MG	08DEC94	29	14DEC94	35	7
	00059	Oral	6	0 MG	15DEC94	36	21DEC94	42	7
	00059	Oral	6	0 MG	22DEC94	43	28DEC94	49	7
	00059	Oral	6	0 MG	29DEC94	50	05JAN95	57	8
		Oral	6	0 MG	06JAN95	58	21JAN95	73	16
329.002.00060		Oral	1	0 MG	31JAN95	1	06FEB95	7	7
	00060	Oral	2	0 MG	07FEB95	8	13FEB95	14	7
	00060	Oral	3	0 MG	14FEB95	15	20FEB95	21	7
	00060	Oral	4	0 MG	21FEB95	22	27FEB95	28	7

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00060	00060	Oral	5	0 MG	28FEB95	29	06MAR95	35	7
	00060	Oral	6	0 MG	07MAR95	36	13MAR95	42	7
	00060	Oral	6	0 MG	14MAR95	43	20MAR95	49	7
	00060	Oral	6	0 MG	21MAR95	50	27MAR95	56	7
	00065	Oral	6	0 MG	28MAR95	57	25APR95	85	29
329.002.00097		Oral	1	0 MG	03JAN95	1	09JAN95	7	7
	00097	Oral	2	0 MG	10JAN95	8	17JAN95	15	8
	00097	Oral	3	0 MG	18JAN95	16	24JAN95	22	7
	00097	Oral	4	0 MG	25JAN95	23	31JAN95	29	7
	00097	Oral	5	0 MG	01FEB95	30	06FEB95	35	6
	00097	Oral	6	0 MG	07FEB95	36	13FEB95	42	7
	00097	Oral	6	0 MG	14FEB95	43	20FEB95	49	7
	00097	Oral	6	0 MG	21FEB95	50	01MAR95	58	9
	00026	Oral	6	0 MG	02MAR95	59	29MAR95	86	28
	00026	Oral	6	0 MG	30MAR95	87	26APR95	114	28
	00026	Oral	6	0 MG	27APR95	115	22MAY95	140	26
	00026	Oral	6	0 MG	23MAY95	141	28JUN95	177	37
	00026	Oral	6	0 MG	29JUN95	178	01AUG95	211	34
	00026	Oral	6	0 MG	02AUG95	212	04SEP95	245	34
	00097	Oral	5	0 MG	05SEP95	246	06SEP95	247	2
	00097	Oral	4	0 MG	07SEP95	248	08SEP95	249	2
	00097	Oral	3	0 MG	09SEP95	250	10SEP95	251	2
	00097	Oral	2	0 MG	11SEP95	252	13SEP95	254	3
	00097	Oral	1	0 MG	14SEP95	255	20SEP95	261	7
329.002.00101		Oral	1	0 MG	28MAR95	1	03APR95	7	7
	00101	Oral	2	0 MG	04APR95	8	12APR95	16	9
	00101	Oral	3	0 MG	13APR95	17	19APR95	23	7
	00101	Oral	4	0 MG	20APR95	24	26APR95	30	7
	00101	Oral	5	0 MG	27APR95	31	03MAY95	37	7
	00101	Oral	6	0 MG	04MAY95	38	10MAY95	44	7
	00101	Oral	6	0 MG	11MAY95	45	17MAY95	51	7
	00101	Oral	6	0 MG	18MAY95	52	24MAY95	58	7
	00066	Oral	6	0 MG	25MAY95	59	21JUN95	86	28
		Oral	6	0 MG	22JUN95	87	26JUN95	91	5
	00101	Oral	5	0 MG	27JUN95	92	27JUN95	92	1
	00101	Oral	4	0 MG	28JUN95	93	29JUN95	94	2
	00101	Oral	3	0 MG	30JUN95	95	01JUL95	96	2
	00101	Oral	2	0 MG	02JUL95	97	04JUL95	99	3

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00101	00101	Oral	1	0 MG	05JUL95	100	11JUL95	106	7
329.002.00107		Oral	1	0 MG	25JAN96	1	31JAN96	7	7
	00107	Oral	2	0 MG	01FEB96	8	07FEB96	14	7
	00107	Oral	3	0 MG	08FEB96	15	12FEB96	19	5
	00107	Oral	4	0 MG	13FEB96	20	19FEB96	26	7
	00107	Oral	4	0 MG	20FEB96	27	26FEB96	33	7
	00107	Oral	4	0 MG	27FEB96	34	04MAR96	40	7
	00107	Oral	5	0 MG	05MAR96	41	14MAR96	50	10
	00107	Oral	6	0 MG	15MAR96	51	20MAR96	56	6
	00176	Oral	6	0 MG	21MAR96	57	22APR96	89	33
	00176	Oral	6	0 MG	23APR96	90	20MAY96	117	28
	00176	Oral	6	0 MG	21MAY96	118	19JUN96	147	30
	00176	Oral	6	0 MG	20JUN96	148	24JUL96	182	35
	00176	Oral	6	0 MG	25JUL96	183	28AUG96	217	35
	00176	Oral	6	0 MG	29AUG96	218	25SEP96	245	28
	00176	Oral	5	0 MG	26SEP96	246	08OCT96	258	13
329.002.00241		Oral	1	0 MG	06FEB96	1	12FEB96	7	7
	00241	Oral	2	0 MG	13FEB96	8	21FEB96	16	9
	00241	Oral	3	0 MG	22FEB96	17	26FEB96	21	5
	00241	Oral	4	0 MG	27FEB96	22	04MAR96	28	7
	00241	Oral	4	0 MG	05MAR96	29	11MAR96	35	7
	00241	Oral	5	0 MG	12MAR96	36	18MAR96	42	7
	00241	Oral	5	0 MG	19MAR96	43	25MAR96	49	7
	00241	Oral	6	0 MG	26MAR96	50	01APR96	56	7
	00145	Oral	6	0 MG	02APR96	57	30APR96	85	29
	00145	Oral	6	0 MG	01MAY96	86	23MAY96	108	23
329.002.00246		Oral	1	0 MG	18APR96	1	24APR96	7	7
	00246	Oral	2	0 MG	25APR96	8	01MAY96	14	7
	00246	Oral	3	0 MG	02MAY96	15	08MAY96	21	7
	00246	Oral	4	0 MG	09MAY96	22	15MAY96	28	7
	00246	Oral	5	0 MG	16MAY96	29	22MAY96	35	7
	00246	Oral	5	0 MG	23MAY96	36	29MAY96	42	7
	00246	Oral	5	0 MG	30MAY96	43	03JUN96	47	5
	00246	Oral	6	0 MG	04JUN96	48	17JUN96	61	14
		Oral	6	0 MG	18JUN96	62	28JUN96	72	11
329.002.00320		Oral	1	0 MG	16MAY96	1	22MAY96	7	7

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.002.00320	00320	Oral	2	0 MG	23MAY96	8	29MAY96	14	7
	00320	Oral	3	0 MG	30MAY96	15	03JUN96	19	5
	00320	Oral	4	0 MG	04JUN96	20	17JUN96	33	14
	00320	Oral	5	0 MG	18JUN96	34	24JUN96	40	7
	00320	Oral	5	0 MG	25JUN96	41	01JUL96	47	7
	00320	Oral	6	0 MG	02JUL96	48	08JUL96	54	7
	00320	Oral	6	0 MG	09JUL96	55	15JUL96	61	7
	00182	Oral	6	0 MG	16JUL96	62	12AUG96	89	28
	00182	Oral	6	0 MG	13AUG96	90	16SEP96	124	35
	00182	Oral	6	0 MG	17SEP96	125	25SEP96	133	9
	00320	Oral	5	0 MG	26SEP96	134	08OCT96	146	13
329.002.00323		Oral	1	0 MG	12NOV96	1	18NOV96	7	7
	00323	Oral	2	0 MG	19NOV96	8	25NOV96	14	7
	00323	Oral	3	0 MG	26NOV96	15	04DEC96	23	9
	00323	Oral	4	0 MG	05DEC96	24	09DEC96	28	5
	00323	Oral	4	0 MG	10DEC96	29	16DEC96	35	7
	00323	Oral	4	0 MG	17DEC96	36	25DEC96	44	9
	00323	Oral	4	0 MG	26DEC96	45	01JAN97	51	7
	00323	Oral	4	0 MG	02JAN97	52	08JAN97	58	7
	00175	Oral	4	0 MG	09JAN97	59	03FEB97	84	26
	00175	Oral	4	0 MG	04FEB97	85	03MAR97	112	28
	00175	Oral	5	0 MG	04MAR97	113	02APR97	142	30
	00175	Oral	5	0 MG	03APR97	143	29APR97	169	27
	00175	Oral	5	0 MG	30APR97	170	26MAY97	196	27
	00175	Oral	5	0 MG	27MAY97	197	11JUN97	212	16
	00323	Oral	5	0 MG	12JUN97	213	14JUN97	215	3
	00323	Oral	4	0 MG	15JUN97	216	16JUN97	217	2
	00323	Oral	3	0 MG	17JUN97	218	18JUN97	219	2
	00323	Oral	2	0 MG	19JUN97	220	20JUN97	221	2
	00323	Oral	1	0 MG	21JUN97	222	26JUN97	227	6
329.003.00074		Oral	1	0 MG	25JAN95	1	31JAN95	7	7
	00074	Oral	2	0 MG	01FEB95	8	07FEB95	14	7
	00074	Oral	3	0 MG	08FEB95	15	14FEB95	21	7
	00074	Oral	4	0 MG	15FEB95	22	20FEB95	27	6
	00074	Oral	5	0 MG	21FEB95	28	28FEB95	35	8
	00074	Oral	6	0 MG	01MAR95	36	14MAR95	49	14
	00074	Oral	6	0 MG	15MAR95	50	21MAR95	56	7
	00043	Oral	6	0 MG	22MAR95	57	18APR95	84	28

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00074	00043	Oral	6	0 MG	19APR95	85	16MAY95	112	28
	00043	Oral	6	0 MG	17MAY95	113	18JUN95	145	33
	00043	Oral	6	0 MG	19JUN95	146	23JUL95	180	35
	00043	Oral	6	0 MG	24JUL95	181	29AUG95	217	37
	00043	Oral	6	0 MG	30AUG95	218	11OCT95	260	43
	00074	Oral	5	0 MG	25OCT95	274	.	.	.
329.003.00078		Oral	1	0 MG	26APR95	1	01MAY95	6	6
	00078	Oral	2	0 MG	02MAY95	7	09MAY95	14	8
	00078	Oral	3	0 MG	10MAY95	15	16MAY95	21	7
	00078	Oral	4	0 MG	17MAY95	22	23MAY95	28	7
	00078	Oral	5	0 MG	24MAY95	29	29MAY95	34	6
	00078	Oral	6	0 MG	30MAY95	35	06JUN95	42	8
	00078	Oral	6	0 MG	07JUN95	43	14JUN95	50	8
	00078	Oral	6	0 MG	15JUN95	51	21JUN95	57	7
		Oral	6	0 MG	22JUN95	58	28JUN95	64	7
329.003.00080		Oral	1	0 MG	27NOV95	1	03DEC95	7	7
	00080	Oral	2	0 MG	04DEC95	8	10DEC95	14	7
	00080	Oral	3	0 MG	11DEC95	15	17DEC95	21	7
	00080	Oral	4	0 MG	18DEC95	22	28DEC95	32	11
		Oral	4	0 MG	29DEC95	33	03JAN96	38	6
	00080	Oral	5	0 MG	04JAN96	39	09JAN96	44	6
	00080	Oral	6	0 MG	10JAN96	45	16JAN96	51	7
	00080	Oral	6	0 MG	17JAN96	52	23JAN96	58	7
	00080	Oral	5	0 MG	24JAN96	59	09FEB96	75	17
329.003.00085		Oral	1	0 MG	08NOV94	1	14NOV94	7	7
	00085	Oral	2	0 MG	15NOV94	8	20NOV94	13	6
	00085	Oral	3	0 MG	21NOV94	14	27NOV94	20	7
	00085	Oral	4	0 MG	28NOV94	21	05DEC94	28	8
	00085	Oral	5	0 MG	06DEC94	29	12DEC94	35	7
	00085	Oral	6	0 MG	13DEC94	36	19DEC94	42	7
	00085	Oral	6	0 MG	20DEC94	43	27DEC94	50	8
	00085	Oral	6	0 MG	28DEC94	51	03JAN95	57	7
		Oral	5	0 MG	04JAN95	58	17JAN95	71	14
329.003.00086		Oral	1	0 MG	28NOV94	1	04DEC94	7	7
	00086	Oral	2	0 MG	05DEC94	8	12DEC94	15	8
	00086	Oral	3	0 MG	13DEC94	16	19DEC94	22	7

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00086	00086	Oral	4	0 MG	20DEC94	23	27DEC94	30	8
	00086	Oral	5	0 MG	28DEC94	31	03JAN95	37	7
	00086	Oral	6	0 MG	04JAN95	38	09JAN95	43	6
	00086	Oral	6	0 MG	10JAN95	44	17JAN95	51	8
	00086	Oral	6	0 MG	18JAN95	52	23JAN95	57	6
	00038	Oral	6	0 MG	24JAN95	58	19FEB95	84	27
	00038	Oral	6	0 MG	20FEB95	85	28MAR95	121	37
	00038	Oral	6	0 MG	29MAR95	122	25APR95	149	28
	00038	Oral	6	0 MG	26APR95	150	30MAY95	184	35
	00038	Oral	6	0 MG	31MAY95	185	11JUL95	226	42
	00038	Oral	6	0 MG	12JUL95	227	16AUG95	262	36
	00086	Oral	5	0 MG	17AUG95	263	18AUG95	264	2
	00086	Oral	4	0 MG	19AUG95	265	20AUG95	266	2
	00086	Oral	3	0 MG	21AUG95	267	22AUG95	268	2
	00086	Oral	2	0 MG	23AUG95	269	25AUG95	271	3
	00086	Oral	1	0 MG	26AUG95	272	02SEP95	279	8
329.003.00094		Oral	1	0 MG	24OCT95	1	30OCT95	7	7
	00094	Oral	2	0 MG	31OCT95	8	06NOV95	14	7
	00094	Oral	3	0 MG	07NOV95	15	13NOV95	21	7
	00094	Oral	4	0 MG	14NOV95	22	20NOV95	28	7
	00094	Oral	5	0 MG	21NOV95	29	27NOV95	35	7
	00094	Oral	6	0 MG	28NOV95	36	04DEC95	42	7
	00094	Oral	6	0 MG	05DEC95	43	11DEC95	49	7
	00094	Oral	6	0 MG	12DEC95	50	19DEC95	57	8
		Oral	5	0 MG	20DEC95	58	04JAN96	73	16
329.003.00251		Oral	1	0 MG	28MAR96	1	04APR96	8	8
	00251	Oral	2	0 MG	05APR96	9	08APR96	12	4
	00251	Oral	3	0 MG	09APR96	13	.	.	.
329.003.00252		Oral	1	0 MG	10APR96	1	16APR96	7	7
	00252	Oral	2	0 MG	17APR96	8	23APR96	14	7
	00252	Oral	3	0 MG	24APR96	15	30APR96	21	7
	00252	Oral	4	0 MG	01MAY96	22	09MAY96	30	9
	00252	Oral	4	0 MG	10MAY96	31	14MAY96	35	5
	00252	Oral	5	0 MG	15MAY96	36	20MAY96	41	6
	00252	Oral	4	0 MG	21MAY96	42	27MAY96	48	7
	00252	Oral	4	0 MG	28MAY96	49	10JUN96	62	14
		Oral	3	0 MG	11JUN96	63	18JUN96	70	8

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.003.00291		Oral	1	0 MG	03JUL96	1	14JUL96	12	12
	00291	Oral	2	0 MG	15JUL96	13	23JUL96	21	9
	00291	Oral	3	0 MG	24JUL96	22	30JUL96	28	7
	00291	Oral	4	0 MG	31JUL96	29	06AUG96	35	7
	00291	Oral	4	0 MG	07AUG96	36	13AUG96	42	7
	00291	Oral	4	0 MG	14AUG96	43	20AUG96	49	7
	00291	Oral	4	0 MG	21AUG96	50	27AUG96	56	7
	00291	Oral	5	0 MG	28AUG96	57	05SEP96	65	9
	00135	Oral	5	0 MG	06SEP96	66	01OCT96	91	26
	00135	Oral	5	0 MG	02OCT96	92	29OCT96	119	28
	00135	Oral	5	0 MG	30OCT96	120	.	.	.
329.003.00315		Oral	1	0 MG	12NOV96	1	21NOV96	10	10
	00315	Oral	2	0 MG	22NOV96	11	25NOV96	14	4
	00315	Oral	3	0 MG	26NOV96	15	02DEC96	21	7
	00315	Oral	4	0 MG	03DEC96	22	11DEC96	30	9
	00315	Oral	4	0 MG	12DEC96	31	17DEC96	36	6
	00315	Oral	4	0 MG	18DEC96	37	22DEC96	41	5
	00315	Oral	4	0 MG	23DEC96	42	29DEC96	48	7
	00315	Oral	4	0 MG	30DEC96	49	06JAN97	56	8
		Oral	4	0 MG	07JAN97	57	10JAN97	60	4
329.003.00316		Oral	1	0 MG	17DEC96	1	23DEC96	7	7
	00316	Oral	2	0 MG	24DEC96	8	30DEC96	14	7
	00316	Oral	3	0 MG	31DEC96	15	07JAN97	22	8
	00316	Oral	4	0 MG	08JAN97	23	14JAN97	29	7
	00316	Oral	5	0 MG	15JAN97	30	21JAN97	36	7
	00316	Oral	6	0 MG	22JAN97	37	28JAN97	43	7
	00316	Oral	6	0 MG	29JAN97	44	03FEB97	49	6
	00316	Oral	6	0 MG	04FEB97	50	09FEB97	55	6
		Oral	5	0 MG	10FEB97	56	18FEB97	64	9
329.004.00016		Oral	1	0 MG	13MAR95	1	19MAR95	7	7
	00016	Oral	2	0 MG	20MAR95	8	28MAR95	16	9
	00016	Oral	3	0 MG	29MAR95	17	04APR95	23	7
	00016	Oral	4	0 MG	05APR95	24	11APR95	30	7
	00016	Oral	4	0 MG	12APR95	31	19APR95	38	8
329.004.00018		Oral	1	0 MG	03MAY95	1	10MAY95	8	8
	00018	Oral	2	0 MG	11MAY95	9	17MAY95	15	7

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.004.00018	00018	Oral	3	0 MG	18MAY95	16	24MAY95	22	7
	00018	Oral	4	0 MG	25MAY95	23	31MAY95	29	7
	00018	Oral	5	0 MG	01JUN95	30	07JUN95	36	7
	00018	Oral	5	0 MG	08JUN95	37	18JUN95	47	11
	00018	Oral	6	0 MG	19JUN95	48	21JUN95	50	3
	00018	Oral	6	0 MG	22JUN95	51	28JUN95	57	7
	00018	Oral	5	0 MG	29JUN95	58	14JUL95	73	16
329.004.00020		Oral	1	0 MG	09NOV95	1	15NOV95	7	7
	00020	Oral	2	0 MG	16NOV95	8	24NOV95	16	9
329.004.00213		Oral	1	0 MG	02AUG96	1	07AUG96	6	6
	00213	Oral	2	0 MG	08AUG96	7	14AUG96	13	7
	00213	Oral	3	0 MG	15AUG96	14	20AUG96	19	6
	00213	Oral	4	0 MG	21AUG96	20	28AUG96	27	8
	00213	Oral	4	0 MG	29AUG96	28	02SEP96	32	5
	00213	Oral	4	0 MG	03SEP96	33	09SEP96	39	7
	00213	Oral	4	0 MG	10SEP96	40	16SEP96	46	7
	00213	Oral	4	0 MG	17SEP96	47	24SEP96	54	8
	00122	Oral	4	0 MG	25SEP96	55	21OCT96	81	27
	00122	Oral	4	0 MG	22OCT96	82	18NOV96	109	28
	00122	Oral	4	0 MG	19NOV96	110	19DEC96	140	31
	00122	Oral	4	0 MG	20DEC96	141	20JAN97	172	32
	00122	Oral	4	0 MG	21JAN97	173	17FEB97	200	28
	00122	Oral	4	0 MG	18FEB97	201	18MAR97	229	29
	00213	Oral	3	0 MG	19MAR97	230	20MAR97	231	2
	00213	Oral	2	0 MG	21MAR97	232	23MAR97	234	3
	00213	Oral	1	0 MG	24MAR97	235	30MAR97	241	7
329.005.00001		Oral	1	0 MG	20APR94	1	26APR94	7	7
	00001	Oral	2	0 MG	27APR94	8	03MAY94	14	7
	00001	Oral	3	0 MG	04MAY94	15	10MAY94	21	7
	00001	Oral	4	0 MG	11MAY94	22	17MAY94	28	7
	00001	Oral	5	0 MG	18MAY94	29	24MAY94	35	7
	00001	Oral	6	0 MG	25MAY94	36	31MAY94	42	7
	00001	Oral	6	0 MG	01JUN94	43	07JUN94	49	7
	00001	Oral	6	0 MG	08JUN94	50	14JUN94	56	7
		Oral	6	0 MG	15JUN94	57	28JUN94	70	14
329.005.00005		Oral	1	0 MG	01NOV94	1	09NOV94	9	9

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00010		Oral	1	0 MG	13DEC94	1	19DEC94	7	7
	00010	Oral	2	0 MG	20DEC94	8	26DEC94	14	7
	00010	Oral	3	0 MG	27DEC94	15	03JAN95	22	8
	00010	Oral	4	0 MG	04JAN95	23	10JAN95	29	7
	00010	Oral	5	0 MG	11JAN95	30	17JAN95	36	7
	00010	Oral	6	0 MG	18JAN95	37	24JAN95	43	7
	00010	Oral	6	0 MG	25JAN95	44	01FEB95	51	8
	00010	Oral	6	0 MG	02FEB95	52	07FEB95	57	6
	00090	Oral	6	0 MG	08FEB95	58	09MAR95	87	30
	00090	Oral	6	0 MG	10MAR95	88	12APR95	121	34
	00090	Oral	6	0 MG	13APR95	122	09MAY95	148	27
	00090	Oral	6	0 MG	10MAY95	149	05JUN95	175	27
	00090	Oral	6	0 MG	06JUN95	176	11JUL95	211	36
	00090	Oral	6	0 MG	12JUL95	212	08AUG95	239	28
	00010	Oral	5	0 MG	09AUG95	240	10AUG95	241	2
	00010	Oral	4	0 MG	11AUG95	242	12AUG95	243	2
	00010	Oral	3	0 MG	13AUG95	244	14AUG95	245	2
	00010	Oral	2	0 MG	15AUG95	246	17AUG95	248	3
	00010	Oral	1	0 MG	18AUG95	249	24AUG95	255	7
329.005.00012		Oral	1	0 MG	19DEC94	1	26DEC94	8	8
	00012	Oral	2	0 MG	27DEC94	9	04JAN95	17	9
	00012	Oral	3	0 MG	05JAN95	18	11JAN95	24	7
	00012	Oral	4	0 MG	12JAN95	25	17JAN95	30	6
	00012	Oral	5	0 MG	18JAN95	31	24JAN95	37	7
	00012	Oral	6	0 MG	25JAN95	38	30JAN95	43	6
	00012	Oral	6	0 MG	31JAN95	44	07FEB95	51	8
	00012	Oral	6	0 MG	08FEB95	52	15FEB95	59	8
	00096	Oral	6	0 MG	16FEB95	60	26MAR95	98	39
	00096	Oral	6	0 MG	27MAR95	99	03MAY95	136	38
	00096	Oral	6	0 MG	04MAY95	137	30MAY95	163	27
	00096	Oral	6	0 MG	31MAY95	164	01JUN95	165	2
329.005.00111		Oral	1	0 MG	11JAN95	1	17JAN95	7	7
	00111	Oral	2	0 MG	18JAN95	8	24JAN95	14	7
	00111	Oral	3	0 MG	25JAN95	15	31JAN95	21	7
	00111	Oral	4	0 MG	01FEB95	22	07FEB95	28	7
	00111	Oral	4	0 MG	08FEB95	29	14FEB95	35	7
	00111	Oral	4	0 MG	15FEB95	36	21FEB95	42	7
	00111	Oral	4	0 MG	22FEB95	43	28FEB95	49	7

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00111	00111	Oral	4	0 MG	01MAR95	50	07MAR95	56	7
	00018	Oral	4	0 MG	08MAR95	57	04APR95	84	28
	00018	Oral	4	0 MG	05APR95	85	18APR95	98	14
	00111	Oral	3	0 MG	19APR95	99	20APR95	100	2
	00111	Oral	2	0 MG	21APR95	101	23APR95	103	3
	00111	Oral	1	0 MG	24APR95	104	30APR95	110	7
329.005.00114		Oral	1	0 MG	31JAN95	1	06FEB95	7	7
	00114	Oral	2	0 MG	07FEB95	8	13FEB95	14	7
	00114	Oral	3	0 MG	14FEB95	15	20FEB95	21	7
	00114	Oral	4	0 MG	21FEB95	22	27FEB95	28	7
	00114	Oral	4	0 MG	28FEB95	29	08MAR95	37	9
	00114	Oral	4	0 MG	09MAR95	38	14MAR95	43	6
	00114	Oral	4	0 MG	15MAR95	44	21MAR95	50	7
	00114	Oral	4	0 MG	22MAR95	51	28MAR95	57	7
	00020	Oral	4	0 MG	29MAR95	58	25APR95	85	28
	00114	Oral	4	0 MG	26APR95	86	26APR95	86	1
	00114	Oral	3	0 MG	27APR95	87	28APR95	88	2
	00114	Oral	2	0 MG	29APR95	89	01MAY95	91	3
	00114	Oral	1	0 MG	02MAY95	92	08MAY95	98	7
329.005.00115		Oral	1	0 MG	06FEB95	1	12FEB95	7	7
	00115	Oral	2	0 MG	13FEB95	8	19FEB95	14	7
	00115	Oral	3	0 MG	20FEB95	15	01MAR95	24	10
	00115	Oral	4	0 MG	02MAR95	25	09MAR95	32	8
	00115	Oral	4	0 MG	10MAR95	33	16MAR95	39	7
	00115	Oral	4	0 MG	17MAR95	40	27MAR95	50	11
	00115	Oral	4	0 MG	28MAR95	51	09APR95	63	13
	00115	Oral	4	0 MG	10APR95	64	17APR95	71	8
	00003	Oral	4	0 MG	18APR95	72	21APR95	75	4
329.005.00120		Oral	1	0 MG	30AUG95	1	06SEP95	8	8
	00120	Oral	2	0 MG	07SEP95	9	13SEP95	15	7
	00120	Oral	3	0 MG	14SEP95	16	20SEP95	22	7
	00120	Oral	4	0 MG	21SEP95	23	27SEP95	29	7
	00120	Oral	5	0 MG	28SEP95	30	04OCT95	36	7
	00120	Oral	5	0 MG	05OCT95	37	11OCT95	43	7
	00120	Oral	6	0 MG	12OCT95	44	18OCT95	50	7
	00120	Oral	6	0 MG	19OCT95	51	26OCT95	58	8

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Listing of Study Medication Data
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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00253		Oral	1	0 MG	08FEB96	1	13FEB96	6	6
	00253	Oral	2	0 MG	14FEB96	7	20FEB96	13	7
	00253	Oral	3	0 MG	21FEB96	14	27FEB96	20	7
	00253	Oral	4	0 MG	28FEB96	21	05MAR96	27	7
	00253	Oral	5	0 MG	06MAR96	28	13MAR96	35	8
	00253	Oral	6	0 MG	14MAR96	36	19MAR96	41	6
	00253	Oral	6	0 MG	20MAR96	42	26MAR96	48	7
	00253	Oral	6	0 MG	27MAR96	49	02APR96	55	7
		Oral	5	0 MG	03APR96	56	.	.	.
329.005.00254		Oral	1	0 MG	15FEB96	1	20FEB96	6	6
	00254	Oral	2	0 MG	21FEB96	7	27FEB96	13	7
	00254	Oral	3	0 MG	28FEB96	14	05MAR96	20	7
	00254	Oral	4	0 MG	06MAR96	21	12MAR96	27	7
	00254	Oral	4	0 MG	13MAR96	28	19MAR96	34	7
	00254	Oral	4	0 MG	20MAR96	35	26MAR96	41	7
	00254	Oral	4	0 MG	27MAR96	42	02APR96	48	7
	00254	Oral	4	0 MG	03APR96	49	09APR96	55	7
	00146	Oral	4	0 MG	10APR96	56	08MAY96	84	29
	00146	Oral	4	0 MG	09MAY96	85	11JUN96	118	34
	00146	Oral	4	0 MG	12JUN96	119	09JUL96	146	28
	00146	Oral	4	0 MG	10JUL96	147	07AUG96	175	29
	00146	Oral	4	0 MG	08AUG96	176	11SEP96	210	35
	00146	Oral	4	0 MG	12SEP96	211	15OCT96	244	34
	00254	Oral	4	0 MG	16OCT96	245	17OCT96	246	2
	00254	Oral	3	0 MG	18OCT96	247	19OCT96	248	2
	00254	Oral	2	0 MG	20OCT96	249	22OCT96	251	3
	00254	Oral	1	0 MG	23OCT96	252	29OCT96	258	7
329.005.00293		Oral	1	0 MG	12MAR97	1	18MAR97	7	7
	00293	Oral	2	0 MG	19MAR97	8	24MAR97	13	6
	00293	Oral	3	0 MG	25MAR97	14	01APR97	21	8
	00293	Oral	4	0 MG	02APR97	22	08APR97	28	7
	00293	Oral	5	0 MG	09APR97	29	15APR97	35	7
	00293	Oral	6	0 MG	16APR97	36	22APR97	42	7
	00293	Oral	6	0 MG	23APR97	43	29APR97	49	7
	00293	Oral	6	0 MG	30APR97	50	07MAY97	57	8
329.005.00298		Oral	1	0 MG	22MAY96	1	29MAY96	8	8
	00298	Oral	2	0 MG	30MAY96	9	05JUN96	15	7

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.005.00298	00298	Oral	3	0 MG	06JUN96	16	11JUN96	21	6
	00298	Oral	4	0 MG	12JUN96	22	18JUN96	28	7
	00298	Oral	4	0 MG	19JUN96	29	25JUN96	35	7
	00298	Oral	4	0 MG	26JUN96	36	02JUL96	42	7
	00298	Oral	4	0 MG	03JUL96	43	09JUL96	49	7
	00298	Oral	4	0 MG	10JUL96	50	16JUL96	56	7
	00185	Oral	4	0 MG	17JUL96	57	15AUG96	86	30
	00185	Oral	4	0 MG	16AUG96	87	18SEP96	120	34
	00185	Oral	4	0 MG	19SEP96	121	16OCT96	148	28
	00185	Oral	4	0 MG	17OCT96	149	13NOV96	176	28
	00185	Oral	4	0 MG	14NOV96	177	11DEC96	204	28
	00185	Oral	4	0 MG	12DEC96	205	12JAN97	236	32
	00298	Oral	3	0 MG	13JAN97	237	14JAN97	238	2
	00298	Oral	2	0 MG	15JAN97	239	17JAN97	241	3
	00298	Oral	1	0 MG	18JAN97	242	24JAN97	248	7
329.005.00331		Oral	1	0 MG	21NOV96	1	26NOV96	6	6
	00331	Oral	2	0 MG	27NOV96	7	03DEC96	13	7
	00331	Oral	3	0 MG	04DEC96	14	11DEC96	21	8
	00331	Oral	4	0 MG	12DEC96	22	18DEC96	28	7
	00331	Oral	4	0 MG	19DEC96	29	25DEC96	35	7
	00331	Oral	4	0 MG	26DEC96	36	01JAN97	42	7
	00331	Oral	4	0 MG	02JAN97	43	09JAN97	50	8
	00331	Oral	4	0 MG	10JAN97	51	16JAN97	57	7
329.005.00334		Oral	1	0 MG	31JAN97	1	05FEB97	6	6
	00334	Oral	2	0 MG	06FEB97	7	12FEB97	13	7
	00334	Oral	3	0 MG	13FEB97	14	20FEB97	21	8
	00334	Oral	4	0 MG	21FEB97	22	25FEB97	26	5
	00334	Oral	4	0 MG	26FEB97	27	06MAR97	35	9
	00334	Oral	5	0 MG	07MAR97	36	13MAR97	42	7
	00334	Oral	5	0 MG	14MAR97	43	21MAR97	50	8
	00334	Oral	5	0 MG	22MAR97	51	27MAR97	56	6
329.006.00037		Oral	1	0 MG	28JAN95	1	02FEB95	6	6
	00037	Oral	2	0 MG	03FEB95	7	12FEB95	16	10
	00037	Oral	3	0 MG	13FEB95	17	21FEB95	25	9
329.006.00042		Oral	1	0 MG	07DEC95	1	12DEC95	6	6
	00042	Oral	2	0 MG	13DEC95	7	19DEC95	13	7

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Listing of Study Medication Data
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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.006.00042	00042	Oral	3	0 MG	20DEC95	14	26DEC95	20	7
	00042	Oral	4	0 MG	27DEC95	21	02JAN96	27	7
	00042	Oral	4	0 MG	03JAN96	28	09JAN96	34	7
	00042	Oral	5	0 MG	10JAN96	35	16JAN96	41	7
	00042	Oral	5	0 MG	17JAN96	42	22JAN96	47	6
	00042	Oral	6	0 MG	23JAN96	48	01FEB96	57	10
	00111	Oral	6	0 MG	02FEB96	58	28FEB96	84	27
	00111	Oral	6	0 MG	29FEB96	85	25MAR96	110	26
	00111	Oral	6	0 MG	26MAR96	111	22APR96	138	28
	00111	Oral	6	0 MG	23APR96	139	20MAY96	166	28
	00111	Oral	6	0 MG	21MAY96	167	17JUN96	194	28
	00111	Oral	6	0 MG	18JUN96	195	16JUL96	223	29
	00042	Oral	5	0 MG	17JUL96	224	18JUL96	225	2
	00042	Oral	4	0 MG	19JUL96	226	20JUL96	227	2
	00042	Oral	3	0 MG	21JUL96	228	22JUL96	229	2
	00042	Oral	2	0 MG	23JUL96	230	25JUL96	232	3
	00042	Oral	1	0 MG	26JUL96	233	31JUL96	238	6
329.006.00259		Oral	1	0 MG	24MAY96	1	27MAY96	4	4
	00259	Oral	2	0 MG	28MAY96	5	05JUN96	13	9
	00259	Oral	3	0 MG	06JUN96	14	12JUN96	20	7
	00259	Oral	4	0 MG	13JUN96	21	19JUN96	27	7
	00259	Oral	5	0 MG	20JUN96	28	27JUN96	35	8
	00259	Oral	6	0 MG	28JUN96	36	05JUL96	43	8
	00259	Oral	6	0 MG	06JUL96	44	10JUL96	48	5
	00259	Oral	6	0 MG	11JUL96	49	17JUL96	55	7
		Oral	6	0 MG	18JUL96	56	02AUG96	71	16
329.007.00141		Oral	1	0 MG	21SEP95	1	27SEP95	7	7
	00141	Oral	2	0 MG	28SEP95	8	04OCT95	14	7
	00141	Oral	3	0 MG	05OCT95	15	12OCT95	22	8
329.007.00144		Oral	1	0 MG	07DEC95	1	13DEC95	7	7
	00144	Oral	2	0 MG	14DEC95	8	20DEC95	14	7
	00144	Oral	3	0 MG	21DEC95	15	27DEC95	21	7
	00144	Oral	4	0 MG	28DEC95	22	04JAN96	29	8
	00144	Oral	4	0 MG	05JAN96	30	10JAN96	35	6
	00144	Oral	5	0 MG	11JAN96	36	17JAN96	42	7
	00144	Oral	5	0 MG	18JAN96	43	24JAN96	49	7
	00144	Oral	5	0 MG	25JAN96	50	31JAN96	56	7

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.007.00144	00115	Oral	5	0 MG	01FEB96	57	.	.	.
329.007.00266		Oral	1	0 MG	07MAR96	1	13MAR96	7	7
	00266	Oral	2	0 MG	14MAR96	8	24MAR96	18	11
	00266	Oral	3	0 MG	25MAR96	19	27MAR96	21	3
	00266	Oral	4	0 MG	28MAR96	22	03APR96	28	7
	00266	Oral	5	0 MG	04APR96	29	10APR96	35	7
	00266	Oral	5	0 MG	11APR96	36	17APR96	42	7
	00266	Oral	5	0 MG	18APR96	43	28APR96	53	11
	00266	Oral	5	0 MG	29APR96	54	02MAY96	57	4
	00266	Oral	4	0 MG	03MAY96	58	16MAY96	71	14
329.007.00267		Oral	1	0 MG	07MAR96	1	13MAR96	7	7
	00267	Oral	2	0 MG	14MAR96	8	20MAR96	14	7
	00267	Oral	3	0 MG	21MAR96	15	27MAR96	21	7
	00267	Oral	4	0 MG	28MAR96	22	03APR96	28	7
	00267	Oral	4	0 MG	04APR96	29	10APR96	35	7
	00267	Oral	4	0 MG	11APR96	36	17APR96	42	7
	00267	Oral	5	0 MG	18APR96	43	24APR96	49	7
	00267	Oral	5	0 MG	25APR96	50	01MAY96	56	7
		Oral	.		02MAY96	57	.	.	.
329.007.00311		Oral	1	0 MG	03OCT96	1	09OCT96	7	7
	00311	Oral	2	0 MG	10OCT96	8	16OCT96	14	7
	00311	Oral	3	0 MG	17OCT96	15	27OCT96	25	11
	00311	Oral	4	0 MG	28OCT96	26	30OCT96	28	3
	00311	Oral	4	0 MG	31OCT96	29	06NOV96	35	7
	00311	Oral	4	0 MG	07NOV96	36	13NOV96	42	7
	00311	Oral	4	0 MG	14NOV96	43	21NOV96	50	8
	00311	Oral	5	0 MG	22NOV96	51	01DEC96	60	10
	00160	Oral	5	0 MG	02DEC96	61	01JAN97	91	31
	00160	Oral	5	0 MG	02JAN97	92	29JAN97	119	28
	00160	Oral	5	0 MG	30JAN97	120	12MAR97	161	42
	00160	Oral	5	0 MG	13MAR97	162	10APR97	190	29
	00311	Oral	4	0 MG	11APR97	191	24APR97	204	14
329.008.00158		Oral	1	0 MG	13SEP95	1	18SEP95	6	6
	00158	Oral	2	0 MG	19SEP95	7	26SEP95	14	8
	00158	Oral	3	0 MG	27SEP95	15	02OCT95	20	6
	00158	Oral	4	0 MG	03OCT95	21	09OCT95	27	7

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.008.00158	00158	Oral	4	0 MG	10OCT95	28	15OCT95	33	6
	00158	Oral	5	0 MG	16OCT95	34	23OCT95	41	8
	00158	Oral	6	0 MG	24OCT95	42	30OCT95	48	7
	00158	Oral	6	0 MG	31OCT95	49	13NOV95	62	14
	00009	Oral	6	0 MG	14NOV95	63	26DEC95	105	43
	00009	Oral	6	0 MG	27DEC95	106	.	.	.
329.008.00162		Oral	1	0 MG	01NOV95	1	09NOV95	9	9
	00162	Oral	2	0 MG	10NOV95	10	19NOV95	19	10
	00162	Oral	3	0 MG	20NOV95	20	28NOV95	28	9
	00162	Oral	4	0 MG	29NOV95	29	06DEC95	36	8
	00162	Oral	5	0 MG	07DEC95	37	13DEC95	43	7
	00162	Oral	5	0 MG	14DEC95	44	19DEC95	49	6
	00162	Oral	6	0 MG	20DEC95	50	26DEC95	56	7
	00162	Oral	6	0 MG	27DEC95	57	04JAN96	65	9
	00101	Oral	6	0 MG	05JAN96	66	08FEB96	100	35
	00101	Oral	6	0 MG	09FEB96	101	07MAR96	128	28
	00101	Oral	6	0 MG	08MAR96	129	10APR96	162	34
		Oral	6	0 MG	11APR96	163	30APR96	182	20
	00101	Oral	6	0 MG	01MAY96	183	04JUN96	217	35
	00101	Oral	6	0 MG	05JUN96	218	01JUL96	244	27
	00162	Oral	5	0 MG	02JUL96	245	03JUL96	246	2
	00162	Oral	4	0 MG	04JUL96	247	05JUL96	248	2
	00162	Oral	3	0 MG	06JUL96	249	07JUL96	250	2
	00162	Oral	2	0 MG	08JUL96	251	10JUL96	253	3
	00162	Oral	1	0 MG	11JUL96	254	17JUL96	260	7
329.008.00191		Oral	1	0 MG	01FEB96	1	11FEB96	11	11
	00191	Oral	2	0 MG	12FEB96	12	19FEB96	19	8
	00191	Oral	3	0 MG	20FEB96	20	26FEB96	26	7
	00191	Oral	4	0 MG	27FEB96	27	04MAR96	33	7
	00191	Oral	4	0 MG	05MAR96	34	11MAR96	40	7
	00191	Oral	4	0 MG	12MAR96	41	17MAR96	46	6
	00191	Oral	4	0 MG	18MAR96	47	25MAR96	54	8
	00191	Oral	4	0 MG	26MAR96	55	01APR96	61	7
	00141	Oral	4	0 MG	02APR96	62	01MAY96	91	30
	00141	Oral	4	0 MG	02MAY96	92	04JUN96	125	34
	00141	Oral	4	0 MG	05JUN96	126	12JUN96	133	8
329.009.00128		Oral	1	0 MG	11APR95	1	17APR95	7	7

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TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00128	00128	Oral	2	0 MG	18APR95	8	24APR95	14	7
	00128	Oral	3	0 MG	25APR95	15	25APR95	15	1
		Oral	4	0 MG	26APR95	16	02MAY95	22	7
329.009.00129		Oral	1	0 MG	11APR95	1	17APR95	7	7
	00129	Oral	2	0 MG	18APR95	8	24APR95	14	7
	00129	Oral	3	0 MG	25APR95	15	01MAY95	21	7
	00129	Oral	4	0 MG	02MAY95	22	08MAY95	28	7
	00129	Oral	5	0 MG	09MAY95	29	16MAY95	36	8
329.009.00135		Oral	1	0 MG	02OCT95	1	08OCT95	7	7
	00135	Oral	2	0 MG	09OCT95	8	15OCT95	14	7
	00135	Oral	3	0 MG	16OCT95	15	22OCT95	21	7
	00135	Oral	4	0 MG	23OCT95	22	29OCT95	28	7
	00135	Oral	5	0 MG	30OCT95	29	05NOV95	35	7
	00135	Oral	4	0 MG	06NOV95	36	19NOV95	49	14
329.009.00136		Oral	1	0 MG	03OCT95	1	09OCT95	7	7
	00136	Oral	2	0 MG	10OCT95	8	16OCT95	14	7
	00136	Oral	3	0 MG	17OCT95	15	23OCT95	21	7
	00136	Oral	4	0 MG	24OCT95	22	02NOV95	31	10
	00136	Oral	5	0 MG	03NOV95	32	06NOV95	35	4
	00136	Oral	5	0 MG	07NOV95	36	13NOV95	42	7
	00136	Oral	5	0 MG	14NOV95	43	20NOV95	49	7
	00136	Oral	5	0 MG	21NOV95	50	27NOV95	56	7
	00136	Oral	4	0 MG	28NOV95	57	11DEC95	70	14
329.009.00169		Oral	1	0 MG	31OCT95	1	06NOV95	7	7
	00169	Oral	2	0 MG	07NOV95	8	13NOV95	14	7
	00169	Oral	3	0 MG	14NOV95	15	20NOV95	21	7
	00169	Oral	4	0 MG	21NOV95	22	27NOV95	28	7
	00169	Oral	4	0 MG	28NOV95	29	04DEC95	35	7
	00169	Oral	4	0 MG	05DEC95	36	11DEC95	42	7
	00169	Oral	4	0 MG	12DEC95	43	18DEC95	49	7
	00169	Oral	4	0 MG	19DEC95	50	27DEC95	58	9
	00098	Oral	4	0 MG	04JAN96	66	22JAN96	84	19
	00169	Oral	4	0 MG	23JAN96	85	23JAN96	85	1
	00169	Oral	3	0 MG	24JAN96	86	25JAN96	87	2
	00169	Oral	2	0 MG	26JAN96	88	28JAN96	90	3
	00169	Oral	1	0 MG	29JAN96	91	04FEB96	97	7

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PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00174		Oral	1	0 MG	21NOV95	1	27NOV95	7	7
	00174	Oral	2	0 MG	28NOV95	8	04DEC95	14	7
	00174	Oral	3	0 MG	05DEC95	15	11DEC95	21	7
	00174	Oral	4	0 MG	12DEC95	22	18DEC95	28	7
	00174	Oral	5	0 MG	19DEC95	29	26DEC95	36	8
	00174	Oral	5	0 MG	27DEC95	37	01JAN96	42	6
	00174	Oral	5	0 MG	02JAN96	43	08JAN96	49	7
	00174	Oral	5	0 MG	09JAN96	50	16JAN96	57	8
	00107	Oral	5	0 MG	17JAN96	58	30JAN96	71	14
	00174	Oral	4	0 MG	31JAN96	72	01FEB96	73	2
	00174	Oral	3	0 MG	02FEB96	74	03FEB96	75	2
	00174	Oral	2	0 MG	04FEB96	76	06FEB96	78	3
	00174	Oral	1	0 MG	07FEB96	79	13FEB96	85	7
329.009.00197		Oral	1	0 MG	29DEC95	1	01JAN96	4	4
	00197	Oral	2	0 MG	02JAN96	5	07JAN96	10	6
	00197	Oral	3	0 MG	08JAN96	11	15JAN96	18	8
	00197	Oral	4	0 MG	16JAN96	19	22JAN96	25	7
	00197	Oral	4	0 MG	23JAN96	26	29JAN96	32	7
	00197	Oral	4	0 MG	30JAN96	33	05FEB96	39	7
	00197	Oral	4	0 MG	06FEB96	40	12FEB96	46	7
	00197	Oral	4	0 MG	13FEB96	47	20FEB96	54	8
	00139	Oral	4	0 MG	21FEB96	55	18MAR96	81	27
	00139	Oral	4	0 MG	19MAR96	82	22APR96	116	35
	00139	Oral	4	0 MG	23APR96	117	20MAY96	144	28
	00139	Oral	4	0 MG	21MAY96	145	24JUN96	179	35
	00139	Oral	4	0 MG	25JUN96	180	15JUL96	200	21
	00139	Oral	4	0 MG	16JUL96	201	19AUG96	235	35
	00197	Oral	4	0 MG	20AUG96	236	20AUG96	236	1
	00197	Oral	3	0 MG	21AUG96	237	22AUG96	238	2
	00197	Oral	2	0 MG	23AUG96	239	25AUG96	241	3
	00197	Oral	1	0 MG	26AUG96	242	01SEP96	248	7
329.009.00198		Oral	1	0 MG	02JAN96	1	07JAN96	6	6
	00198	Oral	2	0 MG	08JAN96	7	15JAN96	14	8
	00198	Oral	3	0 MG	16JAN96	15	22JAN96	21	7
	00198	Oral	4	0 MG	23JAN96	22	29JAN96	28	7
	00198	Oral	4	0 MG	30JAN96	29	05FEB96	35	7
	00198	Oral	4	0 MG	06FEB96	36	12FEB96	42	7
	00198	Oral	4	0 MG	13FEB96	43	19FEB96	49	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix B.16

Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00198	00198	Oral	4	0 MG	20FEB96	50	26FEB96	56	7
		Oral	3	0 MG	27FEB96	57	09MAR96	68	12
329.009.00200		Oral	1	0 MG	23JAN96	1	01FEB96	10	10
	00200	Oral	2	0 MG	02FEB96	11	05FEB96	14	4
	00200	Oral	3	0 MG	06FEB96	15	12FEB96	21	7
	00200	Oral	4	0 MG	13FEB96	22	19FEB96	28	7
	00200	Oral	4	0 MG	20FEB96	29	27FEB96	36	8
	00200	Oral	4	0 MG	28FEB96	37	07MAR96	45	9
		Oral	3	0 MG	08MAR96	46	19MAR96	57	12
329.009.00202		Oral	1	0 MG	20FEB96	1	26FEB96	7	7
	00202	Oral	2	0 MG	27FEB96	8	07MAR96	17	10
	00202	Oral	3	0 MG	08MAR96	18	18MAR96	28	11
	00202	Oral	4	0 MG	19MAR96	29	26MAR96	36	8
329.009.00237		Oral	1	0 MG	11NOV96	1	19NOV96	9	9
329.009.00238		Oral	1	0 MG	12NOV96	1	18NOV96	7	7
	00238	Oral	2	0 MG	19NOV96	8	25NOV96	14	7
	00238	Oral	3	0 MG	26NOV96	15	02DEC96	21	7
	00238	Oral	4	0 MG	03DEC96	22	09DEC96	28	7
	00238	Oral	4	0 MG	10DEC96	29	16DEC96	35	7
	00238	Oral	4	0 MG	17DEC96	36	22DEC96	41	6
	00238	Oral	4	0 MG	23DEC96	42	30DEC96	49	8
	00238	Oral	4	0 MG	31DEC96	50	06JAN97	56	7
		Oral	4	0 MG	07JAN97	57	19JAN97	69	13
329.009.00276		Oral	1	0 MG	21JAN97	1	27JAN97	7	7
	00276	Oral	2	0 MG	28JAN97	8	03FEB97	14	7
	00276	Oral	3	0 MG	04FEB97	15	10FEB97	21	7
	00276	Oral	4	0 MG	11FEB97	22	17FEB97	28	7
	00276	Oral	5	0 MG	18FEB97	29	24FEB97	35	7
	00276	Oral	5	0 MG	25FEB97	36	03MAR97	42	7
	00276	Oral	6	0 MG	04MAR97	43	12MAR97	51	9
	00276	Oral	6	0 MG	13MAR97	52	17MAR97	56	5
		Oral	5	0 MG	18MAR97	57	01APR97	71	15
329.009.00302		Oral	1	0 MG	27MAR96	1	02APR96	7	7
	00302	Oral	2	0 MG	03APR96	8	10APR96	15	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.009.00306		Oral	1	0 MG	11JUN96	1	17JUN96	7	7
	00306	Oral	2	0 MG	18JUN96	8	24JUN96	14	7
	00306	Oral	3	0 MG	25JUN96	15	01JUL96	21	7
	00306	Oral	4	0 MG	02JUL96	22	08JUL96	28	7
	00306	Oral	4	0 MG	09JUL96	29	15JUL96	35	7
	00306	Oral	4	0 MG	16JUL96	36	22JUL96	42	7
	00306	Oral	4	0 MG	23JUL96	43	29JUL96	49	7
	00306	Oral	5	0 MG	30JUL96	50	05AUG96	56	7
		Oral	5	0 MG	06AUG96	57	19AUG96	70	14
329.009.00312		Oral	1	0 MG	04NOV96	1	14NOV96	11	11
	00312	Oral	2	0 MG	15NOV96	12	17NOV96	14	3
	00312	Oral	3	0 MG	18NOV96	15	01DEC96	28	14
	00312	Oral	4	0 MG	02DEC96	29	08DEC96	35	7
	00312	Oral	4	0 MG	09DEC96	36	15DEC96	42	7
	00312	Oral	4	0 MG	16DEC96	43	26DEC96	53	11
	00312	Oral	4	0 MG	27DEC96	54	29DEC96	56	3
	00312	Oral	5	0 MG	30DEC96	57	06JAN97	64	8
		Oral	5	0 MG	06JAN97	64	20JAN97	78	15
329.009.00327		Oral	1	0 MG	16SEP96	1	22SEP96	7	7
	00327	Oral	2	0 MG	23SEP96	8	29SEP96	14	7
	00327	Oral	3	0 MG	30SEP96	15	06OCT96	21	7
	00327	Oral	4	0 MG	07OCT96	22	13OCT96	28	7
	00327	Oral	5	0 MG	14OCT96	29	20OCT96	35	7
		Oral	5	0 MG	21OCT96	36	04NOV96	50	15
329.009.00330		Oral	1	0 MG	21OCT96	1	27OCT96	7	7
	00330	Oral	2	0 MG	28OCT96	8	04NOV96	15	8
329.010.00183		Oral	1	0 MG	03DEC95	1	11DEC95	9	9
	00183	Oral	2	0 MG	12DEC95	10	19DEC95	17	8
	00183	Oral	3	0 MG	20DEC95	18	.	.	.
329.010.00263		Oral	1	0 MG	09AUG96	1	13AUG96	5	5
	00263	Oral	2	0 MG	14AUG96	6	20AUG96	12	7
	00263	Oral	3	0 MG	21AUG96	13	27AUG96	19	7
	00263	Oral	4	0 MG	28AUG96	20	03SEP96	26	7
	00263	Oral	5	0 MG	04SEP96	27	10SEP96	33	7
	00263	Oral	6	0 MG	11SEP96	34	17SEP96	40	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.010.00263	00263	Oral	6	0 MG	18SEP96	41	24SEP96	47	7
	00263	Oral	6	0 MG	25SEP96	48	03OCT96	56	9
		Oral	5	0 MG	04OCT96	57	19OCT96	72	16
329.010.00277		Oral	1	0 MG	01MAR96	1	07MAR96	7	7
	00277	Oral	2	0 MG	08MAR96	8	14MAR96	14	7
	00277	Oral	3	0 MG	15MAR96	15	21MAR96	21	7
	00277	Oral	4	0 MG	22MAR96	22	28MAR96	28	7
	00277	Oral	5	0 MG	29MAR96	29	04APR96	35	7
	00277	Oral	5	0 MG	05APR96	36	14APR96	45	10
	00277	Oral	6	0 MG	15APR96	46	18APR96	49	4
	00277	Oral	6	0 MG	19APR96	50	25APR96	56	7
	00156	Oral	6	0 MG	26APR96	57	24MAY96	85	29
	00156	Oral	6	0 MG	25MAY96	86	21JUN96	113	28
329.010.00282		Oral	1	0 MG	26JUL96	1	01AUG96	7	7
	00282	Oral	2	0 MG	02AUG96	8	08AUG96	14	7
	00282	Oral	3	0 MG	09AUG96	15	15AUG96	21	7
	00282	Oral	4	0 MG	16AUG96	22	25AUG96	31	10
	00282	Oral	5	0 MG	26AUG96	32	02SEP96	39	8
	00282	Oral	6	0 MG	03SEP96	40	12SEP96	49	10
	00282	Oral	6	0 MG	13SEP96	50	18SEP96	55	6
	00282	Oral	6	0 MG	19SEP96	56	26SEP96	63	8
		Oral	5	0 MG	27SEP96	64	12OCT96	79	16
329.011.00164		Oral	1	0 MG	22DEC95	1	28DEC95	7	7
	00164	Oral	2	0 MG	29DEC95	8	04JAN96	14	7
	00164	Oral	3	0 MG	05JAN96	15	11JAN96	21	7
	00164	Oral	4	0 MG	12JAN96	22	18JAN96	28	7
	00164	Oral	5	0 MG	19JAN96	29	25JAN96	35	7
	00164	Oral	6	0 MG	26JAN96	36	.	.	.
329.011.00210		Oral	1	0 MG	28SEP96	1	03OCT96	6	6
	00210	Oral	2	0 MG	04OCT96	7	09OCT96	12	6
	00210	Oral	3	0 MG	10OCT96	13	17OCT96	20	8
	00210	Oral	4	0 MG	18OCT96	21	24OCT96	27	7
	00210	Oral	4	0 MG	25OCT96	28	03NOV96	37	10
	00210	Oral	5	0 MG	04NOV96	38	12NOV96	46	9
	00210	Oral	5	0 MG	13NOV96	47	22NOV96	56	10
	00210	Oral	5	0 MG	23NOV96	57	02DEC96	66	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.011.00210	00177	Oral	5	0 MG	03DEC96	67	.	.	.
329.011.00285		Oral	1	0 MG	18MAY96	1	27MAY96	10	10
	00285	Oral	2	0 MG	28MAY96	11	03JUN96	17	7
	00285	Oral	3	0 MG	04JUN96	18	10JUN96	24	7
	00285	Oral	4	0 MG	11JUN96	25	20JUN96	34	10
	00285	Oral	5	0 MG	21JUN96	35	28JUN96	42	8
	00285	Oral	6	0 MG	29JUN96	43	08JUL96	52	10
	00285	Oral	6	0 MG	09JUL96	53	18JUL96	62	10
	00285	Oral	6	0 MG	19JUL96	63	24JUL96	68	6
		Oral	5	0 MG	25JUL96	69	31JUL96	75	7
329.011.00287		Oral	1	0 MG	03JUL96	1	09JUL96	7	7
	00287	Oral	2	0 MG	10JUL96	8	17JUL96	15	8
	00287	Oral	3	0 MG	18JUL96	16	23JUL96	21	6
	00287	Oral	4	0 MG	24JUL96	22	30JUL96	28	7
	00287	Oral	5	0 MG	31JUL96	29	06AUG96	35	7
	00287	Oral	6	0 MG	07AUG96	36	13AUG96	42	7
	00287	Oral	6	0 MG	14AUG96	43	20AUG96	49	7
	00287	Oral	6	0 MG	21AUG96	50	27AUG96	56	7
		Oral	5	0 MG	28AUG96	57	10SEP96	70	14
329.012.00027		Oral	1	0 MG	06DEC95	1	11DEC95	6	6
	00027	Oral	2	0 MG	12DEC95	7	18DEC95	13	7
	00027	Oral	3	0 MG	19DEC95	14	26DEC95	21	8
	00027	Oral	4	0 MG	27DEC95	22	02JAN96	28	7
		Oral	3	0 MG	03JAN96	29	11JAN96	37	9
329.012.00217		Oral	1	0 MG	21MAY96	1	30MAY96	10	10
	00217	Oral	2	0 MG	31MAY96	11	06JUN96	17	7
	00217	Oral	3	0 MG	07JUN96	18	13JUN96	24	7
	00217	Oral	4	0 MG	14JUN96	25	14JUN96	25	1
329.012.00218		Oral	1	0 MG	16JUN96	1	20JUN96	5	5
	00218	Oral	2	0 MG	21JUN96	6	27JUN96	12	7
	00218	Oral	3	0 MG	28JUN96	13	04JUL96	19	7
	00218	Oral	4	0 MG	05JUL96	20	11JUL96	26	7
	00218	Oral	4	0 MG	12JUL96	27	18JUL96	33	7
	00218	Oral	4	0 MG	19JUL96	34	28JUL96	43	10
	00218	Oral	4	0 MG	29JUL96	44	05AUG96	51	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix B.16

Listing of Study Medication Data
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO

PATIENT NUMBER	BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
329.012.00218	00218	Oral	4	0 MG	06AUG96	52	12AUG96	58	7
	00117	Oral	4	0 MG	13AUG96	59	17SEP96	94	36
	00218	Oral	4	0 MG	18SEP96	95	19SEP96	96	2
	00218	Oral	3	0 MG	20SEP96	97	21SEP96	98	2
	00218	Oral	2	0 MG	22SEP96	99	24SEP96	101	3
	00218	Oral	1	0 MG	25SEP96	102	01OCT96	108	7
329.012.00224		Oral	1	0 MG	16SEP96	1	23SEP96	8	8
	00224	Oral	2	0 MG	24SEP96	9	02OCT96	17	9
	00224	Oral	3	0 MG	03OCT96	18	09OCT96	24	7
	00224	Oral	4	0 MG	10OCT96	25	16OCT96	31	7
	00224	Oral	4	0 MG	17OCT96	32	24OCT96	39	8
	00224	Oral	4	0 MG	25OCT96	40	03NOV96	49	10
	00224	Oral	4	0 MG	04NOV96	50	11NOV96	57	8
	00224	Oral	4	0 MG	12NOV96	58	20NOV96	66	9
	00126	Oral	4	0 MG	21NOV96	67	18DEC96	94	28
	00126	Oral	4	0 MG	19DEC96	95	19JAN97	126	32
	00126	Oral	4	0 MG	20JAN97	127	17FEB97	155	29
	00224	Oral	3	0 MG	18FEB97	156	19FEB97	157	2
	00224	Oral	2	0 MG	20FEB97	158	22FEB97	160	3
	00224	Oral	1	0 MG	23FEB97	161	01MAR97	167	7
329.012.00225		Oral	1	0 MG	26NOV96	1	02DEC96	7	7
	00225	Oral	2	0 MG	03DEC96	8	09DEC96	14	7
	00225	Oral	3	0 MG	10DEC96	15	19DEC96	24	10
	00225	Oral	4	0 MG	20DEC96	25	26DEC96	31	7
	00225	Oral	4	0 MG	27DEC96	32	05JAN97	41	10
	00225	Oral	4	0 MG	06JAN97	42	12JAN97	48	7
	00225	Oral	4	0 MG	13JAN97	49	20JAN97	56	8
	00225	Oral	4	0 MG	21JAN97	57	28JAN97	64	8
	00129	Oral	4	0 MG	29JAN97	65	23FEB97	90	26
	00129	Oral	4	0 MG	24FEB97	91	19MAR97	114	24
	00129	Oral	4	0 MG	20MAR97	115	20APR97	146	32
	00129	Oral	4	0 MG	21APR97	147	25MAY97	181	35
	00129	Oral	4	0 MG	26MAY97	182	29JUN97	216	35
	00129	Oral	4	0 MG	30JUN97	217	29JUL97	246	30
	00225	Oral	3	0 MG	30JUL97	247	31JUL97	248	2
	00225	Oral	2	0 MG	01AUG97	249	03AUG97	251	3
	00225	Oral	1	0 MG	04AUG97	252	10AUG97	258	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix C: Patient Data Listings of Efficacy

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.001.00063	SC	02NOV94	-6,	.	3	2	0	0	2	2	4	3	2	0	4	2	2	0	2	0	0	28	.		
	BL	08NOV94	1,	.	3	2	2	1	0	0	4	2	2	0	4	1	1	0	1	0	0	23	.		
	1	15NOV94	8,	.	0	0	0	1	1	0	3	1	0	0	3	2	1	0	0	0	0	12	-47.8	NO	NO
	2	22NOV94	15,	.	0	0	0	0	0	0	4	0	0	0	4	1	2	0	0	0	0	11	-52.2	YES	NO
	3	29NOV94	22,	.	0	0	0	0	0	0	1	0	1	0	1	0	1	1	0	0	0	5	-78.3	YES	YES
	4	06DEC94	29,	.	0	0	0	0	2	0	0	0	1	0	3	0	0	1	0	0	0	7	-69.6	YES	YES
	5	13DEC94	36,	.	3	0	0	0	0	0	2	0	1	3	4	0	2	0	0	0	0	15	-34.8	NO	NO
329.001.00065	SC	07NOV94	-10,	.	3	3	2	2	1	2	4	2	3	2	3	1	2	0	0	0	0	30	.		
	BL	17NOV94	1,	.	4	1	0	2	1	1	3	2	4	2	3	1	2	0	0	0	0	26	.		
	1	21NOV94	5,	.	3	1	0	2	2	0	4	2	2	2	4	1	2	0	0	0	0	25	-3.8	NO	NO
329.001.00068	SC	01FEB95	-7,	.	4	1	2	2	1	0	4	3	2	0	3	1	2	0	1	0	0	26	.		
	BL	08FEB95	1,	.	4	1	0	2	0	1	4	3	2	1	3	1	2	0	0	0	0	24	.		
	1	15FEB95	8,	.	2	0	2	2	2	0	4	2	2	0	2	0	2	0	0	0	0	20	-16.7	NO	NO
	2	22FEB95	15,	.	4	0	2	2	1	1	4	3	2	1	1	0	2	0	0	0	0	23	-4.2	NO	NO
	3	01MAR95	22,	.	3	0	0	2	2	0	3	3	2	0	3	0	2	0	0	0	0	20	-16.7	NO	NO
	4	08MAR95	29,	.	1	0	0	2	1	0	3	2	2	0	1	0	1	0	0	0	0	13	-45.8	NO	NO
	5	15MAR95	36,	.	1	0	0	2	1	0	3	1	2	1	2	0	1	0	0	0	0	14	-41.7	NO	NO
	6	22MAR95	43,	.	2	0	0	2	2	0	3	2	2	2	1	0	2	0	0	0	1	19	-20.8	NO	NO
	7	29MAR95	50,	.	1	0	0	1	2	0	3	1	2	0	2	0	1	0	0	0	0	13	-45.8	NO	NO
	8	05APR95	57,	.	2	0	0	2	2	0	4	2	2	2	3	0	1	0	0	0	0	20	-16.7	NO	NO
329.001.00072	SC	07MAR95	-13,	.	3	0	0	2	0	0	4	2	2	0	0	0	2	0	0	0	1	16	.		
	BL	20MAR95	1,	.	2	0	0	2	1	0	4	3	2	0	0	0	2	0	0	0	1	17	.		
	1	27MAR95	8,	.	0	0	0	1	0	0	3	2	1	0	1	0	1	0	0	0	0	9	-47.1	NO	NO
	2	03APR95	15,	.	0	0	0	0	0	0	2	1	2	0	0	1	0	0	0	1	0	7	-58.8	YES	YES
	3	10APR95	22,	.	0	0	0	0	0	0	3	1	1	0	0	1	0	0	0	0	0	6	-64.7	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.001.00121	SC	22MAR95	-13, -69	4	1	2	1	0	0	4	3	3	1	2	0	2	0	1	0	0	24	.		
	BL	04APR95	1, -56	3	0	0	1	0	0	4	2	3	1	3	0	2	0	0	0	0	19	.		
	1	11APR95	8, -49	2	0	0	0	0	0	3	2	3	0	3	0	1	0	0	0	0	14	-26.3	NO	NO
	2	18APR95	15, -42	1	0	0	1	0	0	4	2	1	0	1	0	2	0	0	0	2	14	-26.3	NO	NO
	3	26APR95	23, -34	2	1	1	1	0	0	3	2	2	0	3	1	2	0	0	1	1	20	5.3	NO	NO
	4	02MAY95	29, -28	2	0	0	0	0	0	3	2	2	0	0	0	2	0	0	0	2	13	-31.6	NO	NO
	5	09MAY95	36, -21	0	0	1	0	0	0	3	1	2	0	0	0	1	0	0	0	0	8	-57.9	YES	YES
	6	16MAY95	43, -14	0	0	0	0	0	0	2	1	2	0	0	0	1	0	0	0	0	6	-68.4	YES	YES
	7	23MAY95	50, -7	0	0	0	0	0	0	3	1	1	0	0	0	1	0	0	0	0	6	-68.4	YES	YES
	8	30MAY95	57, 1	0	0	0	0	0	0	2	1	1	0	0	1	1	0	0	0	0	6	-68.4	YES	YES
	12	27JUN95	85, 29	0	0	0	0	0	0	1	1	1	0	0	0	1	0	0	0	2	6	-68.4	YES	YES
	16	24JUL95	112, 56	2	0	0	0	0	0	3	1	1	0	0	0	1	0	0	0	2	10	-47.4	NO	NO
	20	21AUG95	140, 84	2	1	0	1	0	0	3	2	1	0	0	0	1	0	0	0	2	13	-31.6	NO	NO
329.001.00205	SC	29JAN96	-9, .	3	1	0	1	0	0	4	2	1	2	1	0	1	0	0	0	0	16	.		
	BL	07FEB96	1, .	3	0	0	0	0	0	4	2	2	0	0	0	2	0	0	0	2	15	.		
	1	14FEB96	8, .	0	0	0	2	2	0	4	0	3	0	0	1	0	0	0	0	0	12	-20.0	NO	NO
329.001.00206	SC	12FEB96	-9, .	4	2	2	1	1	0	4	3	0	1	3	0	1	0	0	0	0	22	.		
	BL	21FEB96	1, .	4	0	0	2	0	0	4	3	0	0	0	0	2	0	0	0	0	15	.		
	1	28FEB96	8, .	2	0	0	2	0	0	4	3	1	0	0	0	1	0	0	0	0	13	-13.3	NO	NO
	2	06MAR96	15, .	4	0	0	1	0	0	4	3	0	0	0	0	2	0	0	0	0	14	-6.7	NO	NO
	3	13MAR96	22, .	1	0	0	0	0	0	3	2	0	0	0	0	0	0	0	0	0	6	-60.0	YES	YES
	4	20MAR96	29, .	2	2	0	0	0	0	4	3	0	0	0	0	2	0	0	0	0	13	-13.3	NO	NO
	5	26MAR96	35, .	2	0	0	2	0	0	4	3	0	0	0	0	2	0	0	0	0	13	-13.3	NO	NO
	6	03APR96	43, .	1	0	0	2	0	0	4	2	0	0	0	0	1	0	0	1	0	11	-26.7	NO	NO
	7	10APR96	50, .	2	0	0	1	0	0	4	2	0	0	0	0	1	0	0	0	0	10	-33.3	NO	NO
	8	17APR96	57, .	3	0	0	2	0	0	4	3	1	0	0	0	1	0	0	0	0	14	-6.7	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00055	SC	09JUN94	-15, -70	3	2	3	2	2	0	3	2	1	1	2	1	2	0	0	1	0	25	.		
	BL	23JUN94	-1, -56	3	1	2	1	0	0	3	2	0	1	1	0	2	0	0	0	2	18	.		
	1	30JUN94	7, -49	3	2	1	2	0	0	3	2	0	2	1	0	1	0	0	0	1	18	0.0	NO	NO
	2	07JUL94	14, -42	2	1	0	2	1	0	2	1	0	1	0	0	1	0	0	0	1	12	-33.3	NO	NO
	3	14JUL94	21, -35	1	0	0	0	1	0	1	1	0	0	1	0	1	0	0	0	1	7	-61.1	YES	YES
	4	21JUL94	28, -28	1	1	0	0	0	0	2	2	0	1	0	0	1	0	0	0	1	9	-50.0	YES	NO
	5	28JUL94	35, -21	2	0	0	0	0	0	3	2	0	3	1	1	2	0	0	1	1	16	-11.1	NO	NO
	6	04AUG94	42, -14	2	0	0	0	0	0	1	1	0	1	1	0	0	0	0	0	1	7	-61.1	YES	YES
	7	11AUG94	49, -7	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1	5	-72.2	YES	YES
	8	18AUG94	56, 1	0	0	0	0	2	0	1	1	1	1	0	1	1	0	0	1	1	10	-44.4	NO	NO
	12	15SEP94	84, 29	0	0	0	1	1	0	1	1	0	1	1	0	1	0	0	0	2	9	-50.0	YES	NO
	16	13OCT94	112, 57	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	3	-83.3	YES	YES
	20	10NOV94	140, 85	3	2	2	2	1	0	3	2	0	1	3	1	2	0	0	0	0	22	22.2	NO	NO
329.002.00058	SC	08SEP94	-12, -70	1	2	3	0	1	2	0	0	4	2	2	0	2	0	2	1	1	23	.		
	BL	20SEP94	1, -58	3	2	0	2	2	0	3	2	0	2	2	0	1	0	2	0	0	21	.		
	1	29SEP94	10, -49	1	1	0	0	1	0	2	2	3	2	1	1	1	0	1	1	1	18	-14.3	NO	NO
	2	07OCT94	18, -41	2	1	0	0	0	0	3	1	1	2	1	0	1	0	1	0	0	13	-38.1	NO	NO
	3	13OCT94	24, -35	1	1	0	0	0	0	1	1	1	1	1	0	1	0	1	0	0	9	-57.1	YES	NO
	4	20OCT94	31, -28	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	4	-81.0	YES	YES
	5	27OCT94	38, -21	0	0	0	0	0	0	1	2	3	1	0	0	1	0	0	0	0	8	-61.9	YES	YES
	6	03NOV94	45, -14	0	0	0	0	0	0	1	0	2	1	1	0	0	0	0	0	0	5	-76.2	YES	YES
	7	10NOV94	52, -7	0	0	0	1	1	0	0	1	1	1	1	0	0	0	0	0	1	7	-66.7	YES	YES
	8	17NOV94	59, 1	1	0	0	0	0	0	1	0	3	1	0	0	0	0	1	0	0	7	-66.7	YES	YES
	12	15DEC94	87, 29	0	0	0	0	0	0	3	0	3	1	0	0	1	0	0	0	1	9	-57.1	YES	NO
	16	13JAN95	116, 58	1	0	0	0	0	0	0	0	3	0	0	0	0	0	1	0	0	5	-76.2	YES	YES
	20	27JAN95	130, 72	3	0	0	0	0	0	0	0	2	3	0	0	1	0	0	1	0	10	-52.4	YES	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00099	SC	23FEB95	-7, -62	2	1	1	0	1	0	2	0	1	2	2	0	1	0	1	0	0	14	.		
	BL	02MAR95	1, -55	3	2	2	1	0	0	3	1	0	1	2	0	1	0	2	0	0	18	.		
	1	07MAR95	6, -50	3	1	0	0	1	0	1	1	1	3	1	0	1	0	0	1	0	14	-22.2	NO	NO
	2	14MAR95	13, -43	1	1	0	0	0	0	1	1	1	1	1	0	1	0	1	0	0	9	-50.0	YES	NO
	3	21MAR95	20, -36	1	0	0	2	1	0	0	0	1	1	1	0	0	0	1	0	0	8	-55.6	YES	YES
	4	28MAR95	27, -29	0	0	0	1	0	0	0	0	1	1	1	0	0	0	0	0	0	4	-77.8	YES	YES
	5	04APR95	34, -22	0	0	0	1	0	0	0	0	1	1	1	0	1	0	0	0	0	5	-72.2	YES	YES
	6	11APR95	41, -15	0	0	0	0	0	0	1	0	1	1	1	0	1	0	0	0	0	5	-72.2	YES	YES
	7	18APR95	48, -8	2	0	0	0	0	0	0	0	1	1	1	0	0	0	1	0	0	6	-66.7	YES	YES
	8	25APR95	55, -1	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	3	-83.3	YES	YES
	12	23MAY95	83, 28	0	0	0	0	0	0	1	0	1	0	0	0	2	0	0	0	0	4	-77.8	YES	YES
	16	27JUN95	118, 63	0	0	0	2	0	0	0	0	1	1	0	0	0	0	0	0	0	4	-77.8	YES	YES
	20	01AUG95	153, 98	0	0	0	0	0	0	0	0	1	0	3	0	2	0	1	0	2	9	-50.0	YES	NO
	24	31AUG95	183, 128	0	0	0	1	0	0	0	0	1	0	0	0	1	0	0	0	0	3	-83.3	YES	YES
	28	28SEP95	211, 156	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
	32	26OCT95	239, 184	3	1	2	1	0	0	2	2	1	3	0	0	1	1	0	0	0	17	-5.6	NO	NO
329.002.00102	SC	03APR95	-10, -64	3	1	2	2	0	0	3	0	4	1	2	0	2	0	1	1	0	22	.		
	BL	13APR95	1, -54	3	0	1	2	0	0	3	0	3	2	2	0	1	0	1	0	0	18	.		
	1	18APR95	6, -49	1	0	0	2	0	0	1	0	3	3	1	1	1	0	1	1	0	15	-16.7	NO	NO
	2	25APR95	13, -42	2	0	0	2	0	0	3	0	4	3	1	1	1	0	0	0	0	17	-5.6	NO	NO
	3	02MAY95	20, -35	1	0	0	2	1	0	1	0	1	2	1	0	1	0	0	0	0	10	-44.4	NO	NO
	4	09MAY95	27, -28	2	0	0	2	0	0	1	0	3	2	1	1	1	0	0	0	0	13	-27.8	NO	NO
	5	16MAY95	34, -21	0	0	0	0	0	0	1	0	3	0	1	0	1	0	0	0	0	6	-66.7	YES	YES
	6	23MAY95	41, -14	0	0	0	0	0	0	0	0	3	0	1	1	0	0	0	0	0	5	-72.2	YES	YES
	7	30MAY95	48, -7	0	0	0	0	0	0	0	0	3	0	0	1	0	0	0	0	0	4	-77.8	YES	YES
	8	06JUN95	55, 1	0	0	0	0	0	0	0	0	2	0	1	0	0	0	0	0	0	3	-83.3	YES	YES
	12	13JUL95	92, 38	0	0	0	0	0	0	0	0	3	0	1	0	0	0	0	0	0	4	-77.8	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00102	16	10AUG95	120, 66	0	0	0	0	0	1	0	0	2	0	1	1	2	0	0	1	0	8	-55.6	YES	YES
	20	12SEP95	153, 99	0	0	0	0	0	0	0	0	3	0	1	0	0	0	0	0	0	4	-77.8	YES	YES
	24	10OCT95	181, 127	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	3	-83.3	YES	YES
	28	09NOV95	211, 157	0	0	0	0	0	0	1	0	3	0	1	0	1	0	0	0	0	6	-66.7	YES	YES
	32	05DEC95	237, 183	0	0	0	0	0	0	0	0	3	0	1	0	0	0	0	0	0	4	-77.8	YES	YES
329.002.00105	SC	20JUL95	-7, .	2	0	2	2	2	0	2	2	0	3	0	0	2	0	0	0	0	17	.		
	BL	27JUL95	1, .	3	2	3	0	0	0	1	2	1	1	2	0	2	0	1	0	0	18	.		
	1	03AUG95	8, .	2	0	1	2	0	2	3	2	1	1	2	0	0	0	1	0	0	17	-5.6	NO	NO
	2	10AUG95	15, .	0	0	0	1	0	0	2	1	0	1	1	0	1	0	1	0	0	8	-55.6	YES	YES
	3	17AUG95	22, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.002.00106	SC	20JUL95	-7, .	3	1	1	1	1	0	3	1	0	3	1	1	1	1	0	2	0	20	.		
	BL	27JUL95	1, .	3	1	1	0	1	0	2	1	0	1	2	0	1	0	0	0	0	13	.		
	1	03AUG95	8, .	1	1	1	2	0	0	2	1	0	2	1	0	1	0	0	0	0	12	-7.7	NO	NO
	2	08AUG95	13, .	0	0	2	1	0	1	2	1	0	3	2	0	1	0	0	0	0	13	0.0	NO	NO
	3	17AUG95	22, .	0	0	0	2	0	0	3	2	0	4	0	0	1	0	0	0	0	12	-7.7	NO	NO
	4	24AUG95	29, .	0	1	0	2	0	1	1	1	0	1	0	0	1	0	0	0	0	8	-38.5	YES	YES
	5	31AUG95	36, .	2	1	0	2	0	0	2	1	0	3	1	0	0	0	0	0	0	12	-7.7	NO	NO
	6	05SEP95	41, .	1	1	2	0	1	0	0	1	0	3	0	0	0	0	0	0	0	9	-30.8	NO	NO
	7	12SEP95	48, .	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	3	-76.9	YES	YES
329.002.00242	SC	26JAN96	-12, -70	4	2	0	0	2	2	0	2	0	3	1	1	2	0	3	2	0	24	.		
	1	14FEB96	8, -51	1	0	0	0	2	1	3	2	0	1	1	2	1	0	0	0	0	14	-41.7	NO	NO
	2	21FEB96	15, -44	0	0	0	0	1	0	1	0	0	2	0	2	1	0	2	0	0	9	-62.5	YES	NO
	3	29FEB96	23, -36	1	0	0	0	0	0	2	1	0	0	0	1	1	0	0	0	0	6	-75.0	YES	YES
	4	06MAR96	29, -30	0	0	0	0	0	0	0	1	0	1	0	1	1	0	0	0	0	4	-83.3	YES	YES
	5	14MAR96	37, -22	0	0	0	0	0	0	2	1	0	1	0	1	1	0	0	0	0	6	-75.0	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00242	6	20MAR96	43, -16	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0	0	0	3	-87.5	YES	YES
	7	28MAR96	51, -8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	05APR96	59, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	08MAY96	92, 34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	05JUN96	120, 62	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	3	-87.5	YES	YES
	20	10JUL96	155, 97	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	-95.8	YES	YES
329.002.00245	SC	21MAR96	-7, .	3	1	2	0	2	2	3	0	1	3	1	0	1	0	0	0	2	21	.		
	BL	28MAR96	1, .	3	1	2	0	2	2	1	0	3	1	1	0	2	0	0	0	0	18	.		
	1	04APR96	8, .	1	2	0	2	1	2	2	0	2	3	1	0	1	0	0	0	1	18	0.0	NO	NO
329.002.00319	SC	23APR96	-7, -63	4	1	1	2	2	1	2	2	0	4	0	1	2	0	0	0	0	22	.		
	BL	30APR96	1, -56	4	0	1	1	1	0	2	2	0	3	2	0	2	0	0	0	0	18	.		
	1	07MAY96	8, -49	0	1	0	2	1	1	1	2	0	3	1	1	2	0	0	0	0	15	-16.7	NO	NO
	2	14MAY96	15, -42	1	0	0	0	1	0	1	1	0	0	1	1	0	0	0	0	0	6	-66.7	YES	YES
	3	21MAY96	22, -35	3	0	0	1	0	0	1	2	0	3	0	0	0	0	0	0	0	10	-44.4	NO	NO
	4	28MAY96	29, -28	3	1	1	2	1	0	2	2	0	4	0	0	2	0	0	0	0	18	0.0	NO	NO
	5	04JUN96	36, -21	1	0	0	0	1	0	1	1	0	1	0	0	2	0	0	0	0	7	-61.1	YES	YES
	6	11JUN96	43, -14	1	0	0	0	1	1	0	1	0	0	0	1	0	0	0	0	0	5	-72.2	YES	YES
	7	18JUN96	50, -7	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	2	-88.9	YES	YES
	8	25JUN96	57, 1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	12	23JUL96	85, 29	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	-88.9	YES	YES
	16	15AUG96	108, 52	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	20	24SEP96	148, 92	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	24	22OCT96	176, 120	3	1	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0	8	-55.6	YES	YES
	28	19NOV96	204, 148	1	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	3	-83.3	YES	YES
	32	17DEC96	232, 176	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	2	-88.9	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00075	SC	18JAN95	-7, -63	2	2	0	0	0	0	3	0	0	3	2	1	2	0	0	0	0	15	.		
	BL	25JAN95	1, -56	2	1	0	0	0	0	3	0	0	3	2	1	2	0	0	0	0	14	.		
	1	01FEB95	8, -49	1	1	1	0	0	0	1	0	1	2	2	1	1	0	0	0	0	11	-21.4	NO	NO
	2	08FEB95	15, -42	1	1	1	0	0	0	1	0	0	1	0	1	1	0	0	0	0	7	-50.0	YES	YES
	3	15FEB95	22, -35	3	0	1	0	0	0	1	0	1	1	1	1	2	0	0	0	0	11	-21.4	NO	NO
	4	21FEB95	28, -29	1	0	1	0	0	0	1	0	0	1	1	1	1	0	0	0	0	7	-50.0	YES	YES
	5	01MAR95	36, -21	1	0	2	0	0	0	0	0	1	0	0	0	0	0	0	0	0	4	-71.4	YES	YES
	6	08MAR95	43, -14	1	0	1	0	0	0	1	0	0	1	0	0	1	0	0	0	0	5	-64.3	YES	YES
	7	15MAR95	50, -7	3	1	2	0	1	0	3	1	0	2	2	1	1	0	0	0	0	17	21.4	NO	NO
	8	22MAR95	57, 1	2	0	2	0	0	0	2	0	0	2	0	0	0	0	0	0	0	8	-42.9	YES	YES
	12	19APR95	85, 29	1	0	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	4	-71.4	YES	YES
	16	17MAY95	113, 57	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	-92.9	YES	YES
	20	14JUN95	141, 85	1	1	2	0	0	0	1	0	1	1	2	0	1	0	0	0	0	10	-28.6	NO	NO
	24	12JUL95	169, 113	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
	28	09AUG95	197, 141	1	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	3	-78.6	YES	YES
	32	13SEP95	232, 176	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-92.9	YES	YES
329.003.00077	SC	01MAR95	-5, -64	3	1	1	1	0	0	4	2	1	0	1	0	0	0	2	0	0	16	.		
	BL	06MAR95	1, -59	3	1	1	1	0	0	4	2	1	0	0	1	2	0	1	0	0	17	.		
	1	13MAR95	8, -52	1	0	0	2	0	0	1	1	2	2	0	1	1	0	0	0	0	11	-35.3	NO	NO
	2	20MAR95	15, -45	1	0	0	0	0	0	4	1	1	0	0	0	2	0	0	0	0	9	-47.1	NO	NO
	3	27MAR95	22, -38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	4	05APR95	31, -29	1	1	0	0	0	0	2	0	1	1	0	0	1	0	0	0	0	7	-58.8	YES	YES
	5	12APR95	38, -22	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	-94.1	YES	YES
	6	19APR95	45, -15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	7	26APR95	52, -8	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-94.1	YES	YES
	8	03MAY95	59, -1	1	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	3	-82.4	YES	YES
	12	07JUN95	94, 35	0	1	0	2	0	0	0	0	1	0	0	0	0	0	0	0	0	4	-76.5	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00081	BL	11DEC95	1, .	3	0	1	2	2	0	3	3	0	3	2	1	1	2	0	1	0	24	.		
	1	18DEC95	8, .	1	0	1	0	0	0	3	1	1	1	1	0	2	2	0	0	0	13	-45.8	NO	NO
	2	28DEC95	18, .	1	0	0	0	0	0	3	2	0	0	0	0	1	0	0	0	0	7	-70.8	YES	YES
	3	03JAN96	24, .	2	0	0	0	0	0	2	0	0	0	1	0	2	0	0	0	0	7	-70.8	YES	YES
	4	10JAN96	31, .	2	0	0	2	0	2	3	1	0	0	0	0	0	0	0	0	1	11	-54.2	YES	NO
	5	17JAN96	38, .	2	0	0	1	0	2	2	0	0	0	0	0	0	0	0	0	0	7	-70.8	YES	YES
	6	24JAN96	45, .	1	0	1	0	0	0	2	0	2	3	0	0	1	1	0	0	0	11	-54.2	YES	NO
	7	31JAN96	52, .	1	0	0	0	0	0	3	1	3	3	0	0	1	0	0	0	0	12	-50.0	YES	NO
	8	07FEB96	59, .	1	0	0	2	0	0	3	1	1	2	0	0	1	0	0	0	0	11	-54.2	YES	NO
329.003.00087	SC	23JAN95	-8, .	2	0	0	1	0	0	3	1	2	4	2	0	2	0	3	0	0	20	.		
	BL	30JAN95	-1, .	3	2	3	2	0	0	4	0	2	3	3	0	2	1	2	0	0	27	.		
329.003.00089	SC	24FEB95	-11, .	2	1	2	0	1	0	3	1	2	2	2	0	1	0	0	0	0	17	.		
	BL	07MAR95	1, .	2	2	2	2	2	1	2	0	2	2	1	0	0	0	0	0	0	18	.		
	1	14MAR95	8, .	2	1	0	2	2	2	3	0	2	0	0	0	2	0	0	0	0	16	-11.1	NO	NO
	2	21MAR95	15, .	2	0	1	0	0	2	2	0	2	0	0	0	2	0	0	0	0	11	-38.9	NO	NO
	3	28MAR95	22, .	1	0	0	0	0	1	1	0	2	1	1	0	1	0	0	0	0	8	-55.6	YES	YES
	4	04APR95	29, .	1	0	0	2	0	0	1	0	1	0	0	1	1	0	0	0	0	7	-61.1	YES	YES
	5	11APR95	36, .	0	1	0	0	0	0	1	0	2	1	0	0	0	0	0	0	0	5	-72.2	YES	YES
	6	18APR95	43, .	0	0	0	1	0	0	0	0	1	0	0	0	1	0	0	0	0	3	-83.3	YES	YES
	7	25APR95	50, .	1	0	0	2	0	0	1	0	2	0	0	0	0	0	0	0	0	6	-66.7	YES	YES
	8	02MAY95	57, .	0	0	0	2	2	2	0	0	2	0	0	0	0	0	0	0	0	8	-55.6	YES	YES
329.003.00091	SC	14MAR95	-10, -64	2	0	2	0	0	0	2	1	2	2	2	0	2	0	0	0	0	15	.		
	BL	24MAR95	1, -54	2	1	1	2	0	0	1	1	2	1	0	0	0	0	0	1	0	12	.		
	1	28MAR95	5, -50	2	0	0	0	0	0	1	0	2	1	0	0	0	0	0	0	0	6	-50.0	YES	YES
	2	04APR95	12, -43	1	0	0	0	0	0	2	0	2	0	0	0	1	0	0	0	0	6	-50.0	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00091	3	11APR95	19, -36	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-83.3	YES	YES
	4	18APR95	26, -29	1	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	5	-58.3	YES	YES
	5	25APR95	33, -22	2	0	2	1	0	0	3	0	2	0	0	0	0	0	0	0	0	10	-16.7	NO	NO
	6	02MAY95	40, -15	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	3	-75.0	YES	YES
	7	09MAY95	47, -8	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-83.3	YES	YES
	8	16MAY95	54, -1	1	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	3	-75.0	YES	YES
	12	16JUN95	85, 31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	14JUL95	113, 59	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	20	10AUG95	140, 86	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-91.7	YES	YES
	24	05SEP95	166, 112	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	-91.7	YES	YES
	28	03OCT95	194, 140	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-91.7	YES	YES
	32	07NOV95	229, 175	0	0	0	0	0	0	0	0	0	1	0	0	2	0	0	0	0	3	-75.0	YES	YES
329.003.00248	SC	14FEB96	-16, .	4	0	3	0	0	0	3	2	0	2	0	0	2	0	0	0	0	16	.		
	BL	22FEB96	-8, .	3	0	1	2	0	0	3	2	2	2	0	0	2	0	0	0	0	17	.		
	1	05MAR96	5, .	3	0	0	1	0	0	3	3	2	3	0	0	2	0	0	1	0	18	5.9	NO	NO
	2	12MAR96	12, .	1	0	1	0	0	0	3	2	2	3	0	1	2	0	0	1	0	16	-5.9	NO	NO
	3	19MAR96	19, .	2	0	0	0	0	1	3	2	0	0	0	0	2	0	0	0	0	10	-41.2	NO	NO
	4	26MAR96	26, .	3	0	0	0	0	0	3	2	1	3	0	0	2	0	0	0	0	14	-17.6	NO	NO
	5	02APR96	33, .	1	0	0	0	0	0	3	1	1	0	0	0	2	0	0	0	0	8	-52.9	YES	YES
	6	11APR96	42, .	3	0	0	0	0	0	3	2	2	0	0	0	2	0	0	0	0	12	-29.4	NO	NO
	7	16APR96	47, .	3	0	0	0	0	0	3	2	1	1	0	1	2	0	0	0	0	13	-23.5	NO	NO
	8	23APR96	54, .	3	0	0	0	0	0	3	1	2	1	0	1	2	0	0	0	0	13	-23.5	NO	NO
329.003.00250	BL	14MAR96	1, -57	2	0	3	2	0	0	3	2	0	3	0	1	2	0	0	0	0	18	.		
	1	19MAR96	6, -52	2	0	1	0	0	0	3	1	1	3	0	1	2	1	0	0	0	15	-16.7	NO	NO
	2	26MAR96	13, -45	1	0	0	0	0	0	3	0	0	0	0	0	2	1	0	0	0	7	-61.1	YES	YES
	3	02APR96	20, -38	2	1	1	0	0	0	3	0	1	2	0	0	2	1	0	0	0	13	-27.8	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00250	4	12APR96	30, -28	1	0	0	0	0	0	3	0	0	0	0	1	2	1	0	0	0	8	-55.6	YES	YES
	5	16APR96	34, -24	3	1	3	0	0	0	3	1	3	3	0	1	2	1	0	0	0	21	16.7	NO	NO
	6	23APR96	41, -17	2	1	3	0	0	0	3	1	2	3	0	1	2	1	0	1	0	20	11.1	NO	NO
	7	30APR96	48, -10	0	0	1	0	0	0	3	0	0	1	0	0	2	0	0	0	0	7	-61.1	YES	YES
	8	09MAY96	57, -1	1	0	1	0	0	0	1	0	0	0	0	1	2	0	0	0	0	6	-66.7	YES	YES
	12	28MAY96	76, 19	3	3	4	0	0	0	3	0	1	0	0	0	2	1	0	0	0	17	-5.6	NO	NO
329.003.00292	BL	07AUG96	1, -58	4	2	0	2	0	0	3	2	0	0	0	0	2	0	2	0	1	18	.		
	1	16AUG96	10, -49	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	4	-77.8	YES	YES
	2	21AUG96	15, -44	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	2	-88.9	YES	YES
	3	30AUG96	24, -35	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	3	-83.3	YES	YES
	4	04SEP96	29, -30	1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	-83.3	YES	YES
	6	18SEP96	43, -16	3	1	0	1	0	0	3	2	1	3	2	0	1	1	0	0	1	19	5.6	NO	NO
	7	25SEP96	50, -9	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	4	-77.8	YES	YES
	8	04OCT96	59, 1	0	0	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	-83.3	YES	YES
329.003.00313	SC	08MAY96	-9, .	4	2	3	2	1	0	3	2	0	4	0	0	2	1	0	0	0	24	.		
	BL	17MAY96	1, .	4	3	3	2	2	0	3	2	0	3	0	0	2	1	0	0	0	25	.		
	1	21MAY96	5, .	4	3	0	0	1	0	3	2	1	3	0	0	2	1	0	0	0	20	-20.0	NO	NO
	2	28MAY96	12, .	3	4	4	0	0	0	3	2	1	3	0	1	2	1	0	2	0	26	4.0	NO	NO
329.004.00015	SC	30NOV94	-8, -65	3	0	0	2	1	0	3	1	2	2	0	1	2	2	0	0	0	19	.		
	BL	07DEC94	-1, -58	3	0	0	2	1	0	3	1	2	2	0	1	2	2	0	0	0	19	.		
	1	14DEC94	7, -51	3	0	0	2	2	0	3	2	2	1	1	1	2	1	0	0	0	20	5.3	NO	NO
	2	21DEC94	14, -44	3	2	1	2	0	0	2	0	2	3	1	1	1	1	0	0	0	19	0.0	NO	NO
	3	28DEC94	21, -37	2	2	1	1	1	0	1	0	1	1	0	1	2	1	0	0	0	14	-26.3	NO	NO
	4	04JAN95	28, -30	2	0	1	2	0	0	2	0	1	1	0	1	2	0	0	0	0	12	-36.8	NO	NO
	5	11JAN95	35, -23	3	0	1	2	1	0	1	0	1	1	0	1	2	0	0	0	0	13	-31.6	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.004.00015	6	18JAN95	42, -16	0	0	0	0	0	0	2	1	2	1	0	1	2	0	0	0	0	9	-52.6	YES	NO
	7	25JAN95	49, -9	0	0	0	2	1	0	2	0	2	1	0	0	2	0	0	0	0	10	-47.4	NO	NO
	8	03FEB95	58, 1	0	0	0	0	0	0	2	0	0	1	0	0	1	0	0	0	0	4	-78.9	YES	YES
	12	27FEB95	82, 25	0	1	0	0	1	0	1	0	1	1	1	1	1	0	0	2	0	10	-47.4	NO	NO
	16	22MAR95	105, 48	1	2	0	1	0	0	0	0	2	1	0	0	0	0	0	0	0	7	-63.2	YES	YES
	20	19APR95	133, 76	1	0	0	0	0	0	1	1	2	1	0	0	0	0	0	0	0	6	-68.4	YES	YES
	24	17MAY95	161, 104	1	0	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	4	-78.9	YES	YES
	28	14JUN95	189, 132	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-89.5	YES	YES
329.004.00017	SC	15MAR95	-7, -63	3	2	2	2	1	0	1	1	2	2	0	0	2	0	0	0	0	18	.		
	BL	22MAR95	1, -56	3	2	2	2	0	0	2	1	2	1	0	0	1	1	0	0	0	17	.		
	1	30MAR95	9, -48	2	0	1	2	2	1	2	1	2	3	1	2	0	0	1	0	0	20	17.6	NO	NO
	2	06APR95	16, -41	2	1	1	0	2	0	2	2	2	1	1	0	1	0	0	1	0	16	-5.9	NO	NO
	3	13APR95	23, -34	2	1	1	1	2	0	2	1	1	1	0	0	0	0	0	0	0	12	-29.4	NO	NO
	4	20APR95	30, -27	2	0	2	0	2	0	2	1	2	1	0	0	1	0	0	0	0	13	-23.5	NO	NO
	5	26APR95	36, -21	2	0	2	0	2	0	2	1	1	1	0	0	2	0	0	0	0	13	-23.5	NO	NO
	6	03MAY95	43, -14	2	0	1	0	2	1	1	1	1	1	0	0	2	0	0	0	0	12	-29.4	NO	NO
	7	10MAY95	50, -7	2	0	1	0	1	1	0	0	1	1	0	0	1	0	0	0	0	8	-52.9	YES	YES
	8	17MAY95	57, 1	1	0	1	0	2	1	0	1	1	1	0	0	0	0	0	0	0	8	-52.9	YES	YES
	12	14JUN95	85, 29	1	0	1	0	2	1	1	1	1	1	0	0	0	0	0	1	0	10	-41.2	NO	NO
	16	13JUL95	114, 58	1	0	1	1	1	1	2	0	0	0	0	0	1	0	0	0	0	8	-52.9	YES	YES
	20	10AUG95	142, 86	2	0	1	0	2	0	2	1	2	0	0	0	0	0	0	0	0	10	-41.2	NO	NO
	24	06SEP95	169, 113	0	0	0	0	2	0	1	0	1	0	0	0	0	0	0	0	0	4	-76.5	YES	YES
	28	04OCT95	197, 141	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	4	-76.5	YES	YES
	32	01NOV95	225, 169	1	0	1	0	1	0	1	0	0	1	0	0	0	0	0	0	0	5	-70.6	YES	YES
329.004.00019	SC	24MAY95	-7, .	3	1	0	2	0	1	2	1	1	1	1	1	2	0	2	2	0	20	.		
	BL	31MAY95	1, .	3	1	0	2	2	0	3	2	2	2	1	1	2	0	0	0	0	21	.		

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.004.00019	1	07JUN95	8, .	3	1	0	0	0	2	3	1	2	3	1	1	2	0	1	0	0	20	-4.8	NO	NO
	2	14JUN95	15, .	2	0	0	2	0	2	2	1	2	2	0	1	2	0	0	0	0	16	-23.8	NO	NO
329.004.00212	SC	24MAY96	-10, .	3	2	1	2	0	2	4	1	0	1	0	1	2	1	1	0	0	21	.		
	BL	03JUN96	1, .	3	1	2	2	0	1	3	1	0	1	0	2	2	1	0	1	0	20	.		
	1	10JUN96	8, .	3	2	1	1	2	1	3	0	1	1	0	2	2	1	0	0	0	20	0.0	NO	NO
	3	21JUN96	19, .	4	2	2	0	0	0	4	1	0	1	0	2	2	2	0	0	0	20	0.0	NO	NO
	4	28JUN96	26, .	2	1	2	0	1	1	4	1	0	1	1	2	2	2	0	0	0	20	0.0	NO	NO
329.004.00214	SC	27SEP96	-7, -67	3	2	2	0	0	0	3	1	4	3	2	1	2	0	1	0	0	24	.		
	BL	04OCT96	1, -60	2	2	0	0	1	0	3	1	2	3	3	0	2	0	1	2	0	22	.		
	1	09OCT96	6, -55	3	2	2	0	2	0	3	1	2	3	3	0	2	0	1	0	0	24	9.1	NO	NO
	2	15OCT96	12, -49	1	2	0	0	1	0	3	1	2	2	1	0	2	0	2	0	0	17	-22.7	NO	NO
	2	21OCT96	18, -43	1	0	0	0	0	1	2	1	2	2	2	0	2	0	2	0	0	15	-31.8	NO	NO
	4	01NOV96	29, -32	1	2	1	0	1	0	2	1	2	2	3	0	2	0	1	0	0	18	-18.2	NO	NO
	5	11NOV96	39, -22	0	2	0	0	1	1	2	0	2	2	2	1	2	0	0	0	0	15	-31.8	NO	NO
	6	18NOV96	46, -15	1	1	1	0	1	1	2	1	2	2	2	0	2	0	0	0	0	16	-27.3	NO	NO
	7	25NOV96	53, -8	1	1	0	0	1	0	2	0	2	2	1	0	2	0	1	1	0	14	-36.4	NO	NO
	8	03DEC96	61, 1	1	0	0	0	1	0	2	0	2	2	1	0	2	0	2	0	0	13	-40.9	NO	NO
	12	30DEC96	88, 28	1	2	3	0	1	0	2	0	2	2	1	0	2	0	0	0	0	16	-27.3	NO	NO
329.005.00002	SC	20MAY94	-5, -61	3	0	0	2	2	2	4	1	1	0	1	0	1	0	0	1	0	18	.		
	BL	25MAY94	1, -56	2	0	0	2	2	2	3	0	3	0	0	0	2	0	0	1	0	17	.		
	1	01JUN94	8, -49	2	0	0	2	2	2	2	2	2	0	0	0	0	0	0	0	0	14	-17.6	NO	NO
	2	08JUN94	15, -42	2	0	0	2	2	2	2	1	2	0	0	0	0	0	0	0	0	13	-23.5	NO	NO
	3	15JUN94	22, -35	3	0	0	2	2	2	2	0	2	0	0	0	0	0	0	1	0	14	-17.6	NO	NO
	4	23JUN94	30, -27	2	0	0	2	2	2	2	1	2	0	0	0	0	0	0	0	0	13	-23.5	NO	NO
	5	30JUN94	37, -20	2	0	0	2	2	2	2	0	0	0	0	1	1	0	0	1	0	13	-23.5	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00002	6	07JUL94	44, -13	2	0	0	2	1	1	2	0	1	0	0	1	0	0	0	0	0	10	-41.2	NO	NO
	7	14JUL94	51, -6	2	0	0	2	1	2	1	0	0	0	0	0	1	0	0	0	0	9	-47.1	NO	NO
	8	20JUL94	57, 1	1	0	0	2	2	1	0	0	0	0	0	1	1	0	0	1	0	9	-47.1	NO	NO
	12	17AUG94	85, 29	3	0	0	2	1	0	0	0	0	0	0	0	0	0	0	0	0	6	-64.7	YES	YES
	16	15SEP94	114, 58	2	0	0	2	2	0	1	1	0	1	0	1	0	0	0	1	0	11	-35.3	NO	NO
	20	18OCT94	147, 91	3	0	0	0	2	0	2	0	0	0	0	1	0	0	0	1	0	9	-47.1	NO	NO
329.005.00004	SC	22SEP94	-18, -77	3	2	0	2	1	2	0	2	0	0	0	0	0	0	0	2	0	14	.		
	BL	10OCT94	1, -59	3	1	0	2	1	2	1	2	1	0	0	0	0	0	0	1	0	14	.		
	1	20OCT94	11, -49	2	0	2	2	2	2	2	2	2	0	1	1	0	0	0	0	0	18	28.6	NO	NO
	2	27OCT94	18, -42	1	0	2	1	0	0	0	1	1	0	0	0	0	0	0	0	2	8	-42.9	YES	YES
	3	03NOV94	25, -35	1	0	0	1	0	0	0	1	1	1	0	0	0	0	0	0	2	7	-50.0	YES	YES
	4	10NOV94	32, -28	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	0	4	-71.4	YES	YES
	5	17NOV94	39, -21	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-85.7	YES	YES
	6	23NOV94	45, -15	1	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	4	-71.4	YES	YES
	7	01DEC94	53, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	-85.7	YES	YES
	8	08DEC94	60, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	-85.7	YES	YES
	12	05JAN95	88, 29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00008	SC	10NOV94	-6, -61	1	0	0	2	0	2	0	1	3	1	1	1	1	0	0	1	1	15	.		
	BL	16NOV94	1, -55	3	0	0	1	0	0	1	1	4	1	0	1	1	0	0	0	2	15	.		
	1	23NOV94	8, -48	2	0	0	0	0	2	1	1	3	1	0	0	1	0	0	1	2	14	-6.7	NO	NO
	2	30NOV94	15, -41	0	0	0	0	0	0	1	0	3	1	0	0	1	0	0	0	0	6	-60.0	YES	YES
	3	07DEC94	22, -34	1	0	0	2	0	0	1	0	0	0	0	0	0	0	0	1	0	5	-66.7	YES	YES
	4	14DEC94	29, -27	0	0	0	0	0	0	1	0	3	0	0	0	0	0	0	0	2	6	-60.0	YES	YES
	5	21DEC94	36, -20	0	0	0	0	2	2	2	1	1	1	0	0	2	0	0	0	0	11	-26.7	NO	NO
	6	28DEC94	43, -13	0	0	0	0	0	2	1	0	1	0	0	0	0	0	0	0	0	4	-73.3	YES	YES
	7	03JAN95	49, -7	1	2	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	4	-73.3	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00008	8	10JAN95	56, 1	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	3	-80.0	YES	YES
	12	06FEB95	83, 28	1	1	0	0	2	2	1	0	1	1	0	0	0	0	0	0	0	9	-40.0	NO	NO
	16	08MAR95	113, 58	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-86.7	YES	YES
	24	10MAY95	176, 121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00011	SC	06DEC94	-7, -63	3	0	1	2	1	1	2	1	3	1	0	1	1	0	1	1	0	19	.		
	BL	13DEC94	1, -56	3	0	1	2	2	2	2	1	2	1	0	1	1	0	0	0	0	18	.		
	1	20DEC94	8, -49	2	0	0	0	2	2	2	1	2	1	0	1	0	0	0	0	0	13	-27.8	NO	NO
	2	27DEC94	15, -42	1	0	0	0	1	1	1	0	3	1	0	0	2	0	0	1	0	11	-38.9	NO	NO
	3	03JAN95	22, -35	1	0	0	1	2	2	2	1	3	1	0	0	1	0	0	0	0	14	-22.2	NO	NO
	4	09JAN95	28, -29	1	0	0	2	2	0	1	1	2	1	0	1	0	0	0	0	0	11	-38.9	NO	NO
	5	17JAN95	36, -21	1	0	0	2	1	0	1	1	1	1	0	1	1	0	0	0	0	10	-44.4	NO	NO
	6	23JAN95	42, -15	0	0	0	1	1	2	1	0	1	1	0	0	0	0	0	0	0	7	-61.1	YES	YES
	7	31JAN95	50, -7	1	0	0	0	1	2	1	1	1	1	0	0	2	0	0	1	0	11	-38.9	NO	NO
	8	07FEB95	57, 1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	12	09MAR95	87, 31	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	1	0	4	-77.8	YES	YES
	16	06APR95	115, 59	0	0	0	0	2	0	1	0	1	0	0	1	1	0	0	0	0	6	-66.7	YES	YES
	20	03MAY95	142, 86	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
329.005.00109	SC	22DEC94	-8, -61	3	0	0	2	2	2	3	2	0	1	2	2	2	2	0	2	0	25	.		
	BL	30DEC94	1, -53	3	0	0	2	2	2	3	2	0	1	0	2	2	2	0	2	0	23	.		
	1	05JAN95	7, -47	0	0	0	2	2	2	0	0	3	0	0	0	0	2	0	0	0	11	-52.2	YES	NO
	2	12JAN95	14, -40	1	0	0	0	0	1	0	0	2	1	0	0	0	2	0	1	0	8	-65.2	YES	YES
	3	19JAN95	21, -33	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	1	0	4	-82.6	YES	YES
	4	26JAN95	28, -26	2	0	0	0	0	0	0	1	0	1	0	0	0	2	0	0	0	6	-73.9	YES	YES
	5	02FEB95	35, -19	0	0	0	0	0	0	1	0	1	1	0	1	2	0	0	2	0	8	-65.2	YES	YES
	6	08FEB95	41, -13	1	0	0	0	0	0	0	0	0	1	0	1	0	1	0	0	0	4	-82.6	YES	YES
	7	16FEB95	49, -5	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-95.7	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00109	8	21FEB95	54, 1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0	3	-87.0	YES	YES
	12	23MAR95	84, 31	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	2	-91.3	YES	YES
	16	24APR95	116, 63	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	20	25MAY95	147, 94	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00112	SC	17JAN95	-9, -64	3	2	0	2	0	0	2	1	0	2	1	0	2	0	0	0	0	15	.		
	BL	26JAN95	1, -55	2	0	0	0	0	0	3	2	1	1	0	1	2	0	0	1	0	13	.		
	1	01FEB95	7, -49	2	0	0	1	1	2	0	1	1	0	0	0	0	0	0	0	0	8	-38.5	YES	YES
	2	08FEB95	14, -42	1	1	0	2	0	0	0	0	3	1	0	0	0	0	0	0	0	8	-38.5	YES	YES
	3	15FEB95	21, -35	1	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	4	-69.2	YES	YES
	4	23FEB95	29, -27	0	0	0	0	1	0	0	1	3	0	0	0	0	0	0	0	0	5	-61.5	YES	YES
	5	01MAR95	35, -21	3	1	0	2	1	1	2	0	3	3	0	0	0	0	0	0	0	16	23.1	NO	NO
	6	08MAR95	42, -14	2	0	0	2	2	2	4	0	0	0	0	1	0	0	0	0	0	13	0.0	NO	NO
	7	15MAR95	49, -7	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-84.6	YES	YES
	8	22MAR95	56, 1	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	2	-84.6	YES	YES
	12	19APR95	84, 29	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
	20	21JUN95	147, 92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00116	SC	30JAN95	-8, -66	2	2	2	0	2	0	2	1	3	1	0	1	1	2	0	0	0	19	.		
	BL	07FEB95	1, -58	2	1	0	0	1	1	2	1	2	1	0	1	1	2	0	0	0	15	.		
	1	13FEB95	7, -52	1	0	0	0	2	0	0	0	3	1	0	0	0	2	0	0	0	9	-40.0	NO	NO
	2	20FEB95	14, -45	1	0	0	0	1	0	1	0	2	1	0	0	0	0	0	1	0	7	-53.3	YES	YES
	3	27FEB95	21, -38	1	1	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	5	-66.7	YES	YES
	4	09MAR95	31, -28	0	1	0	0	0	0	1	0	1	1	0	0	2	0	0	1	0	7	-53.3	YES	YES
	5	16MAR95	38, -21	2	1	0	1	1	0	1	0	1	1	0	0	0	0	0	0	0	8	-46.7	YES	YES
	6	23MAR95	45, -14	1	0	0	0	1	0	0	0	1	1	0	0	0	1	0	0	0	5	-66.7	YES	YES
	7	30MAR95	52, -7	1	0	0	0	1	0	0	0	3	0	0	0	0	1	0	0	0	6	-60.0	YES	YES
	8	06APR95	59, 1	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0	0	3	-80.0	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00116	12	04MAY95	87, 29	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-93.3	YES	YES
	16	31MAY95	114, 56	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0	0	3	-80.0	YES	YES
	20	28JUN95	142, 84	3	2	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	7	-53.3	YES	YES
	24	26JUL95	170, 112	0	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	-80.0	YES	YES
329.005.00119	SC	27JUN95	-14, -73	3	0	0	1	2	0	2	2	0	0	2	0	0	0	0	0	0	12	.		
	BL	11JUL95	1, -59	3	0	0	0	2	2	2	1	0	0	0	0	2	0	0	0	0	12	.		
	1	18JUL95	8, -52	2	0	0	2	2	1	0	1	0	0	2	0	1	0	0	0	0	11	-8.3	NO	NO
	2	26JUL95	16, -44	2	0	0	0	2	2	2	1	0	0	1	0	0	0	0	0	0	10	-16.7	NO	NO
	3	02AUG95	23, -37	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	4	-66.7	YES	YES
	4	08AUG95	29, -31	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	2	-83.3	YES	YES
	5	15AUG95	36, -24	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-91.7	YES	YES
	6	23AUG95	44, -16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	7	29AUG95	50, -10	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-91.7	YES	YES
	8	08SEP95	60, 1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-91.7	YES	YES
	12	03OCT95	85, 26	1	0	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	4	-66.7	YES	YES
	16	30OCT95	112, 53	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	2	-83.3	YES	YES
	20	28NOV95	141, 82	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	-83.3	YES	YES
	24	02JAN96	176, 117	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00151	SC	29AUG95	-8, -65	3	2	0	2	0	0	1	0	4	1	2	1	1	0	2	0	0	19	.		
	BL	06SEP95	1, -57	3	2	0	0	0	0	3	0	0	1	1	1	1	0	2	0	1	15	.		
	1	14SEP95	9, -49	2	0	2	1	2	2	1	1	3	1	0	1	1	1	0	1	0	19	26.7	NO	NO
	2	20SEP95	15, -43	2	0	0	2	1	0	1	1	1	1	0	1	0	0	0	1	0	11	-26.7	NO	NO
	3	28SEP95	23, -35	3	0	2	1	0	0	0	0	0	1	0	1	0	0	0	0	0	8	-46.7	YES	YES
	4	03OCT95	28, -30	2	0	1	0	0	0	0	0	1	1	0	1	0	0	1	1	0	8	-46.7	YES	YES
	5	11OCT95	36, -22	2	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	4	-73.3	YES	YES
	6	19OCT95	44, -14	2	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	4	-73.3	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00151	7	26OCT95	51, -7	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	-86.7	YES	YES
	8	02NOV95	58, 1	2	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	4	-73.3	YES	YES
	12	28NOV95	84, 27	2	0	0	1	0	0	0	0	0	2	0	0	0	0	0	0	0	5	-66.7	YES	YES
	16	02JAN96	119, 62	2	0	1	0	0	0	2	0	0	1	0	0	0	0	0	0	0	6	-60.0	YES	YES
	20	31JAN96	148, 91	1	0	2	0	0	0	0	0	1	1	0	0	0	0	0	0	0	5	-66.7	YES	YES
	24	27FEB96	175, 118	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	-73.3	YES	YES
	28	27MAR96	204, 147	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	3	-80.0	YES	YES
	32	01MAY96	239, 182	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-93.3	YES	YES
329.005.00152	SC	12OCT95	-14, .	3	2	0	1	1	0	1	1	2	2	0	0	1	0	0	0	0	14	.		
	BL	23OCT95	-3, .	3	0	0	1	0	0	3	2	0	2	1	0	0	0	0	0	0	12	.		
	1	02NOV95	8, .	3	0	0	0	0	2	2	1	2	1	0	1	2	0	0	1	0	15	25.0	NO	NO
329.005.00257	SC	05MAR96	-6, -62	3	2	0	0	0	0	3	1	0	1	0	0	2	0	0	0	1	13	.		
	BL	11MAR96	1, -56	3	2	0	0	0	0	3	1	0	1	2	0	2	0	0	0	1	15	.		
	1	18MAR96	8, -49	1	0	0	1	0	0	2	0	0	1	0	0	0	0	0	1	0	6	-60.0	YES	YES
	2	25MAR96	15, -42	1	0	0	1	0	0	2	1	0	0	0	0	0	0	0	0	0	5	-66.7	YES	YES
	3	01APR96	22, -35	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-86.7	YES	YES
	4	08APR96	29, -28	1	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	3	-80.0	YES	YES
	5	15APR96	36, -21	2	0	0	0	0	0	2	0	0	0	0	0	1	0	0	1	0	6	-60.0	YES	YES
	6	22APR96	43, -14	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	3	-80.0	YES	YES
	7	29APR96	50, -7	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-86.7	YES	YES
	8	06MAY96	57, 1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-93.3	YES	YES
	12	03JUN96	85, 29	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-86.7	YES	YES
	16	08JUL96	120, 64	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	-86.7	YES	YES
	20	07AUG96	150, 94	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	24	27AUG96	170, 114	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	-93.3	YES	YES
	28	01OCT96	205, 149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00257	32	21OCT96	225, 169	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	-86.7	YES	YES
329.005.00258	SC	06FEB96	-35, .	3	1	0	1	0	0	3	2	0	0	0	0	0	0	0	0	2	12	.		
	BL	20FEB96	-21, .	3	0	0	0	0	0	3	2	0	1	0	0	2	0	0	0	2	13	.		
	1	19MAR96	8, .	3	0	0	0	0	0	3	1	0	1	0	0	0	0	0	0	0	8	-38.5	YES	YES
	2	26MAR96	15, .	1	0	0	0	0	0	2	2	0	1	1	0	0	0	0	0	0	7	-46.2	YES	YES
	3	02APR96	22, .	3	0	0	0	0	0	2	1	0	0	0	0	1	0	0	0	0	7	-46.2	YES	YES
	4	09APR96	29, .	1	0	0	0	0	0	2	0	0	1	1	0	1	0	0	0	0	6	-53.8	YES	YES
	5	18APR96	38, .	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	3	-76.9	YES	YES
	6	23APR96	43, .	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	-84.6	YES	YES
	7	30APR96	50, .	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	-84.6	YES	YES
	8	07MAY96	57, .	1	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	4	-69.2	YES	YES
329.005.00299	SC	28MAY96	-11, -71	3	2	1	2	0	0	3	2	0	1	0	0	2	0	0	0	2	18	.		
	BL	04JUN96	-4, -64	3	0	0	2	0	0	3	1	0	1	0	0	1	0	0	0	2	13	.		
	1	18JUN96	11, -50	1	0	0	0	0	0	1	0	.	1	0	0	0	0	0	0	0	3	-75.5	YES	YES
	2	25JUN96	18, -43	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0	3	-76.9	YES	YES
	3	02JUL96	25, -36	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	-84.6	YES	YES
	5	10JUL96	33, -28	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-92.3	YES	YES
	5	16JUL96	39, -22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	6	22JUL96	45, -16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	31JUL96	54, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	07AUG96	61, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	03SEP96	88, 28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	01OCT96	116, 56	0	0	0	1	0	0	1	0	0	1	0	0	1	0	0	0	0	4	-69.2	YES	YES
	20	29OCT96	144, 84	2	0	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	5	-61.5	YES	YES
	20	05NOV96	151, 91	2	0	1	0	0	0	2	1	0	1	0	0	0	0	0	0	2	9	-30.8	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
					HAMD Scores																				
329.005.00300	SC	12SEP96	-7,	.	3	0	2	1	0	0	0	3	1	1	0	0	0	0	0	0	2	13	.		
	BL	19SEP96	1,	.	2	0	2	1	0	0	1	2	1	1	0	1	0	0	0	0	2	13	.		
	1	26SEP96	8,	.	2	0	2	0	0	0	1	1	2	1	0	0	1	0	0	1	2	13	0.0	NO	NO
	2	03OCT96	15,	.	1	0	0	1	0	0	0	1	3	1	0	1	0	0	0	1	2	11	-15.4	NO	NO
	3	10OCT96	22,	.	1	0	1	0	0	0	2	1	0	1	0	0	0	0	0	0	2	8	-38.5	YES	YES
	4	17OCT96	29,	.	1	1	1	0	0	0	0	1	2	1	0	1	0	0	0	0	2	10	-23.1	NO	NO
	5	24OCT96	36,	.	0	0	1	0	0	0	0	1	1	1	0	1	0	0	0	1	2	8	-38.5	YES	YES
	6	31OCT96	43,	.	1	0	2	0	0	0	0	2	3	1	0	1	0	0	0	0	2	12	-7.7	NO	NO
	7	07NOV96	50,	.	2	0	2	0	0	0	0	1	2	1	0	0	0	0	0	0	2	10	-23.1	NO	NO
	8	14NOV96	57,	.	3	0	2	0	0	0	1	3	3	1	0	1	2	0	0	0	2	18	38.5	NO	NO
329.005.00333	SC	15JAN97	-8,	.	3	1	2	2	0	0	2	2	0	1	2	1	2	0	0	1	0	19	.		
	BL	23JAN97	1,	.	4	0	0	0	0	0	3	2	0	1	0	1	2	0	0	1	0	14	.		
	1	31JAN97	9,	.	2	0	0	0	0	0	1	1	2	1	0	0	1	0	0	0	0	8	-42.9	YES	YES
	2	06FEB97	15,	.	4	0	1	0	0	0	3	2	2	1	0	0	2	0	0	0	0	15	7.1	NO	NO
	3	13FEB97	22,	.	2	0	0	0	0	0	2	1	2	1	0	0	2	0	0	1	0	11	-21.4	NO	NO
	4	20FEB97	29,	.	2	0	1	0	2	0	1	1	2	1	0	1	1	0	0	0	0	12	-14.3	NO	NO
	5	26FEB97	35,	.	3	0	2	0	0	0	3	2	3	2	1	1	2	0	1	0	0	20	42.9	NO	NO
329.005.00336	SC	26FEB97	-6,	.	3	1	1	0	1	0	2	2	3	2	1	1	2	0	3	2	0	24	.		
	BL	04MAR97	1,	.	2	1	0	1	2	1	2	1	2	1	0	0	2	0	1	0	0	16	.		
	1	12MAR97	9,	.	1	0	0	0	2	2	1	1	3	1	0	1	0	0	1	1	0	14	-12.5	NO	NO
	2	19MAR97	16,	.	1	0	0	0	2	1	0	0	1	1	0	1	0	0	0	1	0	8	-50.0	YES	YES
	3	25MAR97	22,	.	1	1	1	0	2	1	0	1	2	0	0	0	0	0	0	0	0	9	-43.7	NO	NO
	4	02APR97	30,	.	1	0	0	0	2	1	0	0	1	0	0	1	1	0	1	0	0	8	-50.0	YES	YES
	5	09APR97	37,	.	0	0	0	0	2	0	1	1	1	1	0	0	1	0	0	0	0	7	-56.3	YES	YES
	6	16APR97	44,	.	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	1	0	3	-81.3	YES	YES
	7	23APR97	51,	.	1	1	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	6	-62.5	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00336	8	30APR97	58, .	1	0	1	0	0	0	1	0	2	0	0	1	0	0	0	0	0	6	-62.5	YES	YES
329.006.00038	SC	01FEB95	-14, .	1	2	0	2	2	1	3	2	2	3	1	0	2	0	0	0	0	21	.		
	BL	08FEB95	-7, .	1	2	0	2	2	1	2	0	3	2	2	2	2	1	1	2	0	25	.		
	1	22FEB95	8, .	2	2	0	2	2	0	3	0	0	2	0	1	1	2	0	0	0	17	-32.0	NO	NO
	2	03MAR95	17, .	0	1	0	1	0	0	0	0	0	0	0	1	1	0	1	2	0	7	-72.0	YES	YES
	3	08MAR95	22, .	0	0	0	2	1	0	1	0	1	0	0	1	1	0	0	0	0	7	-72.0	YES	YES
	4	15MAR95	29, .	0	1	0	2	1	0	0	0	1	2	1	1	2	0	3	2	0	16	-36.0	NO	NO
	5	22MAR95	36, .	0	0	0	2	1	1	0	0	1	1	1	1	1	0	0	0	0	9	-64.0	YES	NO
	6	29MAR95	43, .	0	0	0	2	1	2	0	0	1	0	0	1	1	0	0	0	0	8	-68.0	YES	YES
	7	05APR95	50, .	0	0	0	2	1	0	1	0	0	0	0	1	1	0	0	0	0	6	-76.0	YES	YES
329.006.00039	SC	03FEB95	-5, -66	3	1	1	2	0	0	3	2	2	3	2	0	1	1	1	0	0	22	.		
	BL	10FEB95	3, -59	3	1	2	2	0	0	3	2	0	3	2	0	2	0	0	0	0	20	.		
	1	13FEB95	6, -56	3	1	2	0	0	0	3	2	2	2	3	0	2	0	2	0	0	22	10.0	NO	NO
	2	22FEB95	15, -47	3	2	2	0	0	0	3	2	0	2	3	0	2	0	2	0	0	21	5.0	NO	NO
	3	01MAR95	22, -40	3	2	1	1	0	0	2	2	2	3	0	0	2	0	3	0	0	21	5.0	NO	NO
	4	08MAR95	29, -33	1	2	2	1	1	0	2	2	1	2	1	1	1	0	1	0	0	18	-10.0	NO	NO
	5	17MAR95	38, -24	3	2	3	0	0	0	1	1	2	2	0	0	1	0	1	0	0	16	-20.0	NO	NO
	6	22MAR95	43, -19	1	1	3	0	0	0	2	1	2	1	0	0	2	0	0	0	0	13	-35.0	NO	NO
	7	29MAR95	50, -12	3	1	2	0	0	0	2	2	1	2	0	0	2	0	0	0	0	15	-25.0	NO	NO
	8	05APR95	57, -5	1	1	1	1	0	0	1	0	1	1	1	0	1	0	0	0	0	9	-55.0	YES	NO
	12	01MAY95	83, 22	3	2	2	2	0	1	2	1	0	3	3	0	2	0	3	0	0	24	20.0	NO	NO
329.006.00260	SC	12JUL96	-6, -64	3	2	0	0	0	0	1	0	1	1	2	0	1	0	0	0	2	13	.		
	BL	18JUL96	1, -58	3	2	0	0	0	0	3	0	2	1	2	0	1	0	0	0	2	16	.		
	1	26JUL96	9, -50	1	1	0	0	0	0	0	0	2	1	2	0	0	0	0	0	2	9	-43.7	NO	NO
	2	01AUG96	15, -44	1	2	0	0	0	0	1	0	2	1	1	0	1	0	0	1	2	12	-25.0	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.006.00260	3	07AUG96	21, -38	1	2	0	0	0	0	1	0	2	3	1	0	0	0	0	0	0	10	-37.5	NO	NO
	4	14AUG96	28, -31	1	2	0	0	0	0	1	0	2	2	1	0	1	0	1	2	0	13	-18.8	NO	NO
	5	21AUG96	35, -24	1	1	0	0	0	0	0	0	2	1	1	0	0	0	0	0	0	6	-62.5	YES	YES
	6	28AUG96	42, -17	3	1	0	0	0	0	1	0	2	2	1	0	0	0	0	0	0	10	-37.5	NO	NO
	7	04SEP96	49, -10	2	2	1	0	0	0	0	0	2	2	1	0	1	0	0	0	0	11	-31.3	NO	NO
	8	18SEP96	63, 5	1	2	0	0	0	0	0	0	2	1	1	0	0	0	0	0	0	7	-56.3	YES	YES
	12	09OCT96	84, 26	1	1	0	0	0	0	0	0	2	2	1	0	1	0	0	2	0	10	-37.5	NO	NO
	16	06NOV96	112, 54	3	2	0	0	0	0	0	0	2	3	1	0	0	0	0	0	0	11	-31.3	NO	NO
329.006.00261	SC	07NOV96	-19, -77	3	4	4	2	1	0	2	2	1	2	2	0	2	0	3	0	0	28	.		
	BL	22NOV96	-4, -62	3	3	0	1	0	0	2	2	1	2	2	0	1	1	3	1	0	22	.		
	1	03DEC96	8, -51	3	2	2	0	2	0	3	2	4	3	3	0	0	2	1	0	0	27	22.7	NO	NO
	2	10DEC96	15, -44	2	2	0	0	0	0	2	2	4	3	2	1	1	2	0	0	0	21	-4.5	NO	NO
	3	17DEC96	22, -37	3	2	2	1	1	0	3	1	4	3	2	1	1	0	1	2	0	27	22.7	NO	NO
	4	24DEC96	29, -30	3	2	2	0	0	0	3	2	4	2	2	1	0	0	0	0	0	21	-4.5	NO	NO
	5	02JAN97	38, -21	1	1	0	0	1	0	1	1	4	0	2	0	1	1	2	0	0	15	-31.8	NO	NO
	6	09JAN97	45, -14	0	2	0	0	0	0	0	1	4	0	2	0	0	0	0	0	0	9	-59.1	YES	NO
	7	15JAN97	51, -8	1	1	0	0	0	0	0	1	4	0	1	0	0	0	0	0	0	8	-63.6	YES	YES
	8	23JAN97	59, 1	2	2	0	2	0	0	2	1	4	3	2	0	2	0	1	0	0	21	-4.5	NO	NO
	12	20FEB97	87, 29	0	1	0	0	0	0	1	1	1	0	2	0	1	0	3	0	0	10	-54.5	YES	NO
	20	02APR97	128, 70	3	2	0	0	0	0	1	1	1	2	1	0	1	0	2	0	0	14	-36.4	NO	NO
329.007.00140	SC	07SEP95	-8, -63	3	1	2	2	0	0	1	2	1	1	1	0	1	0	0	0	0	15	.		
	BL	14SEP95	-1, -56	2	0	1	2	1	0	2	0	2	0	2	0	2	0	0	0	1	15	.		
	1	21SEP95	7, -49	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0	1	0	4	-73.3	YES	YES
	2	28SEP95	14, -42	0	0	0	0	0	0	0	0	2	1	0	0	0	0	0	1	0	4	-73.3	YES	YES
	3	05OCT95	21, -35	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-93.3	YES	YES
	4	12OCT95	28, -28	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	-93.3	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.007.00140	5	18OCT95	34, -22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	6	26OCT95	42, -14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	7	02NOV95	49, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	09NOV95	56, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	22NOV95	69, 14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.007.00142	SC	12OCT95	-6, .	2	1	0	2	0	0	3	1	1	1	0	0	2	0	1	0	0	14	.		
	BL	18OCT95	1, .	4	2	0	0	0	0	3	2	2	3	1	0	1	0	1	0	0	19	.		
	1	26OCT95	9, .	3	1	0	0	0	0	3	2	0	1	0	0	0	0	0	0	1	11	-42.1	NO	NO
	2	02NOV95	16, .	3	1	0	0	0	0	3	2	1	0	0	0	1	0	1	1	0	13	-31.6	NO	NO
	3	09NOV95	23, .	2	1	0	0	0	0	1	1	1	1	0	0	1	0	0	0	0	8	-57.9	YES	YES
	4	16NOV95	30, .	2	0	0	0	0	0	3	1	1	1	0	0	1	0	0	0	0	9	-52.6	YES	NO
	5	22NOV95	36, .	2	1	0	0	0	0	1	1	1	1	1	0	0	0	0	0	1	9	-52.6	YES	NO
	6	30NOV95	44, .	3	1	0	0	0	0	3	2	2	3	1	0	1	0	0	0	0	16	-15.8	NO	NO
	8	21DEC95	65, .	3	0	0	2	1	0	3	2	1	2	1	0	1	0	0	0	0	16	-15.8	NO	NO
329.007.00145	SC	04JAN96	-7, -63	3	1	0	1	1	0	2	2	0	3	0	1	0	0	0	1	1	16	.		
	BL	11JAN96	1, -56	1	0	0	1	0	0	2	2	0	3	0	1	0	0	0	1	2	13	.		
	1	18JAN96	8, -49	2	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0	1	8	-38.5	YES	YES
	2	25JAN96	15, -42	3	1	0	0	0	0	3	3	1	1	0	0	0	0	0	0	2	14	7.7	NO	NO
	3	01FEB96	22, -35	2	0	0	0	0	0	3	2	1	1	1	0	1	0	0	0	2	13	0.0	NO	NO
	4	08FEB96	29, -28	0	1	0	0	0	1	1	1	1	0	0	0	0	0	0	0	1	6	-53.8	YES	YES
	5	12FEB96	33, -24	0	1	0	0	0	0	1	1	1	0	1	0	0	0	0	0	1	6	-53.8	YES	YES
	6	21FEB96	42, -15	3	0	0	0	0	0	1	2	1	0	0	0	0	0	0	0	2	9	-30.8	NO	NO
	7	26FEB96	47, -10	0	0	0	0	0	0	1	1	0	2	0	0	0	0	0	0	0	4	-69.2	YES	YES
	8	07MAR96	57, 1	1	1	0	0	0	0	1	0	2	1	0	0	0	0	0	0	0	6	-53.8	YES	YES
	12	04APR96	85, 29	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
	16	02MAY96	113, 57	0	0	0	0	0	1	0	0	1	0	0	0	1	0	0	0	0	3	-76.9	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.007.00145	20	30MAY96	141, 85	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	24	27JUN96	169, 113	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	28	25JUL96	197, 141	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	23AUG96	226, 170	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.007.00265	SC	25JAN96	-7, .	4	2	2	2	0	0	3	3	1	3	0	0	0	0	0	0	1	21	.		
	BL	01FEB96	1, .	3	1	0	1	0	0	3	2	2	3	1	0	1	0	0	0	1	18	.		
	2	15FEB96	15, .	3	1	0	0	1	0	3	2	2	3	1	1	0	0	0	2	1	20	11.1	NO	NO
329.007.00268	SC	21MAR96	-11, -70	3	1	1	0	0	0	3	1	0	3	2	0	1	0	0	0	0	15	.		
	BL	01APR96	1, -59	3	2	1	0	0	2	1	0	4	4	0	1	0	0	0	1	0	19	.		
	1	11APR96	11, -49	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	-89.5	YES	YES
	2	18APR96	18, -42	0	1	0	0	0	0	0	0	1	1	1	1	0	0	0	1	0	6	-68.4	YES	YES
	3	25APR96	25, -35	1	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	4	-78.9	YES	YES
	4	02MAY96	32, -28	1	0	0	0	1	0	0	0	0	2	0	0	0	0	0	0	0	4	-78.9	YES	YES
	5	09MAY96	39, -21	2	0	0	2	0	0	1	0	2	1	0	0	0	0	0	0	0	8	-57.9	YES	YES
	6	16MAY96	46, -14	2	0	0	0	0	0	2	0	2	2	0	0	0	0	0	1	1	10	-47.4	NO	NO
	8	30MAY96	60, 1	0	1	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	3	-84.2	YES	YES
	12	27JUN96	88, 29	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-94.7	YES	YES
	16	01AUG96	123, 64	2	0	0	1	0	0	1	0	2	1	0	0	0	0	0	0	0	7	-63.2	YES	YES
	20	30AUG96	152, 93	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	24	30SEP96	183, 124	0	0	0	0	0	2	1	0	2	0	1	0	2	0	0	0	0	8	-57.9	YES	YES
	32	07NOV96	221, 162	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-94.7	YES	YES
	32	05DEC96	249, 190	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.007.00294	SC	20FEB97	-8, .	4	2	1	2	1	1	3	2	0	3	1	1	1	0	0	0	0	22	.		
	BL	27FEB97	-1, .	3	2	0	2	2	2	3	0	2	3	2	0	1	0	0	0	0	22	.		
	1	10MAR97	11, .	2	1	2	2	2	2	2	0	2	3	2	1	1	0	0	1	0	23	4.5	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.007.00294	2	17MAR97	18, .	3	1	0	2	2	1	2	2	0	0	2	1	2	0	0	1	0	19	-13.6	NO	NO
	4	28MAR97	29, .	4	0	0	1	1	1	2	1	2	3	0	0	0	0	0	0	1	16	-27.3	NO	NO
	5	03APR97	35, .	3	0	0	1	2	2	3	1	2	3	2	1	1	0	0	0	0	21	-4.5	NO	NO
	6	10APR97	42, .	3	1	0	2	1	1	3	2	1	3	1	1	0	0	0	0	0	19	-13.6	NO	NO
329.007.00309	SC	02JUL96	-13, -65	2	1	1	1	1	1	3	0	1	3	2	2	1	0	3	1	0	23	.		
	BL	15JUL96	1, -52	4	2	2	0	2	0	3	0	3	4	3	2	2	0	1	0	0	28	.		
	1	18JUL96	4, -49	1	1	0	1	0	0	0	0	2	0	0	0	0	0	0	0	0	5	-82.1	YES	YES
	1	25JUL96	11, -42	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	-96.4	YES	YES
	2	01AUG96	18, -35	2	0	0	1	1	1	0	0	1	1	1	1	0	0	0	0	0	9	-67.9	YES	NO
	3	08AUG96	25, -28	1	1	0	0	0	0	1	0	2	1	0	0	1	0	0	1	0	8	-71.4	YES	YES
	4	15AUG96	32, -21	1	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	3	-89.3	YES	YES
	6	23AUG96	40, -13	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	2	-92.9	YES	YES
	7	30AUG96	47, -6	1	0	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0	4	-85.7	YES	YES
	7	05SEP96	53, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	03OCT96	81, 29	0	0	0	0	0	0	0	0	1	2	1	0	0	0	0	0	0	4	-85.7	YES	YES
	16	31OCT96	109, 57	0	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	3	-89.3	YES	YES
	20	13DEC96	152, 100	1	0	0	0	1	1	0	0	1	1	1	0	0	0	0	1	0	7	-75.0	YES	YES
	24	09JAN97	179, 127	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	-96.4	YES	YES
	28	10FEB97	211, 159	2	2	0	1	1	1	0	0	2	2	2	1	1	1	0	1	0	17	-39.3	NO	NO
	32	13MAR97	242, 190	2	0	1	2	1	0	1	0	0	2	1	0	0	0	0	0	0	10	-64.3	YES	NO
329.007.00310	SC	19SEP96	-7, -67	3	2	0	0	1	0	3	1	2	3	0	0	1	0	0	0	1	17	.		
	BL	26SEP96	1, -60	3	1	0	1	1	0	2	0	2	3	1	0	0	0	0	0	0	14	.		
	1	03OCT96	8, -53	3	1	0	0	0	1	1	0	1	2	0	0	0	0	0	0	0	9	-35.7	NO	NO
	2	10OCT96	15, -46	0	0	0	0	1	1	0	0	0	0	0	1	1	0	0	0	0	4	-71.4	YES	YES
	3	17OCT96	22, -39	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-85.7	YES	YES
	5	28OCT96	33, -28	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	-85.7	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.007.00310	5	31OCT96	36, -25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	6	08NOV96	44, -17	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	-78.6	YES	YES
	8	18NOV96	54, -7	1	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	7	-50.0	YES	YES
	8	25NOV96	61, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	02JAN97	99, 39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	-92.9	YES	YES
	20	14FEB97	142, 82	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	24	13MAR97	169, 109	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	28	17APR97	204, 144	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	15MAY97	232, 172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	12JUN97	260, 200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.007.00318	SC	22NOV96	-10, .	3	1	0	1	0	0	3	0	2	2	1	1	1	0	0	0	1	16	.		
	BL	02DEC96	1, .	3	2	0	1	0	0	3	0	2	2	0	0	0	0	0	0	1	14	.		
329.008.00157	SC	16AUG95	-14, -69	3	2	0	1	0	0	3	1	3	3	0	0	1	0	0	0	0	17	.		
	BL	29AUG95	-1, -56	3	0	0	0	0	0	3	2	2	2	0	0	1	0	0	0	0	13	.		
	1	05SEP95	7, -49	1	1	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	6	-53.8	YES	YES
	2	12SEP95	14, -42	1	0	0	1	0	0	1	0	1	2	0	0	0	0	0	1	0	7	-46.2	YES	YES
	3	20SEP95	22, -34	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
	4	26SEP95	28, -28	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-84.6	YES	YES
	5	04OCT95	36, -20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	6	10OCT95	42, -14	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
	7	16OCT95	48, -8	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	2	-84.6	YES	YES
	8	24OCT95	56, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	23NOV95	86, 31	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	2	-84.6	YES	YES
	16	15DEC95	108, 53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	20	23JAN96	147, 92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	24	20FEB96	175, 120	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.008.00160	SC	25OCT95	-7, -73	2	2	2	2	1	0	2	1	3	2	0	0	1	0	1	0	0	19	.		
	BL	01NOV95	1, -66	1	2	2	2	1	0	2	1	3	2	0	0	2	0	0	0	0	18	.		
	1	10NOV95	10, -57	2	1	0	1	1	0	1	0	0	2	0	1	2	0	0	0	0	11	-38.9	NO	NO
	3	20NOV95	20, -47	2	2	0	0	0	2	2	0	1	2	0	1	2	0	1	0	0	15	-16.7	NO	NO
	4	27NOV95	27, -40	2	0	0	0	0	2	0	1	1	0	0	0	0	0	0	0	0	6	-66.7	YES	YES
	5	05DEC95	35, -32	2	0	0	0	1	2	1	0	0	0	0	0	1	0	0	0	0	7	-61.1	YES	YES
	6	13DEC95	43, -24	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	4	-77.8	YES	YES
	7	20DEC95	50, -17	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
	8	27DEC95	57, -10	0	0	0	0	0	2	0	0	0	0	0	0	1	0	0	0	0	3	-83.3	YES	YES
	8	05JAN96	66, -1	0	0	0	0	0	2	0	0	0	0	0	0	1	0	0	0	0	3	-83.3	YES	YES
	12	31JAN96	92, 26	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	2	-88.9	YES	YES
	16	05MAR96	126, 60	2	0	1	0	0	0	3	1	1	0	0	0	0	0	0	0	0	8	-55.6	YES	YES
	24	09APR96	161, 95	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	28	16MAY96	198, 132	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
	32	18JUN96	231, 165	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	23JUL96	266, 200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.008.00188	SC	14DEC95	-21, .	4	1	3	2	2	2	3	2	0	3	0	1	2	0	1	0	0	26	.		
	BL	04JAN96	1, .	3	2	0	2	2	1	3	2	2	2	0	0	2	0	1	0	0	22	.		
	1	10JAN96	7, .	2	1	0	1	2	1	3	1	0	0	0	0	1	0	0	0	0	12	-45.5	NO	NO
	2	17JAN96	14, .	2	1	0	1	2	1	3	2	0	1	0	0	1	1	0	0	0	15	-31.8	NO	NO
	3	24JAN96	21, .	1	1	0	2	1	0	1	1	0	1	0	0	1	0	0	0	0	9	-59.1	YES	NO
	4	31JAN96	28, .	2	1	3	0	2	1	0	1	1	0	0	1	2	0	0	0	0	14	-36.4	NO	NO
	5	07FEB96	35, .	2	1	2	0	2	0	2	1	0	0	0	0	1	0	0	0	0	11	-50.0	YES	NO
	6	14FEB96	42, .	1	0	0	1	2	1	2	0	2	1	0	0	1	0	0	0	0	11	-50.0	YES	NO
	7	21FEB96	49, .	0	1	0	1	2	2	3	1	0	0	0	0	2	0	1	0	0	13	-40.9	NO	NO
	8	27FEB96	55, .	2	2	1	0	2	2	3	1	2	2	2	1	2	0	1	0	0	23	4.5	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.008.00271	SC	25JAN96	-46,-110	4	2	0	2	0	0	3	2	0	3	0	0	2	0	0	0	0	18	.		
	BL	11MAR96	1, -64	4	2	1	2	0	0	3	2	0	2	0	0	2	0	0	0	0	18	.		
	1	18MAR96	8, -57	1	2	0	2	1	1	1	0	1	2	1	1	1	0	0	1	0	15	-16.7	NO	NO
	2	25MAR96	15, -50	1	2	0	1	1	0	3	1	0	2	0	1	1	0	0	1	0	14	-22.2	NO	NO
	3	01APR96	22, -43	1	2	0	0	1	1	1	0	1	2	1	0	1	0	1	0	0	12	-33.3	NO	NO
	4	08APR96	29, -36	1	2	0	0	0	0	1	1	1	2	1	1	1	0	1	0	0	12	-33.3	NO	NO
	5	15APR96	36, -29	1	0	0	0	1	0	0	0	0	2	0	0	0	0	1	0	0	5	-72.2	YES	YES
	6	22APR96	43, -22	1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	-83.3	YES	YES
	7	02MAY96	53, -12	0	1	0	0	1	0	0	0	0	2	1	0	0	0	0	0	0	5	-72.2	YES	YES
	8	14MAY96	65, 1	1	1	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0	6	-66.7	YES	YES
	12	10JUN96	92, 28	1	2	0	0	0	0	1	0	0	2	0	0	1	0	0	0	0	7	-61.1	YES	YES
	16	12JUL96	124, 60	2	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	5	-72.2	YES	YES
	20	09AUG96	152, 88	2	0	0	0	0	1	3	1	0	1	0	0	0	0	0	0	0	8	-55.6	YES	YES
	24	06SEP96	180, 116	2	0	0	2	0	0	0	1	0	1	1	0	0	0	0	0	0	7	-61.1	YES	YES
	28	07OCT96	211, 147	2	0	0	2	1	0	2	1	1	0	0	0	0	0	0	0	0	9	-50.0	YES	NO
	32	05NOV96	240, 176	3	0	0	1	1	1	4	2	0	0	0	0	0	0	0	0	0	12	-33.3	NO	NO
329.008.00275	SC	30APR96	-8, -63	2	1	0	2	0	0	2	0	0	3	2	0	1	0	0	0	0	13	.		
	BL	07MAY96	-1, -56	2	1	0	2	0	0	3	1	3	2	2	0	2	0	0	0	0	18	.		
	1	15MAY96	8, -48	2	0	0	2	1	0	3	1	0	4	2	1	0	0	0	0	0	16	-11.1	NO	NO
	2	21MAY96	14, -42	2	0	0	1	0	2	4	2	0	2	2	1	1	0	0	0	0	17	-5.6	NO	NO
	3	28MAY96	21, -35	3	2	1	0	0	1	3	2	0	1	2	1	1	0	1	0	0	18	0.0	NO	NO
	4	04JUN96	28, -28	1	0	0	0	0	1	0	1	1	0	1	1	1	0	0	1	0	8	-55.6	YES	YES
	5	11JUN96	35, -21	1	0	0	1	0	0	0	0	0	0	1	0	1	0	0	0	0	4	-77.8	YES	YES
	7	25JUN96	49, -7	1	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	3	-83.3	YES	YES
	8	02JUL96	56, 1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	-94.4	YES	YES
	12	23JUL96	77, 22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	20AUG96	105, 50	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	1	0	3	-83.3	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.008.00275	20	16SEP96	132, 77	1	1	0	1	0	0	1	0	0	2	1	0	1	0	1	0	0	9	-50.0	YES	NO
	24	21OCT96	167, 112	1	0	0	0	0	0	1	1	2	1	1	0	1	0	0	0	0	8	-55.6	YES	YES
	28	25NOV96	202, 147	1	1	0	0	0	0	1	1	0	1	0	0	1	0	1	0	0	7	-61.1	YES	YES
	32	16DEC96	223, 168	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
329.009.00130	SC	12APR95	-6, -62	3	1	2	2	2	1	2	1	3	2	3	1	2	0	2	0	1	28	.		
	BL	18APR95	1, -56	2	1	1	2	2	1	2	1	3	2	2	0	1	0	1	0	1	22	.		
	1	25APR95	8, -49	3	1	1	2	1	0	2	2	2	2	2	1	1	0	2	0	0	22	0.0	NO	NO
	2	02MAY95	15, -42	2	1	1	2	1	0	2	2	2	2	2	1	1	0	2	0	0	21	-4.5	NO	NO
	3	09MAY95	22, -35	2	1	0	1	1	0	2	1	2	1	1	0	0	0	1	0	0	13	-40.9	NO	NO
	4	16MAY95	29, -28	1	1	0	1	0	0	1	1	2	1	0	0	0	0	1	0	0	9	-59.1	YES	NO
	5	23MAY95	36, -21	3	1	1	2	1	1	1	1	2	1	1	1	1	0	1	0	1	19	-13.6	NO	NO
	6	30MAY95	43, -14	1	1	1	0	0	0	2	1	2	2	2	1	0	0	1	0	0	14	-36.4	NO	NO
	7	06JUN95	50, -7	0	1	0	1	0	0	0	0	3	0	0	0	0	0	0	0	0	5	-77.3	YES	YES
	8	13JUN95	57, 1	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-90.9	YES	YES
	16	07AUG95	112, 56	0	0	0	2	0	0	2	0	1	0	0	0	0	0	0	0	0	5	-77.3	YES	YES
	20	19SEP95	155, 99	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-90.9	YES	YES
	24	03OCT95	169, 113	2	1	1	2	1	1	1	1	2	2	2	0	0	0	1	0	0	17	-22.7	NO	NO
329.009.00131	SC	26APR95	-6, -62	3	3	3	2	2	2	3	2	4	3	3	1	2	1	2	2	0	38	.		
	BL	02MAY95	1, -56	4	2	1	2	2	2	2	2	2	3	2	1	2	0	1	0	1	29	.		
	1	09MAY95	8, -49	3	2	1	2	1	0	2	2	2	1	1	1	1	0	1	1	0	21	-27.6	NO	NO
	2	16MAY95	15, -42	3	2	1	2	1	0	2	2	1	2	1	1	1	0	2	0	0	21	-27.6	NO	NO
	3	23MAY95	22, -35	3	2	1	2	1	0	1	1	1	1	1	1	1	0	0	0	0	16	-44.8	NO	NO
	4	30MAY95	29, -28	1	1	0	1	1	0	1	1	2	1	2	1	1	0	0	1	0	14	-51.7	YES	NO
	5	06JUN95	36, -21	0	0	0	1	0	1	1	1	1	0	1	0	0	0	0	0	0	6	-79.3	YES	YES
	6	13JUN95	43, -14	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-93.1	YES	YES
	7	20JUN95	50, -7	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	4	-86.2	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00131	8	27JUN95	57, 1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2	-93.1	YES	YES
	12	25JUL95	85, 29	1	1	0	1	0	0	0	1	2	3	1	0	0	0	1	0	0	11	-62.1	YES	NO
	16	24AUG95	115, 59	1	1	0	0	0	0	1	0	2	2	1	1	1	0	1	0	0	11	-62.1	YES	NO
	20	26SEP95	148, 92	1	1	0	2	0	0	0	1	1	1	0	0	0	0	0	1	0	8	-72.4	YES	YES
329.009.00133	SC	07JUN95	-6, .	2	1	2	2	2	0	3	2	1	2	1	0	1	0	1	0	1	21	.		
	BL	13JUN95	1, .	3	1	2	2	1	1	3	1	2	2	2	1	1	0	1	0	0	23	.		
	1	20JUN95	8, .	3	1	2	2	2	2	3	1	2	2	2	1	1	0	1	0	0	25	8.7	NO	NO
	2	27JUN95	15, .	3	1	2	2	2	2	3	2	2	2	2	1	1	0	2	0	0	27	17.4	NO	NO
	3	05JUL95	23, .	3	1	1	2	1	2	2	2	1	3	2	0	1	0	1	0	0	22	-4.3	NO	NO
	4	11JUL95	29, .	4	2	1	2	1	1	3	2	2	3	2	0	1	0	1	0	0	25	8.7	NO	NO
	5	18JUL95	36, .	4	2	2	2	2	0	3	2	2	2	2	0	1	0	1	0	0	25	8.7	NO	NO
	6	27JUL95	45, .	2	1	1	2	1	1	2	2	1	3	2	0	1	0	1	0	0	20	-13.0	NO	NO
329.009.00138	SC	02OCT95	-8, .	2	2	2	2	2	0	3	2	1	2	2	2	2	0	0	2	0	26	.		
	BL	10OCT95	1, .	3	1	1	2	1	0	3	2	2	3	2	1	2	0	2	2	0	27	.		
	1	17OCT95	8, .	3	2	1	2	1	1	2	1	2	2	2	1	1	0	1	1	0	23	-14.8	NO	NO
329.009.00170	SC	26OCT95	-12, -69	3	0	1	1	0	1	3	0	3	2	2	0	1	1	1	0	2	21	.		
	BL	07NOV95	1, -57	3	1	2	2	1	0	3	3	0	3	2	1	1	0	3	1	2	28	.		
	1	14NOV95	8, -50	3	1	0	2	1	1	3	2	0	2	2	1	0	0	2	0	2	22	-21.4	NO	NO
	2	21NOV95	15, -43	3	1	1	1	1	0	3	2	1	2	1	1	1	0	1	0	2	21	-25.0	NO	NO
	3	28NOV95	22, -36	3	1	0	1	2	0	3	2	0	2	1	1	0	0	2	0	2	20	-28.6	NO	NO
	4	05DEC95	29, -29	3	2	0	1	2	0	3	3	0	3	1	1	1	1	2	0	2	25	-10.7	NO	NO
	5	12DEC95	36, -22	2	1	0	1	0	0	2	1	0	2	0	0	0	0	0	0	1	10	-64.3	YES	NO
	6	21DEC95	45, -13	1	1	0	0	1	0	1	1	0	1	1	1	0	0	0	0	0	8	-71.4	YES	YES
	7	29DEC95	53, -5	1	1	0	0	0	0	2	1	0	1	0	2	0	0	0	0	0	8	-71.4	YES	YES
	8	03JAN96	58, 1	0	1	0	0	1	0	1	0	1	1	1	1	0	0	0	0	0	7	-75.0	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00170	12	29JAN96	84, 27	1	0	0	0	0	0	2	1	0	1	0	0	0	0	0	0	1	6	-78.6	YES	YES
	16	26FEB96	112, 55	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	-92.9	YES	YES
	20	01APR96	147, 90	0	0	0	0	2	0	1	0	1	0	0	0	1	0	0	0	0	5	-82.1	YES	YES
	24	22APR96	168, 111	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	3	-89.3	YES	YES
	28	23MAY96	199, 142	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-92.9	YES	YES
	32	24JUN96	231, 174	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-96.4	YES	YES
329.009.00173	SC	08NOV95	-12, -75	3	3	2	2	0	2	3	1	2	2	2	0	2	1	1	0	0	26	.		
	BL	20NOV95	1, -63	3	2	2	2	0	2	4	3	1	2	2	0	2	0	0	0	1	26	.		
	1	27NOV95	8, -56	3	3	2	2	0	2	3	2	2	2	2	0	2	1	1	0	0	27	3.8	NO	NO
	2	04DEC95	15, -49	3	2	2	0	0	0	4	3	1	2	2	2	2	0	0	0	1	24	-7.7	NO	NO
	3	11DEC95	22, -42	4	3	2	0	0	0	4	2	1	3	1	2	1	0	1	0	0	24	-7.7	NO	NO
	4	18DEC95	29, -35	3	2	1	0	0	1	4	1	0	2	1	2	2	0	0	1	0	20	-23.1	NO	NO
	6	29DEC95	40, -24	2	2	0	1	0	0	4	0	3	1	1	1	2	0	0	1	0	18	-30.8	NO	NO
	7	08JAN96	50, -14	2	2	0	0	0	0	4	0	3	1	1	1	1	0	0	1	0	16	-38.5	NO	NO
	8	15JAN96	57, -7	2	1	0	0	1	1	4	1	2	2	1	1	1	0	1	0	0	18	-30.8	NO	NO
	8	22JAN96	64, 1	1	1	0	0	1	0	2	1	0	1	0	0	1	0	0	0	0	8	-69.2	YES	YES
	12	26FEB96	99, 36	1	1	1	2	0	0	2	1	0	1	0	0	1	0	0	0	1	11	-57.7	YES	NO
329.009.00193	SC	21NOV95	-7, .	4	2	2	2	2	2	3	1	2	2	1	1	2	1	0	1	0	28	.		
	BL	28NOV95	1, .	4	2	1	2	2	2	3	2	2	2	2	1	2	0	1	1	0	29	.		
	1	05DEC95	8, .	4	2	1	2	1	1	3	2	3	2	2	1	1	0	2	0	0	27	-6.9	NO	NO
	2	12DEC95	15, .	4	2	1	2	1	1	3	2	3	2	2	1	1	0	2	0	0	27	-6.9	NO	NO
	3	19DEC95	22, .	3	1	2	2	1	1	3	2	1	2	1	2	1	0	0	0	1	23	-20.7	NO	NO
	4	27DEC95	30, .	3	1	1	2	2	1	2	2	2	2	1	1	0	0	1	0	0	21	-27.6	NO	NO
	5	05JAN96	39, .	3	1	1	2	2	1	2	2	2	2	1	1	1	0	1	1	1	24	-17.2	NO	NO
	6	09JAN96	43, .	4	2	1	2	2	1	3	2	1	2	2	1	1	0	1	0	1	26	-10.3	NO	NO
	7	16JAN96	50, .	4	2	1	2	2	1	3	2	1	2	2	1	1	0	1	0	1	26	-10.3	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00193	8	24JAN96	58, .	4	2	1	2	2	2	3	2	1	2	2	0	1	0	1	0	1	26	-10.3	NO	NO
329.009.00196	SC	11DEC95	-7, .	3	2	3	1	2	2	3	1	0	2	1	1	2	2	2	1	0	28	.		
	BL	18DEC95	1, .	3	2	2	2	0	2	3	1	0	1	0	1	2	2	1	1	0	23	.		
	1	27DEC95	10, .	2	2	1	1	2	2	3	1	0	2	1	2	2	2	1	1	0	25	8.7	NO	NO
	2	02JAN96	16, .	2	1	0	1	2	1	3	1	0	1	0	0	2	1	1	0	0	16	-30.4	NO	NO
	3	08JAN96	22, .	3	2	0	0	2	2	3	1	1	2	1	0	1	2	0	0	0	20	-13.0	NO	NO
	4	15JAN96	29, .	2	1	0	0	1	1	3	1	0	2	0	0	1	2	0	0	0	14	-39.1	NO	NO
	5	22JAN96	36, .	1	1	0	0	0	0	3	0	0	2	1	0	1	2	0	0	0	11	-52.2	YES	NO
	6	29JAN96	43, .	2	1	0	1	0	0	2	1	0	1	0	0	1	2	0	0	0	11	-52.2	YES	NO
	7	05FEB96	50, .	2	1	0	0	0	0	2	1	0	0	0	0	1	1	0	0	0	8	-65.2	YES	YES
	8	12FEB96	57, .	1	1	0	0	0	0	2	1	0	2	0	0	1	2	0	0	0	10	-56.5	YES	NO
329.009.00201	SC	31JAN96	-6, .	3	2	1	2	2	2	4	2	0	3	0	0	1	1	0	0	0	23	.		
	BL	06FEB96	1, .	3	2	1	2	2	1	3	2	3	2	2	0	1	0	1	0	2	27	.		
	1	13FEB96	8, .	3	2	1	2	2	1	3	2	3	2	2	0	1	0	1	0	1	26	-3.7	NO	NO
	2	20FEB96	15, .	1	1	0	0	1	0	2	2	3	2	1	0	0	0	0	0	1	14	-48.1	NO	NO
	3	28FEB96	23, .	1	1	0	2	1	0	2	1	2	1	1	1	0	0	1	0	1	15	-44.4	NO	NO
	4	05MAR96	29, .	0	0	0	2	0	0	0	1	2	0	0	0	0	0	0	0	0	5	-81.5	YES	YES
	5	12MAR96	36, .	0	1	0	2	0	0	0	1	1	0	1	0	0	0	0	0	0	6	-77.8	YES	YES
	6	19MAR96	43, .	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	3	-88.9	YES	YES
	7	26MAR96	50, .	3	2	1	2	1	0	2	1	2	1	0	0	0	0	0	0	1	16	-40.7	NO	NO
	8	02APR96	57, .	0	0	0	2	0	0	0	1	1	0	0	0	0	0	0	0	0	4	-85.2	YES	YES
329.009.00204	SC	13MAR96	-6, -62	3	2	0	2	0	1	3	0	3	3	2	0	1	1	0	0	2	23	.		
	BL	19MAR96	1, -56	3	1	1	2	1	0	2	2	3	2	1	0	2	0	0	0	2	22	.		
	1	26MAR96	8, -49	3	1	1	2	1	0	2	2	2	1	1	0	2	0	0	0	2	20	-9.1	NO	NO
	2	02APR96	15, -42	1	1	0	1	1	0	2	2	2	1	1	0	2	0	0	0	1	15	-31.8	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00204	3	09APR96	22, -35	1	1	0	1	1	0	1	1	1	1	1	0	1	0	0	0	2	12	-45.5	NO	NO
	4	16APR96	29, -28	1	0	0	1	0	0	1	1	1	1	1	0	0	0	0	0	2	9	-59.1	YES	NO
	5	23APR96	36, -21	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	3	-86.4	YES	YES
	6	30APR96	43, -14	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	2	-90.9	YES	YES
	7	07MAY96	50, -7	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	-90.9	YES	YES
	8	14MAY96	57, 1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.5	YES	YES
	12	11JUN96	85, 29	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	-90.9	YES	YES
	16	09JUL96	113, 57	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	20	13AUG96	148, 92	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.5	YES	YES
	24	10SEP96	176, 120	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	2	-90.9	YES	YES
	28	14OCT96	210, 154	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	-90.9	YES	YES
329.009.00235	SC	10DEC96	-8, -62	1	1	0	2	0	0	3	1	1	1	1	0	2	0	0	0	2	15	.		
	BL	17DEC96	-1, -55	3	1	1	0	1	0	2	2	1	1	1	0	2	0	1	0	1	17	.		
	1	23DEC96	6, -49	3	1	1	0	0	0	2	2	1	1	1	0	2	0	0	0	1	15	-11.8	NO	NO
	2	30DEC96	13, -42	1	0	0	0	0	0	2	1	1	1	0	0	0	0	0	0	0	6	-64.7	YES	YES
	3	06JAN97	20, -35	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0	1	0	5	-70.6	YES	YES
	4	15JAN97	29, -26	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	1	0	4	-76.5	YES	YES
	5	20JAN97	34, -21	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	-88.2	YES	YES
	6	27JAN97	41, -14	0	0	0	0	0	0	0	1	0	0	0	0	2	0	1	0	0	4	-76.5	YES	YES
	7	03FEB97	48, -7	0	0	0	2	0	0	1	1	0	0	0	0	0	0	0	0	0	4	-76.5	YES	YES
	8	10FEB97	55, 1	0	0	0	0	0	0	0	1	0	0	0	0	2	0	0	0	0	3	-82.4	YES	YES
	12	17MAR97	90, 36	1	1	0	0	0	0	1	1	1	0	0	0	2	0	0	0	1	8	-52.9	YES	YES
	16	14APR97	118, 64	3	1	1	1	0	1	3	1	2	1	0	1	0	0	1	1	2	19	11.8	NO	NO
329.009.00240	SC	03JAN97	-11, .	4	2	3	2	2	0	4	2	0	1	0	1	2	1	0	0	0	24	.		
	BL	10JAN97	-4, .	4	1	3	2	1	0	4	2	0	0	0	2	1	1	0	0	1	22	.		
	1	21JAN97	8, .	4	0	1	2	2	0	3	2	0	1	0	1	2	1	0	0	0	19	-13.6	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00240	2	28JAN97	15, .	3	1	1	2	0	0	4	2	0	1	0	1	0	0	0	0	1	16	-27.3	NO	NO
	3	04FEB97	22, .	3	1	0	2	0	0	4	1	1	1	0	1	2	0	0	0	0	16	-27.3	NO	NO
	4	11FEB97	29, .	1	0	0	1	0	0	2	1	0	2	0	0	1	0	0	0	0	8	-63.6	YES	YES
	5	18FEB97	36, .	3	1	0	2	1	0	4	2	0	1	1	0	2	1	0	0	1	19	-13.6	NO	NO
	6	25FEB97	43, .	1	1	0	2	0	0	3	1	0	1	0	0	2	0	0	0	1	12	-45.5	NO	NO
	7	04MAR97	50, .	3	1	0	2	0	0	4	1	0	3	0	0	2	1	0	0	1	18	-18.2	NO	NO
329.009.00303	SC	25MAR96	-8, -64	3	2	2	1	2	0	3	2	1	3	3	0	2	0	2	0	0	26	.		
	BL	02APR96	1, -56	3	2	1	2	1	1	3	1	1	4	2	0	2	0	3	0	0	26	.		
	1	09APR96	8, -49	3	2	1	1	1	0	3	1	1	3	1	0	2	0	2	0	0	21	-19.2	NO	NO
	2	16APR96	15, -42	2	1	0	2	1	0	2	1	1	3	1	0	2	0	2	0	0	18	-30.8	NO	NO
	3	23APR96	22, -35	1	1	0	1	0	0	1	1	1	2	0	0	1	0	0	0	0	9	-65.4	YES	NO
	4	30APR96	29, -28	1	0	0	1	0	0	1	1	0	1	0	0	2	0	1	0	0	8	-69.2	YES	YES
	5	07MAY96	36, -21	1	0	0	0	0	0	1	0	0	1	0	0	1	0	1	0	0	5	-80.8	YES	YES
	6	14MAY96	43, -14	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-92.3	YES	YES
	7	22MAY96	51, -6	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-96.2	YES	YES
	8	28MAY96	57, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	25JUN96	85, 29	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-96.2	YES	YES
	16	30JUL96	120, 64	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	20	27AUG96	148, 92	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-96.2	YES	YES
	24	25SEP96	177, 121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	30OCT96	212, 156	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	-92.3	YES	YES
	32	10DEC96	253, 197	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	-92.3	YES	YES
329.009.00304	SC	03APR96	-6, -62	4	3	1	2	0	0	2	2	1	1	0	1	2	1	0	0	1	21	.		
	BL	09APR96	1, -56	4	1	1	2	0	0	2	2	2	2	1	1	1	0	0	1	2	22	.		
	1	16APR96	8, -49	4	1	1	2	0	0	2	2	1	2	1	1	1	0	0	1	2	21	-4.5	NO	NO
	2	23APR96	15, -42	4	1	1	0	1	1	3	2	1	2	1	2	2	0	0	1	0	22	0.0	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00304	3	30APR96	22, -35	3	2	1	0	1	0	2	2	1	1	1	1	1	0	1	0	1	18	-18.2	NO	NO
	4	07MAY96	29, -28	2	2	0	0	0	0	2	2	1	1	1	1	1	0	1	0	1	15	-31.8	NO	NO
	5	14MAY96	36, -21	1	1	0	0	0	0	1	2	1	1	0	0	0	0	0	1	1	9	-59.1	YES	NO
	6	21MAY96	43, -14	1	1	0	0	0	0	2	2	1	1	1	0	2	0	0	0	1	12	-45.5	NO	NO
	7	28MAY96	50, -7	1	1	0	0	0	0	2	2	0	1	0	0	0	0	0	0	1	8	-63.6	YES	YES
	8	04JUN96	57, 1	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0	1	0	4	-81.8	YES	YES
	12	02JUL96	85, 29	0	0	0	0	0	0	0	2	0	1	0	0	0	0	0	0	0	3	-86.4	YES	YES
	16	30JUL96	113, 57	2	1	0	1	0	0	2	1	0	0	0	1	1	0	0	0	0	9	-59.1	YES	NO
	20	27AUG96	141, 85	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	-90.9	YES	YES
	24	23SEP96	168, 112	3	1	1	0	1	0	2	2	1	1	0	0	0	0	0	0	0	12	-45.5	NO	NO
	28	21OCT96	196, 140	3	1	0	0	0	0	1	2	0	0	1	0	0	0	0	0	2	10	-54.5	YES	NO
329.009.00324	SC	21OCT96	-7, .	3	0	3	2	2	2	3	0	2	2	1	1	1	1	0	1	1	25	.		
	BL	28OCT96	1, .	3	1	2	2	2	2	3	2	1	3	2	1	2	0	1	1	1	29	.		
	1	04NOV96	8, .	3	1	2	1	2	2	3	2	1	3	2	1	2	0	1	1	1	28	-3.4	NO	NO
	2	11NOV96	15, .	1	0	0	2	2	2	2	1	1	1	1	1	1	0	0	0	0	15	-48.3	NO	NO
	3	18NOV96	22, .	1	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	4	-86.2	YES	YES
	4	25NOV96	29, .	0	0	0	0	0	0	0	1	0	0	0	0	2	0	0	1	0	4	-86.2	YES	YES
	5	02DEC96	36, .	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	3	-89.7	YES	YES
	6	09DEC96	43, .	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-96.6	YES	YES
	7	16DEC96	50, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	-96.6	YES	YES
	8	27DEC96	61, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.009.00328	SC	30SEP96	-7, .	3	2	0	2	2	1	3	0	4	3	1	2	2	1	0	1	1	28	.		
	BL	07OCT96	1, .	3	1	1	0	1	1	2	2	2	2	2	1	2	0	1	0	1	22	.		
329.009.00329	SC	01OCT96	-8, .	3	1	0	1	0	0	2	2	3	2	0	0	0	1	0	2	2	19	.		
	BL	09OCT96	1, .	3	1	0	0	0	0	4	3	0	3	1	1	2	0	1	2	1	22	.		

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00329	1	16OCT96	8, .	3	1	0	0	0	0	3	2	1	0	0	1	2	0	0	2	1	16	-27.3	NO	NO
	2	23OCT96	15, .	3	0	0	0	0	0	2	2	1	0	0	1	2	0	0	2	1	14	-36.4	NO	NO
	3	29OCT96	21, .	3	0	0	0	0	0	2	2	0	0	0	0	1	0	0	0	1	9	-59.1	YES	NO
	4	05NOV96	28, .	3	1	0	0	0	0	3	3	1	0	0	0	1	0	0	1	1	14	-36.4	NO	NO
	5	12NOV96	35, .	3	0	0	0	0	0	2	1	2	0	0	0	1	0	0	0	2	11	-50.0	YES	NO
	6	19NOV96	42, .	3	1	0	0	0	0	2	2	0	1	0	0	1	0	0	0	1	11	-50.0	YES	NO
	7	26NOV96	49, .	4	1	0	0	0	0	3	3	1	1	0	0	2	0	0	0	1	16	-27.3	NO	NO
	8	03DEC96	56, .	3	0	0	0	0	0	3	3	1	2	0	0	2	0	0	0	1	15	-31.8	NO	NO
329.010.00182	SC	05DEC95	-14, .	3	2	2	2	0	0	4	1	3	1	3	2	2	2	3	2	0	32	.		
	BL	19DEC95	1, .	4	0	2	2	0	0	4	1	4	1	3	2	2	2	3	0	0	30	.		
	3	12JAN96	25, .	2	0	0	1	0	0	2	0	1	1	1	1	1	0	1	1	0	12	-60.0	YES	NO
	4	19JAN96	32, .	1	0	0	0	0	0	1	0	1	1	2	0	1	0	0	0	0	7	-76.7	YES	YES
329.010.00278	SC	02FEB96	-7, -63	4	3	1	2	2	0	3	2	0	3	2	2	2	1	3	2	0	32	.		
	BL	09FEB96	1, -56	4	3	1	2	2	0	3	2	0	3	2	1	2	1	2	0	0	28	.		
	1	16FEB96	8, -49	2	0	0	2	0	0	3	2	1	2	2	2	2	0	1	0	0	19	-32.1	NO	NO
	2	23FEB96	15, -42	2	0	0	0	0	0	3	0	0	1	1	1	1	0	2	1	0	12	-57.1	YES	NO
	3	01MAR96	22, -35	1	0	0	0	1	0	2	1	1	1	2	1	1	0	0	0	0	11	-60.7	YES	NO
	4	08MAR96	29, -28	3	2	0	1	0	0	2	0	1	4	1	1	2	0	0	0	0	17	-39.3	NO	NO
	5	15MAR96	36, -21	0	0	0	0	0	1	2	0	0	0	1	1	0	0	0	0	0	5	-82.1	YES	YES
	6	22MAR96	43, -14	2	0	1	0	1	2	2	1	1	2	1	0	0	0	0	0	0	13	-53.6	YES	NO
	7	29MAR96	50, -7	1	0	0	2	1	0	2	0	1	0	1	1	0	0	0	0	0	9	-67.9	YES	NO
	8	05APR96	57, 1	1	0	0	2	1	0	0	0	2	0	0	1	0	0	0	0	0	7	-75.0	YES	YES
	12	03MAY96	85, 29	1	0	0	0	0	0	2	2	1	0	2	0	2	0	0	0	0	10	-64.3	YES	NO
	16	31MAY96	113, 57	0	0	0	1	1	0	0	0	2	0	0	0	0	0	0	0	0	4	-85.7	YES	YES
	20	27JUN96	140, 84	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-92.9	YES	YES
	24	25JUL96	168, 112	3	0	2	2	0	0	1	0	0	1	0	1	0	0	0	0	0	10	-64.3	YES	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.010.00278	28	22AUG96	196, 140	0	0	0	2	0	0	1	0	0	0	0	1	0	0	1	0	0	5	-82.1	YES	YES
	32	19SEP96	224, 168	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-96.4	YES	YES
329.010.00280	SC	10MAY96	-7, -62	2	2	1	0	0	0	3	0	3	1	0	0	0	0	0	0	1	13	.		
	BL	17MAY96	1, -55	3	2	0	0	0	0	3	1	0	0	1	0	1	0	2	0	1	14	.		
	1	24MAY96	8, -48	3	0	0	1	0	0	2	1	0	0	1	0	0	0	2	0	1	11	-21.4	NO	NO
	2	31MAY96	15, -41	0	0	0	1	0	0	1	2	2	0	0	0	0	0	0	0	2	8	-42.9	YES	YES
	3	07JUN96	22, -34	0	0	0	1	1	0	1	1	2	1	0	0	0	0	0	0	2	9	-35.7	NO	NO
	4	14JUN96	29, -27	0	0	0	2	0	0	3	0	4	0	2	0	0	0	1	0	1	13	-7.1	NO	NO
	5	21JUN96	36, -20	0	0	0	0	0	0	3	0	1	0	0	0	1	0	1	0	1	7	-50.0	YES	YES
	6	27JUN96	42, -14	1	0	0	0	0	0	1	0	1	0	0	0	1	0	1	0	1	6	-57.1	YES	YES
	7	03JUL96	48, -8	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	1	3	-78.6	YES	YES
	8	11JUL96	56, 1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	3	0	1	6	-57.1	YES	YES
	12	21AUG96	97, 42	1	0	0	0	0	0	1	1	1	1	0	0	0	0	3	0	2	10	-28.6	NO	NO
329.011.00283	SC	30JAN96	-9, -66	3	0	0	1	0	0	2	1	1	2	0	1	0	0	0	1	0	12	.		
	BL	07FEB96	-1, -58	3	0	0	2	0	0	1	1	1	2	1	0	1	0	1	0	0	13	.		
	1	14FEB96	7, -51	2	1	0	0	0	0	1	1	2	2	1	0	1	0	1	0	0	12	-7.7	NO	NO
	2	21FEB96	14, -44	1	1	0	0	0	0	1	0	2	2	0	1	1	0	0	1	0	10	-23.1	NO	NO
	3	29FEB96	22, -36	0	0	0	0	0	0	0	0	2	1	1	0	1	0	0	0	0	5	-61.5	YES	YES
	4	07MAR96	29, -29	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	4	-69.2	YES	YES
	5	15MAR96	37, -21	1	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0	4	-69.2	YES	YES
	6	22MAR96	44, -14	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	1	0	3	-76.9	YES	YES
	7	28MAR96	50, -8	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
	8	04APR96	57, -1	1	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	3	-76.9	YES	YES
329.011.00288	SC	01JUL96	-24, .	2	0	3	1	0	0	1	0	4	1	1	0	1	0	0	0	0	14	.		
	BL	18JUL96	-7, .	3	0	0	0	0	0	2	1	4	1	1	1	1	0	0	0	0	14	.		

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.011.00288	1	01AUG96	8, .	2	0	1	1	1	0	1	0	2	2	0	1	1	0	0	1	0	13	-7.1	NO	NO
	2	09AUG96	16, .	2	0	0	0	0	0	2	0	2	1	0	1	1	0	0	1	0	10	-28.6	NO	NO
	4	19AUG96	26, .	3	1	0	0	0	0	1	0	4	0	0	1	1	0	0	0	0	11	-21.4	NO	NO
	5	29AUG96	36, .	2	0	0	0	0	0	1	0	2	1	0	1	1	0	0	1	0	9	-35.7	NO	NO
329.012.00025	SC	17OCT95	-7, .	3	2	1	2	0	1	3	1	0	2	1	1	2	0	1	0	0	20	.		
	BL	24OCT95	1, .	4	1	1	1	1	1	3	2	0	1	1	1	2	0	0	0	0	19	.		
	1	31OCT95	8, .	3	1	0	2	1	1	3	1	0	0	1	1	1	0	0	0	0	15	-21.1	NO	NO
	2	07NOV95	15, .	3	1	0	2	1	1	3	2	0	0	1	1	1	0	0	0	0	16	-15.8	NO	NO
	3	14NOV95	22, .	4	1	1	1	0	1	3	1	0	0	0	2	1	0	0	0	0	15	-21.1	NO	NO
	4	21NOV95	29, .	0	0	0	0	0	0	1	1	0	0	0	1	2	0	0	0	0	5	-73.7	YES	YES
	5	28NOV95	36, .	3	1	1	0	2	0	2	1	1	0	0	2	1	0	0	0	0	14	-26.3	NO	NO
	6	05DEC95	43, .	4	2	2	2	0	0	2	1	0	0	1	2	2	0	0	1	0	19	0.0	NO	NO
	7	12DEC95	50, .	4	0	0	2	1	0	3	0	0	1	0	1	1	0	0	0	0	13	-31.6	NO	NO
	8	19DEC95	57, .	3	1	0	2	1	1	3	0	0	1	1	2	2	0	0	0	0	17	-10.5	NO	NO
329.012.00220	SC	04JUN96	-13, -73	4	1	2	2	2	2	2	0	0	3	1	1	1	0	0	0	0	21	.		
	BL	14JUN96	-3, -63	4	1	0	2	1	0	3	0	3	3	0	1	2	0	0	0	0	20	.		
	1	22JUN96	6, -55	4	2	2	2	2	1	3	0	0	3	0	1	1	0	0	0	0	21	5.0	NO	NO
	2	28JUN96	12, -49	2	1	0	2	1	0	2	0	1	3	0	0	0	0	1	0	0	13	-35.0	NO	NO
	3	05JUL96	19, -42	2	2	1	2	2	0	1	0	2	0	0	0	1	0	0	0	0	13	-35.0	NO	NO
	4	12JUL96	26, -35	1	2	0	1	1	0	2	0	0	2	0	1	1	0	0	0	0	11	-45.0	NO	NO
	5	19JUL96	33, -28	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	-85.0	YES	YES
	6	29JUL96	43, -18	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-90.0	YES	YES
	7	06AUG96	51, -10	1	2	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	6	-70.0	YES	YES
	8	16AUG96	61, 1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	-90.0	YES	YES
	12	13SEP96	89, 29	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-95.0	YES	YES
	16	11OCT96	117, 57	0	2	0	2	0	0	1	0	2	4	0	0	0	0	0	0	0	11	-45.0	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.012.00220	20	08NOV96	145, 85	0	1	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	3	-85.0	YES	YES
	24	06DEC96	173, 113	1	2	0	2	1	0	3	0	2	2	0	0	1	0	0	0	1	15	-25.0	NO	NO
329.012.00222	SC	18JUN96	-10, -73	4	2	3	2	2	1	3	0	0	4	0	2	2	0	0	0	0	25	.		
	BL	28JUN96	1, -63	4	2	3	2	2	2	3	1	0	4	0	1	2	0	0	0	0	26	.		
	1	05JUL96	8, -56	4	1	2	2	2	2	3	1	1	0	0	2	2	0	0	0	0	22	-15.4	NO	NO
	2	12JUL96	15, -49	2	2	2	2	1	0	2	0	0	2	1	2	2	0	0	0	0	18	-30.8	NO	NO
	3	19JUL96	22, -42	1	2	0	2	2	1	0	0	0	1	0	0	0	0	0	0	0	9	-65.4	YES	NO
	4	29JUL96	32, -32	1	1	1	1	1	0	2	0	1	1	0	2	1	0	0	0	0	12	-53.8	YES	NO
	6	06AUG96	40, -24	2	2	0	0	1	2	2	0	0	0	0	2	1	0	0	1	0	13	-50.0	YES	NO
	7	13AUG96	47, -17	2	2	0	2	1	0	0	0	1	1	0	2	2	0	0	0	0	13	-50.0	YES	NO
	8	20AUG96	54, -10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	-96.2	YES	YES
	8	30AUG96	64, 1	0	0	0	0	0	0	0	0	0	1	0	2	0	0	0	0	0	3	-88.5	YES	YES
	12	27SEP96	92, 29	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-96.2	YES	YES
329.012.00226	SC	26NOV96	-7, .	4	2	3	2	2	1	3	1	2	1	0	1	2	0	0	1	0	25	.		
	BL	03DEC96	1, .	4	0	1	2	1	0	3	1	1	1	1	1	1	0	0	1	0	18	.		
	1	10DEC96	8, .	4	0	2	2	1	0	3	1	1	1	1	0	1	0	0	0	0	17	-5.6	NO	NO
	2	20DEC96	18, .	4	1	3	2	2	0	3	0	1	2	0	1	1	0	0	0	0	20	11.1	NO	NO
329.012.00228	SC	04MAR97	-15, .	3	2	1	1	0	2	2	0	1	2	1	1	1	0	1	1	0	19	.		
	BL	19MAR97	1, .	4	2	1	1	2	2	3	0	2	3	0	0	2	0	0	0	0	22	.		
	1	27MAR97	9, .	2	2	1	1	0	0	3	0	1	2	1	1	0	0	1	0	1	16	-27.3	NO	NO
329.012.00231	SC	26FEB97	-9, -70	3	2	2	0	0	0	3	0	2	2	1	1	1	0	1	0	0	18	.		
	BL	07MAR97	1, -61	3	2	0	0	0	0	3	0	2	2	2	1	2	0	0	1	0	18	.		
	1	17MAR97	11, -51	3	1	2	1	0	0	3	0	2	4	0	0	1	0	0	0	0	17	-5.6	NO	NO
	2	24MAR97	18, -44	3	1	0	0	0	1	3	0	2	3	0	2	2	0	0	0	0	17	-5.6	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.012.00231	4	02APR97	27, -35	1	2	0	0	0	0	2	0	2	2	1	0	1	0	0	0	0	11	-38.9	NO	NO
	5	09APR97	34, -28	2	0	0	0	0	0	3	0	2	2	1	1	2	0	0	1	0	14	-22.2	NO	NO
	6	17APR97	42, -20	1	2	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	7	-61.1	YES	YES
	7	25APR97	50, -12	3	2	0	0	0	0	1	0	2	3	2	0	1	1	1	0	0	16	-11.1	NO	NO
	8	01MAY97	56, -6	1	0	0	0	0	0	1	0	1	2	1	0	1	0	1	0	0	8	-55.6	YES	YES
	8	07MAY97	62, 1	2	0	0	0	0	0	1	0	1	1	0	0	1	2	0	0	0	8	-55.6	YES	YES
	12	04JUN97	90, 29	3	0	0	1	0	0	2	1	2	2	2	1	2	0	0	0	0	16	-11.1	NO	NO
	16	30JUN97	116, 55	3	1	0	1	0	0	2	0	1	2	1	0	2	0	1	0	0	14	-22.2	NO	NO
	20	05AUG97	152, 91	1	2	0	1	0	0	2	0	1	1	0	0	0	0	0	0	0	8	-55.6	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
\# Response is defined as a HAMD total of less than or equal to 8 OR a decrease from baseline in HAMD total score of 50% or greater.
\+ Remission is defined as a HAMD total of less than or equal to 8.

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.001.00061	SC	19JUL94	-10, .	4	3	1	2	0	2	4	3	2	0	3	1	2	0	2	2	1	32	.		
	BL	29JUL94	1, .	1	1	0	2	0	0	4	1	2	1	0	1	0	0	0	0	1	14	.		
	1	04AUG94	7, .	0	2	0	0	0	0	4	2	1	0	1	0	2	0	0	0	2	14	0.0	NO	NO
	2	11AUG94	14, .	2	0	0	1	1	0	3	3	0	2	1	0	1	0	0	0	0	14	0.0	NO	NO
	3	18AUG94	21, .	0	0	0	0	0	0	3	1	1	2	0	0	1	0	0	0	0	8	-42.9	YES	YES
	4	25AUG94	28, .	0	0	0	0	1	0	2	0	0	1	0	0	1	0	0	0	0	5	-64.3	YES	YES
	5	01SEP94	35, .	0	0	0	1	2	0	2	0	0	0	1	0	1	0	0	0	0	7	-50.0	YES	YES
329.001.00066	SC	14NOV94	-8, .	3	2	1	2	0	0	4	2	2	3	2	0	2	1	0	0	0	24	.		
	BL	21NOV94	-1, .	3	1	0	0	0	0	4	2	1	2	1	0	2	1	0	0	0	17	.		
	1	28NOV94	7, .	2	1	0	0	0	0	4	2	2	2	3	2	1	1	0	1	1	22	29.4	NO	NO
	2	05DEC94	14, .	0	0	0	0	0	0	1	1	1	1	0	1	1	1	0	0	0	7	-58.8	YES	YES
329.001.00067	SC	15NOV94	-7, .	4	2	1	2	1	0	4	2	3	3	1	0	2	0	1	0	0	26	.		
	BL	22NOV94	1, .	3	0	1	2	0	0	4	2	2	0	1	0	1	0	0	0	0	16	.		
	1	29NOV94	8, .	2	0	0	2	0	0	4	2	1	3	0	0	0	0	0	0	1	15	-6.3	NO	NO
	2	06DEC94	15, .	3	0	0	2	0	0	3	0	3	0	0	0	0	0	0	0	2	13	-18.8	NO	NO
329.001.00070	SC	14FEB95	-8, .	4	3	2	2	1	1	4	3	1	2	2	0	1	0	0	0	0	26	.		
	BL	22FEB95	1, .	3	1	0	1	0	0	4	3	1	2	3	1	2	0	0	0	0	21	.		
	1	28FEB95	7, .	3	2	0	0	2	0	4	3	3	0	3	1	2	0	0	0	0	23	9.5	NO	NO
	2	08MAR95	15, .	1	0	0	1	2	1	3	1	1	0	3	1	1	0	0	0	0	15	-28.6	NO	NO
	3	15MAR95	22, .	0	0	0	0	0	2	3	1	1	0	3	0	1	0	0	0	0	11	-47.6	NO	NO
329.001.00122	SC	13JUN95	-7, -64	3	1	2	1	0	0	4	3	2	2	2	0	2	0	0	0	0	22	.		
	BL	20JUN95	1, -57	2	0	0	1	0	0	3	2	0	2	1	0	2	0	0	0	0	13	.		
	1	27JUN95	8, -50	1	0	0	1	0	0	4	1	1	0	0	0	1	0	0	0	2	11	-15.4	NO	NO
	2	05JUL95	16, -42	0	0	0	0	0	0	3	1	2	1	0	0	1	0	0	0	0	8	-38.5	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.001.00122	3	11JUL95	22, -36	0	0	0	0	0	0	3	1	2	0	1	0	1	0	0	0	0	8	-38.5	YES	YES
	4	18JUL95	29, -29	0	0	0	0	0	0	2	2	0	2	0	0	1	0	0	0	0	7	-46.2	YES	YES
	5	25JUL95	36, -22	0	0	0	1	0	0	2	0	2	2	0	0	0	0	0	0	0	7	-46.2	YES	YES
	6	01AUG95	43, -15	0	0	0	0	0	0	2	0	2	2	0	0	0	0	0	0	0	6	-53.8	YES	YES
	7	08AUG95	50, -8	0	0	0	0	0	0	2	0	1	1	0	0	1	0	0	0	0	5	-61.5	YES	YES
	8	16AUG95	58, 1	0	0	0	0	0	0	2	0	1	2	0	0	1	0	0	0	0	6	-53.8	YES	YES
	12	12SEP95	85, 28	0	0	0	1	0	0	2	0	2	1	0	0	1	0	0	0	0	7	-46.2	YES	YES
	16	10OCT95	113, 56	0	0	0	0	0	0	2	0	1	1	0	0	0	0	1	0	0	5	-61.5	YES	YES
	20	07NOV95	141, 84	1	0	0	1	0	0	2	0	2	1	1	0	1	0	0	0	0	9	-30.8	NO	NO
	24	05DEC95	169, 112	1	0	0	1	0	0	3	0	2	0	2	0	1	0	0	0	0	10	-23.1	NO	NO
329.002.00050	SC	10MAR95	-13, .	4	1	0	2	0	0	3	2	0	0	0	1	1	0	0	0	1	15	.		
	BL	22MAR95	-1, .	4	0	0	2	0	0	4	2	0	0	0	1	2	1	0	0	1	17	.		
	1	29MAR95	7, .	3	0	1	0	0	0	3	2	0	0	0	1	1	0	0	0	0	11	-35.3	NO	NO
	2	05APR95	14, .	4	0	0	0	0	0	3	2	0	1	0	1	1	0	0	0	0	12	-29.4	NO	NO
	3	12APR95	21, .	3	0	0	0	0	0	2	1	0	0	0	1	1	0	0	0	0	8	-52.9	YES	YES
	5	28APR95	37, .	3	0	0	1	0	0	3	2	0	1	0	1	1	0	0	0	1	13	-23.5	NO	NO
329.002.00056	SC	24JUN94	-25, .	3	0	3	0	0	0	3	0	2	2	3	2	1	1	0	2	0	22	.		
	BL	19JUL94	1, .	2	0	0	0	0	0	3	2	0	2	2	0	2	0	0	2	0	15	.		
	1	26JUL94	8, .	2	1	1	0	0	0	3	0	0	2	1	0	1	0	0	1	0	12	-20.0	NO	NO
	2	02AUG94	15, .	1	0	0	0	0	0	2	0	0	1	2	1	1	0	0	0	0	8	-46.7	YES	YES
	3	09AUG94	22, .	1	0	0	0	0	0	2	0	0	0	0	1	1	0	0	0	0	5	-66.7	YES	YES
	4	16AUG94	29, .	1	0	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	5	-66.7	YES	YES
329.002.00057	SC	11AUG94	-28, -85	4	0	2	2	2	2	3	2	2	1	1	0	1	1	0	0	0	23	.		
	BL	08SEP94	1, -57	4	1	2	2	2	2	3	2	2	3	2	0	1	0	0	0	0	26	.		
	1	15SEP94	8, -50	4	0	2	0	2	2	2	0	2	3	0	0	2	0	0	0	0	19	-26.9	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00057	2	22SEP94	15, -43	3	0	1	0	0	0	2	1	1	2	0	0	1	0	1	0	1	13	-50.0	YES	NO
	3	29SEP94	22, -36	3	1	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	8	-69.2	YES	YES
	4	06OCT94	29, -29	3	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	5	-80.8	YES	YES
	5	13OCT94	36, -22	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	-88.5	YES	YES
	6	20OCT94	43, -15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	7	27OCT94	50, -8	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-96.2	YES	YES
	8	03NOV94	57, -1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	01DEC94	85, 28	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	-92.3	YES	YES
	16	29DEC94	113, 56	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	2	5	-80.8	YES	YES
329.002.00098	SC	20DEC94	-14, .	3	1	1	2	2	1	3	2	0	4	0	0	2	0	1	0	0	22	.		
	BL	03JAN95	1, .	3	1	1	2	2	1	3	2	0	4	0	0	2	0	1	0	0	22	.		
	1	10JAN95	8, .	3	0	0	0	2	0	2	2	0	4	2	1	1	0	1	0	0	18	-18.2	NO	NO
	2	18JAN95	16, .	3	1	0	0	1	0	2	1	0	3	1	1	1	0	1	0	0	15	-31.8	NO	NO
	3	24JAN95	22, .	3	1	0	0	1	0	2	1	0	3	1	1	1	0	1	0	0	15	-31.8	NO	NO
	4	31JAN95	29, .	3	0	1	0	1	0	2	2	0	3	2	0	1	0	0	0	0	15	-31.8	NO	NO
	5	07FEB95	36, .	3	0	0	0	0	0	2	1	0	3	1	0	1	0	0	0	0	11	-50.0	YES	NO
	6	14FEB95	43, .	2	1	0	0	1	1	3	1	3	3	1	1	1	0	1	0	0	19	-13.6	NO	NO
	7	21FEB95	50, .	3	2	1	0	0	2	3	2	1	4	1	1	1	0	1	0	0	22	0.0	NO	NO
	8	02MAR95	59, .	3	0	1	0	2	0	3	1	1	3	1	0	1	0	0	0	0	16	-27.3	NO	NO
329.002.00100	SC	16FEB95	-19, -77	3	1	2	2	0	1	2	1	1	1	1	1	1	0	0	0	0	17	.		
	BL	07MAR95	1, -58	3	1	2	2	0	1	2	1	2	2	1	0	1	0	0	0	0	18	.		
	1	14MAR95	8, -51	3	0	0	2	1	0	2	1	1	3	2	0	0	0	0	0	0	15	-16.7	NO	NO
	2	21MAR95	15, -44	2	0	1	0	0	0	1	2	1	3	2	0	2	0	1	0	0	15	-16.7	NO	NO
	3	28MAR95	22, -37	2	0	0	0	1	0	0	1	1	1	2	0	1	0	0	0	0	9	-50.0	YES	NO
	4	04APR95	29, -30	3	0	0	0	0	0	0	1	2	3	1	0	1	0	0	0	0	11	-38.9	NO	NO
	5	11APR95	36, -23	1	0	0	2	0	0	0	0	2	1	2	0	0	0	0	0	0	8	-55.6	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00100	6	18APR95	43, -16	1	0	0	0	0	0	1	0	1	0	2	1	1	0	0	0	0	7	-61.1	YES	YES
	7	25APR95	50, -9	1	0	0	0	0	1	1	0	1	1	2	0	1	0	0	0	0	8	-55.6	YES	YES
	8	04MAY95	59, 1	1	0	0	0	1	0	0	0	0	1	2	1	0	0	0	0	0	6	-66.7	YES	YES
	12	30MAY95	85, 27	2	0	1	0	0	0	1	0	3	1	0	0	1	0	0	0	0	9	-50.0	YES	NO
	16	27JUN95	113, 55	0	0	0	0	0	2	0	0	2	3	2	0	0	0	0	0	0	9	-50.0	YES	NO
	16	06JUL95	122, 64	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	2	6	-66.7	YES	YES
329.002.00103	SC	11APR95	-9, -65	3	3	0	2	1	2	3	2	3	3	2	0	2	1	0	0	0	27	.		
	BL	20APR95	1, -56	3	3	0	2	1	2	3	2	3	3	2	0	2	1	0	0	0	27	.		
	1	27APR95	8, -49	3	2	0	0	1	0	1	1	2	4	1	0	1	0	0	0	0	16	-40.7	NO	NO
	2	02MAY95	13, -44	2	1	0	0	0	0	1	1	1	2	1	0	1	0	0	0	0	10	-63.0	YES	NO
	3	09MAY95	20, -37	1	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0	0	4	-85.2	YES	YES
	4	16MAY95	27, -30	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	3	-88.9	YES	YES
	5	25MAY95	36, -21	1	0	0	0	0	0	0	0	1	0	2	0	0	0	0	0	0	4	-85.2	YES	YES
	6	30MAY95	41, -16	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	-92.6	YES	YES
	7	06JUN95	48, -9	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-96.3	YES	YES
	8	15JUN95	57, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	13JUL95	85, 29	0	0	0	0	0	0	1	0	1	0	1	0	0	0	0	0	0	3	-88.9	YES	YES
	16	10AUG95	113, 57	2	1	0	2	2	1	0	0	1	2	1	0	1	0	0	0	0	13	-51.9	YES	NO
329.002.00104	SC	28APR95	-6, -62	3	0	1	0	1	2	3	2	0	2	2	1	1	0	0	1	0	19	.		
	BL	04MAY95	1, -56	1	1	1	0	2	2	3	1	0	3	2	0	2	0	0	0	0	18	.		
	1	11MAY95	8, -49	1	0	1	0	1	2	2	2	0	1	2	1	1	0	0	1	0	15	-16.7	NO	NO
	2	18MAY95	15, -42	2	0	1	0	1	2	2	2	0	1	1	1	1	0	0	0	0	14	-22.2	NO	NO
	3	25MAY95	22, -35	3	0	1	1	1	2	3	2	0	3	1	1	1	0	0	0	0	19	5.6	NO	NO
	4	01JUN95	29, -28	0	0	0	2	0	2	3	1	0	1	1	0	1	0	0	0	0	11	-38.9	NO	NO
	5	09JUN95	37, -20	2	0	1	2	0	0	2	1	0	1	1	0	1	0	0	0	0	11	-38.9	NO	NO
	6	16JUN95	44, -13	1	0	0	2	0	2	2	1	0	1	1	0	1	0	0	0	0	11	-38.9	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00104	7	22JUN95	50, -7	0	0	0	0	1	0	1	1	0	3	1	0	1	0	0	0	0	8	-55.6	YES	YES
	8	29JUN95	57, 1	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	3	-83.3	YES	YES
	12	25JUL95	83, 27	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	-94.4	YES	YES
	16	29AUG95	118, 62	1	0	0	0	0	0	1	1	0	0	0	0	1	0	0	1	0	5	-72.2	YES	YES
	20	03OCT95	153, 97	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	28	06NOV95	187, 131	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
	32	06DEC95	217, 161	0	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	3	-83.3	YES	YES
	32	02JAN96	244, 188	0	0	0	0	0	1	1	0	0	0	0	0	1	0	0	1	0	4	-77.8	YES	YES
329.002.00243	SC	27FEB96	-16, .	1	1	1	2	2	1	2	0	1	1	1	0	2	0	0	0	0	15	.		
	BL	14MAR96	1, .	2	0	0	2	2	0	3	2	0	1	1	1	2	0	0	2	0	18	.		
	1	21MAR96	8, .	1	0	0	0	1	0	1	2	0	2	0	1	2	0	1	1	0	12	-33.3	NO	NO
	2	28MAR96	15, .	4	2	2	2	2	2	3	1	1	3	2	0	2	0	0	1	0	27	50.0	NO	NO
	3	04APR96	22, .	3	2	1	2	2	1	3	1	0	4	2	0	2	0	1	0	0	24	33.3	NO	NO
329.002.00244	SC	14MAR96	-7, -64	4	0	2	0	1	1	1	2	0	1	0	0	2	0	0	0	0	14	.		
	BL	21MAR96	1, -57	3	1	2	2	2	1	1	2	0	3	0	1	2	0	0	0	0	20	.		
	1	28MAR96	8, -50	4	1	2	0	0	0	1	2	0	3	0	1	2	0	0	0	0	16	-20.0	NO	NO
	2	04APR96	15, -43	4	1	2	0	0	0	3	2	0	1	0	1	2	0	0	0	0	16	-20.0	NO	NO
	3	11APR96	22, -36	2	1	1	0	0	0	1	1	0	1	1	0	1	0	0	0	0	9	-55.0	YES	NO
	4	18APR96	29, -29	3	1	0	0	0	0	2	1	0	1	1	0	1	0	0	0	0	10	-50.0	YES	NO
	5	25APR96	36, -22	1	1	1	0	0	1	1	0	1	1	1	0	1	0	0	0	0	9	-55.0	YES	NO
	6	02MAY96	43, -15	3	1	0	0	0	0	2	2	0	2	1	0	1	0	0	0	0	12	-40.0	NO	NO
	7	09MAY96	50, -8	2	1	0	0	0	0	0	0	0	2	1	0	1	0	0	0	0	7	-65.0	YES	YES
	8	16MAY96	57, -1	2	1	0	0	0	1	1	1	0	1	1	0	1	0	0	0	0	9	-55.0	YES	NO
329.002.00321	SC	15MAY96	-8, .	3	0	0	2	2	0	3	2	1	1	1	0	2	0	0	0	0	17	.		
	BL	23MAY96	1, .	3	0	0	2	2	0	2	3	0	1	2	0	2	0	1	0	0	18	.		

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00321	1	30MAY96	8, .	0	0	0	2	2	0	2	3	1	0	2	0	2	0	0	0	0	14	-22.2	NO	NO
329.002.00322	SC	06JAN97	-3, .	1	0	1	2	1	0	2	0	3	2	1	1	2	0	0	0	0	16	.		
	BL	09JAN97	1, .	2	0	1	2	1	0	2	2	0	2	1	1	2	0	0	1	0	17	.		
	1	16JAN97	8, .	3	0	0	2	0	0	3	2	0	3	2	1	2	0	0	0	0	18	5.9	NO	NO
	2	23JAN97	15, .	1	0	0	2	0	0	2	1	0	3	0	1	2	0	0	0	0	12	-29.4	NO	NO
	3	30JAN97	22, .	1	1	0	2	0	0	2	1	0	0	1	0	2	0	0	0	0	10	-41.2	NO	NO
	4	04FEB97	27, .	1	1	0	2	0	0	1	1	0	1	1	1	2	0	0	0	0	11	-35.3	NO	NO
	5	13FEB97	36, .	1	1	0	2	0	0	2	1	0	2	1	0	2	0	0	0	0	12	-29.4	NO	NO
329.003.00073	SC	11JAN95	-8, .	4	2	0	2	2	0	4	2	2	1	1	0	1	1	0	0	0	22	.		
	BL	18JAN95	-1, .	3	2	0	2	2	1	3	2	1	3	0	0	2	1	0	0	0	22	.		
	1	25JAN95	7, .	3	1	0	2	0	0	3	1	1	3	0	0	2	0	0	0	0	16	-27.3	NO	NO
	2	03FEB95	16, .	2	1	0	2	2	0	3	0	2	1	1	0	1	0	0	0	0	15	-31.8	NO	NO
	3	07FEB95	20, .	1	1	0	2	2	0	3	1	1	3	2	0	1	0	0	0	0	17	-22.7	NO	NO
	4	14FEB95	27, .	1	0	0	2	1	0	3	0	1	2	1	0	1	0	0	0	0	12	-45.5	NO	NO
	5	22FEB95	35, .	3	1	0	2	1	1	2	1	1	1	2	0	2	1	0	0	0	18	-18.2	NO	NO
	6	01MAR95	42, .	3	0	0	2	1	1	2	2	1	0	0	2	2	0	1	0	0	17	-22.7	NO	NO
	7	08MAR95	49, .	3	0	0	2	2	2	4	1	1	1	2	2	2	0	2	1	0	25	13.6	NO	NO
329.003.00076	SC	24JAN95	-7, -62	4	0	3	1	0	0	3	1	1	2	2	0	2	0	0	0	0	19	.		
	BL	31JAN95	1, -55	3	1	3	2	0	0	3	1	1	2	2	0	2	0	1	0	0	21	.		
	1	07FEB95	8, -48	3	1	0	0	0	0	3	0	0	2	2	0	1	1	0	0	0	13	-38.1	NO	NO
	2	14FEB95	15, -41	1	1	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	5	-76.2	YES	YES
	3	21FEB95	22, -34	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	-90.5	YES	YES
	4	27FEB95	28, -28	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	-90.5	YES	YES
	5	06MAR95	35, -21	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-95.2	YES	YES
	6	13MAR95	42, -14	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-95.2	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00076	7	20MAR95	49, -7	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-95.2	YES	YES
	8	27MAR95	56, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	03MAY95	93, 38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	31MAY95	121, 66	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	20	28JUN95	149, 94	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	28	02AUG95	184, 129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	06SEP95	219, 164	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-95.2	YES	YES
	32	11OCT95	254, 199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.003.00079	SC	14APR95	-19, .	4	0	0	0	0	0	4	2	0	3	1	0	2	1	0	0	0	17	.		
	BL	03MAY95	1, .	3	1	1	0	0	0	3	1	1	3	2	1	2	1	0	0	0	19	.		
	1	10MAY95	8, .	2	1	0	0	0	0	3	1	1	3	1	0	2	0	0	0	0	14	-26.3	NO	NO
	2	19MAY95	17, .	3	0	0	1	1	2	3	1	1	1	0	0	1	0	0	0	0	14	-26.3	NO	NO
329.003.00082	SC	11DEC95	1, .	2	0	1	0	2	2	3	0	1	2	1	0	2	0	0	0	0	16	.		
	2	28DEC95	18, .	2	2	1	0	2	0	2	0	0	2	0	1	2	1	0	0	0	15	-6.3	NO	NO
	3	03JAN96	24, .	3	0	1	0	1	2	3	1	0	0	0	0	2	2	0	0	0	15	-6.3	NO	NO
	4	11JAN96	32, .	2	1	1	0	1	1	2	0	2	1	2	0	2	2	0	0	0	17	6.3	NO	NO
	5	17JAN96	38, .	2	0	1	0	1	2	2	1	0	1	1	0	1	2	0	0	0	14	-12.5	NO	NO
329.003.00088	SC	06FEB95	-22, .	3	2	2	0	0	0	2	1	2	0	0	0	0	0	0	0	0	12	.		
	BL	28FEB95	1, .	3	2	2	0	0	0	2	1	2	0	0	0	0	0	0	0	0	12	.		
	1	09MAR95	10, .	3	1	0	0	0	0	3	2	2	3	0	0	1	0	0	1	0	16	33.3	NO	NO
	2	14MAR95	15, .	3	2	0	0	0	0	2	2	2	0	1	0	0	0	0	0	0	12	0.0	NO	NO
	3	21MAR95	22, .	2	1	0	0	1	0	3	0	2	2	1	0	0	0	0	0	0	12	0.0	NO	NO
	4	30MAR95	31, .	2	0	0	0	2	2	3	1	2	1	1	0	2	0	0	0	0	16	33.3	NO	NO
	5	04APR95	36, .	3	2	2	0	0	0	3	0	3	3	0	0	2	0	0	0	0	18	50.0	NO	NO
	6	11APR95	43, .	3	0	3	0	0	0	3	2	2	3	0	0	2	0	0	0	0	18	50.0	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00090	SC	08MAR95	-6, .	3	2	0	0	0	0	3	2	2	2	0	0	0	0	0	0	0	14	.		
	BL	14MAR95	1, .	3	3	0	2	1	0	3	1	2	0	0	0	1	0	0	0	0	16	.		
	2	28MAR95	15, .	2	1	0	0	0	2	3	1	2	2	0	0	0	1	0	0	0	14	-12.5	NO	NO
	3	04APR95	22, .	2	1	2	0	2	2	3	1	1	2	0	0	2	0	0	0	0	18	12.5	NO	NO
	4	11APR95	29, .	1	0	0	0	2	2	1	0	0	2	0	0	0	0	0	0	0	8	-50.0	YES	YES
	5	18APR95	36, .	3	1	1	0	2	2	2	2	2	2	0	0	2	0	0	0	0	19	18.8	NO	NO
	6	25APR95	43, .	1	2	0	2	2	2	2	0	1	2	1	0	0	0	0	0	0	15	-6.3	NO	NO
	7	02MAY95	50, .	3	2	1	2	2	2	3	1	2	3	0	0	1	0	0	1	0	23	43.8	NO	NO
	8	09MAY95	57, .	1	0	0	2	2	2	1	1	1	1	0	2	1	0	0	0	0	14	-12.5	NO	NO
	8	16MAY95	64, .	3	1	1	2	2	2	3	1	1	3	2	0	2	0	0	0	0	23	43.8	NO	NO
329.003.00092	SC	13APR95	-20, -78	3	1	0	1	0	0	2	0	0	2	2	0	1	0	1	0	0	13	.		
	BL	02MAY95	-1, -59	3	0	0	2	1	1	2	0	3	0	0	0	2	0	0	0	0	14	.		
	1	11MAY95	9, -50	0	0	0	0	0	0	1	0	2	0	0	0	2	0	0	0	0	5	-64.3	YES	YES
	2	16MAY95	14, -45	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	-85.7	YES	YES
	3	26MAY95	24, -35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	4	02JUN95	31, -28	0	0	0	1	0	0	0	0	1	0	0	1	1	0	0	0	0	4	-71.4	YES	YES
	5	06JUN95	35, -24	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
	6	13JUN95	42, -17	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	-85.7	YES	YES
	7	20JUN95	49, -10	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
	8	30JUN95	59, 1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
	12	08AUG95	98, 40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	-92.9	YES	YES
	16	05SEP95	126, 68	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
	20	26SEP95	147, 89	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	4	-71.4	YES	YES
	28	07NOV95	189, 131	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	1	0	4	-71.4	YES	YES
	32	05DEC95	217, 159	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	-85.7	YES	YES
	32	02JAN96	245, 187	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	-85.7	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00093	SC	08JUN95	-13, -76	2	2	2	1	1	0	2	1	1	1	0	1	2	0	1	0	0	17	.		
	BL	20JUN95	-1, -64	3	0	2	2	0	0	3	1	1	2	2	0	2	0	0	0	0	18	.		
	1	27JUN95	7, -57	3	0	2	2	0	0	3	1	1	1	0	1	1	0	0	1	0	16	-11.1	NO	NO
	2	06JUL95	16, -48	3	0	0	2	0	0	2	2	1	2	0	1	2	0	0	0	0	15	-16.7	NO	NO
	4	21JUL95	31, -33	2	0	2	2	0	0	2	1	2	2	0	0	2	0	0	0	0	15	-16.7	NO	NO
	5	25JUL95	35, -29	2	0	1	2	0	0	2	0	1	2	1	0	2	0	0	0	0	13	-27.8	NO	NO
	6	01AUG95	42, -22	1	0	1	2	1	0	1	0	0	0	0	0	2	0	0	0	0	8	-55.6	YES	YES
	7	10AUG95	51, -13	1	0	1	1	0	0	1	0	0	0	0	0	2	0	0	0	0	6	-66.7	YES	YES
	8	22AUG95	63, -1	1	0	0	1	0	0	1	0	0	0	0	0	1	0	0	0	0	4	-77.8	YES	YES
	16	03OCT95	105, 42	0	0	0	0	0	0	1	0	0	0	0	0	2	0	0	0	2	5	-72.2	YES	YES
329.003.00247	BL	30JAN96	-2, -56	1	2	1	2	0	0	3	1	2	2	0	1	2	1	0	0	0	18	.		
	1	06FEB96	6, -49	2	1	0	2	2	0	2	1	2	2	0	1	2	1	0	0	0	18	0.0	NO	NO
	2	13FEB96	13, -42	1	0	0	0	0	0	1	0	2	0	0	0	2	0	0	0	0	6	-66.7	YES	YES
	3	20FEB96	20, -35	1	0	0	0	0	0	1	0	2	0	1	0	1	0	0	0	0	6	-66.7	YES	YES
	4	27FEB96	27, -28	0	0	0	0	0	1	1	0	1	0	0	0	1	0	0	1	0	5	-72.2	YES	YES
	5	07MAR96	36, -19	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	3	-83.3	YES	YES
	6	12MAR96	41, -14	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	-88.9	YES	YES
	7	21MAR96	50, -5	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	8	26MAR96	55, 1	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	2	-88.9	YES	YES
	12	30APR96	90, 36	0	0	0	0	0	0	0	1	0	0	0	.	0	0	0	0	0	1	-94.1	YES	YES
	16	21MAY96	111, 57	0	0	0	0	0	0	1	0	1	0	0	0	2	0	0	0	0	4	-77.8	YES	YES
329.003.00249	SC	01MAR96	-6, .	3	2	3	0	0	0	4	1	0	3	3	0	1	0	2	0	0	22	.		
	BL	07MAR96	1, .	3	2	2	0	0	0	4	2	0	2	0	0	1	0	0	0	0	16	.		
	1	12MAR96	6, .	2	1	2	1	0	0	3	1	1	3	0	0	2	0	0	0	0	16	0.0	NO	NO
	2	19MAR96	13, .	2	2	0	1	0	0	3	2	0	2	0	0	1	0	0	0	0	13	-18.8	NO	NO
	3	26MAR96	20, .	2	1	0	1	1	2	3	1	1	3	0	0	2	0	0	0	0	17	6.3	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00249	4	02APR96	27, .	1	1	0	1	0	0	2	1	0	2	0	0	2	0	0	0	0	10	-37.5	NO	NO
	5	09APR96	34, .	3	2	2	0	2	0	1	0	1	2	0	0	0	0	0	0	0	13	-18.8	NO	NO
	6	16APR96	41, .	3	2	0	0	0	0	3	1	2	3	0	0	2	0	0	0	0	16	0.0	NO	NO
	7	23APR96	48, .	3	2	3	2	0	0	3	1	1	3	0	1	2	0	0	1	0	22	37.5	NO	NO
	8	30APR96	55, .	3	1	2	0	0	0	3	1	1	3	1	0	2	0	0	0	0	17	6.3	NO	NO
329.003.00289	SC	12FEB96	-16, -72	3	2	0	1	0	0	4	0	0	3	2	0	2	0	0	0	0	17	.		
	BL	28FEB96	1, -56	3	2	0	2	2	0	2	0	0	2	0	0	1	0	0	1	1	16	.		
	1	06MAR96	8, -49	2	0	0	0	1	2	2	2	0	2	0	0	0	0	0	0	0	11	-31.3	NO	NO
	2	13MAR96	15, -42	1	1	0	0	0	1	2	1	0	1	0	0	0	1	0	0	0	8	-50.0	YES	YES
	3	20MAR96	22, -35	1	0	0	0	0	0	1	0	0	2	0	0	0	1	0	0	0	5	-68.8	YES	YES
	4	27MAR96	29, -28	1	1	0	0	0	0	4	0	0	3	0	0	0	0	0	0	0	9	-43.7	NO	NO
	5	03APR96	36, -21	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	3	-81.3	YES	YES
	6	10APR96	43, -14	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-93.8	YES	YES
	7	17APR96	50, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	24APR96	57, 1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	-87.5	YES	YES
	12	22MAY96	85, 29	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-93.8	YES	YES
	20	19JUL96	143, 87	0	0	0	0	1	0	0	0	1	1	0	0	0	0	0	1	0	4	-75.0	YES	YES
	24	16AUG96	171, 115	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	28	13SEP96	199, 143	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-93.8	YES	YES
	32	11OCT96	227, 171	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.003.00290	BL	11MAR96	1, .	4	0	1	2	0	0	3	3	0	0	0	0	0	1	0	1	0	15	.		
	1	20MAR96	10, .	3	0	2	2	0	0	3	2	0	1	4	1	0	1	0	0	0	19	26.7	NO	NO
329.003.00314	SC	15OCT96	-7, .	3	2	2	0	0	0	2	0	2	2	0	0	1	0	0	0	0	14	.		
	BL	22OCT96	1, .	3	2	2	0	2	0	2	0	2	2	0	0	2	0	0	0	0	17	.		
	1	29OCT96	8, .	1	1	0	1	0	0	2	0	2	2	0	0	2	0	0	0	0	11	-35.3	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00314	2	05NOV96	15, .	2	2	2	0	0	0	3	0	2	2	0	1	2	0	0	0	0	16	-5.9	NO	NO
	5	26NOV96	36, .	2	1	0	0	0	0	1	0	3	1	0	0	0	0	0	0	0	8	-52.9	YES	YES
	6	03DEC96	43, .	1	1	0	0	1	0	0	0	1	0	0	0	1	0	0	0	0	5	-70.6	YES	YES
	7	10DEC96	50, .	1	0	0	1	0	0	1	0	1	2	0	0	1	0	0	0	0	7	-58.8	YES	YES
	8	17DEC96	57, .	2	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	5	-70.6	YES	YES
	8	23DEC96	63, .	2	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	4	-76.5	YES	YES
329.003.00317	BL	17DEC96	-2, .	3	2	2	2	2	0	0	1	0	3	2	1	2	0	0	0	0	20	.		
	1	23DEC96	5, .	2	2	0	2	2	1	1	2	3	2	2	1	1	0	0	1	0	22	10.0	NO	NO
	3	07JAN97	20, .	1	0	0	1	0	1	2	0	0	1	0	0	1	0	0	0	0	7	-65.0	YES	YES
	4	14JAN97	27, .	2	0	0	0	1	1	1	0	0	2	1	0	2	0	0	0	0	10	-50.0	YES	NO
	5	21JAN97	34, .	2	0	0	2	1	0	2	0	1	2	1	0	2	0	0	0	0	13	-35.0	NO	NO
	6	28JAN97	41, .	3	1	0	2	2	0	1	1	1	2	1	0	2	0	0	0	0	16	-20.0	NO	NO
	7	04FEB97	48, .	2	1	0	1	0	1	2	2	1	3	2	0	2	0	0	0	0	17	-15.0	NO	NO
	8	11FEB97	55, .	2	1	1	2	1	2	1	1	1	3	2	2	2	0	0	0	0	21	5.0	NO	NO
329.004.00013	SC	05JUL94	-14, -73	2	2	1	1	0	0	2	1	1	2	2	0	1	0	2	2	0	19	.		
	BL	19JUL94	1, -59	1	0	0	1	0	0	2	1	1	2	1	1	1	0	0	2	0	13	.		
	1	26JUL94	8, -52	1	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0	0	6	-53.8	YES	YES
	2	02AUG94	15, -45	1	1	0	0	0	0	1	1	0	0	0	0	0	0	1	0	0	5	-61.5	YES	YES
	3	09AUG94	22, -38	1	0	0	0	1	0	1	0	0	0	0	0	1	0	0	0	0	4	-69.2	YES	YES
	4	15AUG94	28, -32	0	1	0	0	0	1	0	0	1	0	0	0	1	0	0	0	0	4	-69.2	YES	YES
	5	23AUG94	36, -24	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	2	-84.6	YES	YES
	6	31AUG94	44, -16	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	-84.6	YES	YES
	7	08SEP94	52, -8	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	2	-84.6	YES	YES
	8	16SEP94	60, 1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	-92.3	YES	YES
	12	11OCT94	85, 26	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	-84.6	YES	YES
	16	08NOV94	113, 54	1	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	4	-69.2	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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\+ Remission is defined as a HAMD total of less than or equal to 8.

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.004.00013	20	06DEC94	141, 82	1	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	3	-76.9	YES	YES
	24	10JAN95	176, 117	0	0	0	0	0	0	0	0	1	0	1	0	1	0	0	0	0	3	-76.9	YES	YES
	28	07FEB95	204, 145	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	-84.6	YES	YES
	32	10MAR95	235, 176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.004.00014	SC	22NOV94	-7, .	3	1	0	2	1	0	4	0	1	2	1	0	2	0	2	0	0	19	.		
	BL	29NOV94	1, .	3	1	0	2	1	0	4	0	2	2	2	0	2	0	1	0	0	20	.		
	1	05DEC94	7, .	3	1	0	2	1	0	4	0	1	1	1	0	2	0	2	0	0	18	-10.0	NO	NO
	2	13DEC94	15, .	3	0	0	2	0	0	2	1	2	2	2	0	2	0	2	0	0	18	-10.0	NO	NO
329.004.00211	SC	24JAN96	-9, .	3	1	0	1	0	1	2	0	1	2	1	1	2	0	0	0	0	15	.		
	BL	01FEB96	-1, .	3	2	1	0	0	1	2	0	2	3	2	1	2	0	0	0	0	19	.		
	1	08FEB96	7, .	3	1	0	0	0	0	1	0	2	2	1	1	1	0	0	1	0	13	-31.6	NO	NO
	2	16FEB96	15, .	3	0	0	0	0	1	1	0	2	1	1	1	0	0	0	0	0	10	-47.4	NO	NO
	3	23FEB96	22, .	3	0	0	1	0	1	1	0	2	2	1	1	2	0	0	1	0	15	-21.1	NO	NO
	4	29FEB96	28, .	0	0	0	0	0	0	0	0	2	2	1	0	1	0	0	0	0	6	-68.4	YES	YES
	5	07MAR96	35, .	0	0	0	0	0	0	0	0	2	1	0	0	1	0	0	0	0	4	-78.9	YES	YES
	6	14MAR96	42, .	0	0	0	0	1	0	0	0	2	1	1	0	1	0	0	0	0	6	-68.4	YES	YES
	7	25MAR96	53, .	0	0	0	0	0	0	0	0	2	0	0	2	0	0	0	1	0	5	-73.7	YES	YES
329.004.00215	SC	12MAR97	-8, .	3	1	2	0	0	0	3	2	1	2	0	0	2	2	1	0	1	20	.		
	BL	20MAR97	1, .	3	0	0	0	1	1	3	2	1	2	0	0	2	2	1	0	1	19	.		
	1	27MAR97	8, .	2	1	1	0	1	1	2	2	0	1	0	0	2	2	1	0	1	17	-10.5	NO	NO
	2	03APR97	15, .	1	0	0	0	0	0	1	0	0	1	0	0	2	2	1	0	1	9	-52.6	YES	NO
	3	10APR97	22, .	0	0	0	0	0	0	1	0	0	0	0	0	2	1	0	0	1	5	-73.7	YES	YES
	4	15APR97	27, .	0	0	0	0	0	1	1	0	1	0	0	0	2	1	0	0	1	7	-63.2	YES	YES
	5	24APR97	36, .	0	0	0	0	0	0	1	0	0	1	0	0	2	0	0	0	1	5	-73.7	YES	YES
	6	29APR97	41, .	1	1	0	0	2	2	1	0	1	1	0	1	0	2	0	1	1	14	-26.3	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00003	SC	12SEP94	-8, .	2	1	0	1	0	0	3	1	0	2	1	1	2	0	0	0	0	14	.		
	BL	20SEP94	1, .	2	2	0	0	0	0	3	2	0	2	2	1	2	0	0	0	0	16	.		
	1	27SEP94	8, .	0	1	0	1	0	0	1	1	0	0	1	0	1	0	0	0	0	6	-62.5	YES	YES
	2	04OCT94	15, .	2	1	0	0	0	0	2	0	0	1	2	0	0	0	1	1	0	10	-37.5	NO	NO
329.005.00006	SC	27OCT94	-8, -68	3	2	1	0	0	0	0	2	0	2	0	0	0	0	0	1	1	12	.		
	BL	03NOV94	-1, -61	3	1	1	0	0	0	1	2	2	1	0	1	0	0	0	1	0	13	.		
	1	14NOV94	11, -50	3	1	2	0	0	0	2	2	2	1	0	1	0	0	0	1	0	15	15.4	NO	NO
	2	21NOV94	18, -43	3	1	2	0	0	0	1	1	1	1	0	1	0	0	0	0	0	11	-15.4	NO	NO
	3	28NOV94	25, -36	2	1	2	0	1	0	0	1	1	1	0	0	0	0	0	1	0	10	-23.1	NO	NO
	4	05DEC94	32, -29	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	-76.9	YES	YES
	5	12DEC94	39, -22	1	2	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	5	-61.5	YES	YES
	6	19DEC94	46, -15	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
	8	27DEC94	54, -7	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
	8	03JAN95	61, 1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
	12	02FEB95	91, 31	0	1	2	0	1	1	0	0	2	0	1	0	0	0	0	0	0	8	-38.5	YES	YES
	16	27FEB95	116, 56	0	0	1	0	2	2	0	0	3	1	0	0	0	0	0	0	0	9	-30.8	NO	NO
	20	05APR95	153, 93	0	2	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	6	-53.8	YES	YES
329.005.00007	SC	02NOV94	-7, -70	3	0	3	0	0	0	3	2	2	1	0	0	1	0	0	0	0	15	.		
	BL	09NOV94	1, -63	3	0	1	2	0	2	3	1	1	1	0	0	1	0	0	0	0	15	.		
	2	23NOV94	15, -49	2	0	2	2	1	2	3	1	2	1	1	1	0	0	0	2	0	20	33.3	NO	NO
	3	30NOV94	22, -42	2	0	2	2	1	1	2	0	2	1	0	1	0	0	0	0	0	14	-6.7	NO	NO
	4	07DEC94	29, -35	2	0	2	2	2	2	2	1	2	1	0	1	0	0	0	1	0	18	20.0	NO	NO
	5	14DEC94	36, -28	2	0	1	2	1	2	1	0	2	1	0	0	0	0	0	0	0	12	-20.0	NO	NO
	6	21DEC94	43, -21	2	0	0	2	0	2	1	1	1	1	0	0	0	0	0	0	0	10	-33.3	NO	NO
	7	28DEC94	50, -14	0	0	0	0	2	2	1	0	3	1	0	0	0	0	0	0	0	9	-40.0	NO	NO
	8	04JAN95	57, -7	1	0	0	0	1	2	1	1	2	0	0	0	0	0	0	0	0	8	-46.7	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00007	8	11JAN95	64, 1	1	0	0	0	1	1	1	1	1	0	0	0	0	0	0	0	0	6	-60.0	YES	YES
	12	15FEB95	99, 36	1	0	0	0	0	2	1	1	1	1	0	0	2	0	0	0	0	9	-40.0	NO	NO
	20	22MAR95	134, 71	0	0	0	0	2	1	0	0	1	1	0	0	2	0	0	0	0	7	-53.3	YES	YES
	24	19APR95	162, 99	1	0	2	0	0	0	0	0	1	0	0	0	2	0	0	0	0	6	-60.0	YES	YES
	28	17MAY95	190, 127	1	0	0	0	1	1	1	0	0	0	0	0	2	0	0	0	0	6	-60.0	YES	YES
	32	09AUG95	274, 211	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00009	SC	07DEC94	-5, .	3	2	3	2	2	0	2	2	2	3	2	1	1	0	0	0	0	25	.		
	BL	12DEC94	1, .	3	0	2	2	2	1	3	2	3	1	0	1	1	0	0	1	0	22	.		
	1	19DEC94	8, .	2	0	0	2	0	2	2	1	2	1	0	1	2	0	0	0	0	15	-31.8	NO	NO
	2	27DEC94	16, .	2	0	1	2	1	0	2	1	1	1	0	1	0	0	0	0	0	12	-45.5	NO	NO
	3	03JAN95	23, .	3	0	2	2	2	2	2	1	1	3	0	0	2	0	0	0	0	20	-9.1	NO	NO
	4	11JAN95	31, .	3	0	2	2	2	1	2	2	2	1	0	1	0	0	0	0	0	18	-18.2	NO	NO
	5	18JAN95	38, .	2	0	1	2	1	2	1	1	1	2	1	0	1	0	0	0	0	15	-31.8	NO	NO
	6	25JAN95	45, .	3	0	2	2	1	1	1	1	2	1	0	1	1	1	0	1	0	18	-18.2	NO	NO
	7	31JAN95	51, .	3	0	3	2	2	2	2	1	1	2	0	0	1	0	0	0	0	19	-13.6	NO	NO
	8	07FEB95	58, .	1	0	2	2	2	2	1	1	2	1	0	0	2	0	0	0	0	16	-27.3	NO	NO
329.005.00110	SC	04JAN95	-7, .	3	2	2	2	1	2	2	0	2	1	0	1	1	0	0	0	0	19	.		
	BL	11JAN95	1, .	3	1	2	0	1	1	2	1	2	1	0	1	1	1	0	0	0	17	.		
	1	18JAN95	8, .	1	0	0	0	0	2	2	1	1	2	0	0	1	1	0	0	0	11	-35.3	NO	NO
	2	25JAN95	15, .	2	1	0	1	1	0	1	1	1	1	0	0	0	0	0	0	0	9	-47.1	NO	NO
329.005.00113	SC	20JAN95	-10, .	3	0	2	2	2	2	2	1	3	1	0	1	1	0	0	1	0	21	.		
	BL	30JAN95	1, .	2	0	2	2	2	2	2	2	1	1	0	1	2	2	3	2	0	26	.		
	1	08FEB95	10, .	1	0	1	1	1	1	3	1	1	4	1	1	2	1	3	1	0	23	-11.5	NO	NO
	2	16FEB95	18, .	1	0	0	0	2	2	2	1	3	3	1	1	1	0	2	2	0	21	-19.2	NO	NO
	3	23FEB95	25, .	1	0	1	2	0	2	2	0	2	2	1	0	0	0	2	1	0	16	-38.5	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00113	4	02MAR95	32, .	3	2	3	1	1	1	3	1	3	1	0	2	2	0	2	0	0	25	-3.8	NO	NO
329.005.00117	SC	06MAR95	-12, .	3	2	0	2	0	0	2	1	0	1	1	0	1	1	1	0	0	15	.		
	BL	16MAR95	-2, .	3	1	1	2	2	2	2	1	2	2	2	0	2	1	1	0	0	24	.		
	1	27MAR95	10, .	2	0	0	1	1	0	0	1	0	0	2	0	0	1	1	0	0	9	-62.5	YES	NO
	2	03APR95	17, .	1	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	5	-79.2	YES	YES
	3	10APR95	24, .	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	-91.7	YES	YES
	4	17APR95	31, .	1	0	1	0	0	0	2	0	0	0	0	0	0	0	1	0	1	6	-75.0	YES	YES
	5	24APR95	38, .	0	0	0	0	0	0	0	0	0	1	3	1	0	0	1	0	0	6	-75.0	YES	YES
	6	01MAY95	45, .	2	0	0	0	0	0	0	0	0	0	3	2	2	0	3	0	0	12	-50.0	YES	NO
	7	08MAY95	52, .	0	0	0	0	1	0	0	0	0	1	3	0	2	0	2	0	0	9	-62.5	YES	NO
	8	15MAY95	59, .	1	0	0	0	0	0	0	1	0	0	2	2	1	0	1	1	0	9	-62.5	YES	NO
329.005.00118	SC	09MAY95	-8, .	2	2	2	2	0	0	2	2	0	1	0	0	0	0	0	0	0	13	.		
	BL	17MAY95	1, .	3	1	2	2	0	0	3	2	0	1	0	0	1	0	0	0	1	16	.		
	1	24MAY95	8, .	3	0	3	2	1	1	2	1	2	3	1	1	2	0	0	0	0	22	37.5	NO	NO
	2	30MAY95	14, .	3	0	2	2	0	0	2	1	0	0	2	0	0	0	0	0	0	12	-25.0	NO	NO
	3	06JUN95	21, .	3	0	2	1	0	0	1	1	0	0	0	0	1	0	0	0	0	9	-43.7	NO	NO
	4	14JUN95	29, .	2	0	0	1	0	0	1	1	0	1	1	0	1	0	0	0	0	8	-50.0	YES	YES
	5	20JUN95	35, .	1	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0	5	-68.8	YES	YES
	6	27JUN95	42, .	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	3	-81.3	YES	YES
329.005.00153	SC	11JAN96	-14, -70	3	0	0	0	0	2	3	0	1	1	0	1	1	1	0	1	0	14	.		
	BL	25JAN96	1, -56	3	1	0	0	0	2	3	0	1	1	2	0	0	1	0	0	0	14	.		
	1	01FEB96	8, -49	3	1	0	1	0	1	3	0	1	0	0	1	1	1	0	1	0	14	0.0	NO	NO
	2	08FEB96	15, -42	2	0	0	2	2	1	3	0	1	1	1	1	1	0	0	0	0	15	7.1	NO	NO
	3	15FEB96	22, -35	3	0	0	0	0	0	2	0	1	2	1	1	1	1	0	0	0	12	-14.3	NO	NO
	4	22FEB96	29, -28	3	0	0	0	2	0	2	0	1	2	1	0	1	1	0	0	0	13	-7.1	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00153	5	29FEB96	36, -21	2	0	0	1	1	0	2	0	1	1	0	0	0	0	0	0	0	8	-42.9	YES	YES
	6	06MAR96	42, -15	1	0	0	0	1	0	1	0	1	1	0	0	1	0	0	0	0	6	-57.1	YES	YES
	7	14MAR96	50, -7	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	3	-78.6	YES	YES
	8	21MAR96	57, 1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
	12	17APR96	84, 28	3	1	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	7	-50.0	YES	YES
	16	15MAY96	112, 56	1	0	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0	4	-71.4	YES	YES
	20	12JUN96	140, 84	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
	24	10JUL96	168, 112	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-85.7	YES	YES
	28	05AUG96	194, 138	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	3	-78.6	YES	YES
	32	04SEP96	224, 168	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
329.005.00255	SC	26FEB96	-7, .	3	1	1	2	0	0	2	1	0	1	0	0	0	0	0	1	0	12	.		
	BL	04MAR96	1, .	3	2	0	1	0	0	0	0	2	1	2	0	2	0	0	1	0	14	.		
	1	11MAR96	8, .	1	1	1	0	0	0	2	1	0	1	2	0	2	0	0	0	0	11	-21.4	NO	NO
	2	18MAR96	15, .	2	1	0	0	1	0	3	0	0	1	2	0	2	0	0	1	0	13	-7.1	NO	NO
	3	25MAR96	22, .	1	2	0	0	1	0	2	1	0	1	0	0	1	0	0	0	0	9	-35.7	NO	NO
	4	01APR96	29, .	2	2	0	0	0	0	2	0	0	1	0	0	2	0	0	0	0	9	-35.7	NO	NO
	5	08APR96	36, .	1	2	0	0	0	0	2	0	0	0	0	0	1	0	0	0	0	6	-57.1	YES	YES
	6	15APR96	43, .	2	1	0	0	0	2	1	0	0	0	0	1	0	0	0	1	0	8	-42.9	YES	YES
	7	23APR96	51, .	0	1	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	3	-78.6	YES	YES
	8	29APR96	57, .	3	1	0	0	1	0	2	0	0	1	2	0	0	0	0	1	0	11	-21.4	NO	NO
329.005.00256	SC	20FEB96	-14, -70	1	0	0	2	0	0	0	0	3	1	2	1	0	0	0	2	1	13	.		
	BL	05MAR96	1, -56	1	0	0	2	0	0	0	0	3	1	2	1	0	0	0	2	1	13	.		
	1	12MAR96	8, -49	1	0	0	2	1	0	2	0	0	1	2	1	1	0	0	0	0	11	-15.4	NO	NO
	2	21MAR96	17, -40	1	0	0	2	1	1	1	1	2	1	0	0	1	0	0	0	0	11	-15.4	NO	NO
	3	26MAR96	22, -35	1	0	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0	5	-61.5	YES	YES
	4	02APR96	29, -28	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	-84.6	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00256	5	11APR96	38, -19	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	-84.6	YES	YES
	6	16APR96	43, -14	1	0	0	1	0	0	2	0	0	0	0	0	0	0	0	0	0	4	-69.2	YES	YES
	7	23APR96	50, -7	2	0	0	2	0	0	2	0	0	1	0	0	0	0	0	0	0	7	-46.2	YES	YES
	8	30APR96	57, 1	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	3	-76.9	YES	YES
	12	28MAY96	85, 29	1	0	0	2	0	0	1	0	0	0	0	0	0	0	0	0	0	4	-69.2	YES	YES
	16	02JUL96	120, 64	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	2	-84.6	YES	YES
329.005.00295	SC	21MAR96	-7, .	3	1	3	0	0	0	3	2	2	1	0	0	1	1	0	0	0	17	.		
	BL	28MAR96	1, .	2	2	0	0	0	0	2	1	2	1	0	1	1	0	0	0	0	12	.		
	1	04APR96	8, .	2	0	0	1	0	1	0	0	0	1	0	1	2	0	0	1	0	9	-25.0	NO	NO
	2	11APR96	15, .	2	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	5	-58.3	YES	YES
	3	18APR96	22, .	1	0	0	0	1	0	0	0	1	1	0	0	2	0	0	1	0	7	-41.7	YES	YES
	4	24APR96	28, .	1	0	2	0	0	0	1	0	1	1	0	0	0	0	0	0	0	6	-50.0	YES	YES
	6	06MAY96	40, .	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	-91.7	YES	YES
	6	09MAY96	43, .	2	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	4	-66.7	YES	YES
	7	16MAY96	50, .	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-91.7	YES	YES
	8	22MAY96	56, .	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	3	-75.0	YES	YES
329.005.00297	SC	28MAR96	-22, .	2	0	0	2	0	0	1	1	3	1	0	2	1	0	0	0	0	13	.		
	BL	19APR96	1, .	3	0	0	2	0	0	2	1	3	1	0	2	2	1	0	2	0	19	.		
	1	26APR96	8, .	2	0	0	0	0	0	2	0	3	1	0	2	1	0	0	0	0	11	-42.1	NO	NO
	2	02MAY96	14, .	0	0	0	0	0	0	2	0	3	0	0	1	0	0	0	0	0	6	-68.4	YES	YES
	4	14MAY96	26, .	1	0	0	0	0	0	2	0	1	1	0	0	1	0	0	0	0	6	-68.4	YES	YES
329.005.00332	SC	05DEC96	-7, .	3	1	1	0	0	0	2	2	1	1	0	1	1	0	0	0	0	13	.		
	BL	12DEC96	1, .	3	1	1	0	0	0	2	2	1	1	0	1	1	0	0	0	0	13	.		
	1	19DEC96	8, .	2	0	0	0	0	0	1	2	2	1	0	1	1	0	0	0	0	10	-23.1	NO	NO
	2	26DEC96	15, .	3	0	0	0	0	0	0	2	2	1	0	1	0	0	0	0	0	9	-30.8	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00332	3	02JAN97	22, .	1	0	0	0	0	0	1	2	2	2	0	1	0	0	0	1	0	10	-23.1	NO	NO
	4	09JAN97	29, .	3	0	0	0	0	0	2	2	2	1	0	1	0	0	0	0	0	11	-15.4	NO	NO
	5	16JAN97	36, .	3	0	0	0	0	0	2	2	2	1	0	1	0	0	0	0	0	11	-15.4	NO	NO
	6	23JAN97	43, .	1	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	4	-69.2	YES	YES
	7	30JAN97	50, .	2	0	0	0	0	0	0	0	2	1	0	1	0	0	0	0	0	6	-53.8	YES	YES
	8	06FEB97	57, .	3	0	0	0	0	0	2	2	2	1	0	1	1	0	0	0	0	12	-7.7	NO	NO
329.005.00335	SC	20FEB97	-8, .	3	0	1	0	2	2	2	2	1	1	0	1	1	0	0	0	0	16	.		
	BL	28FEB97	1, .	3	0	0	2	2	1	3	1	2	1	0	1	1	0	0	0	0	17	.		
	1	07MAR97	8, .	4	0	0	0	1	2	2	1	3	1	0	0	1	0	0	1	0	16	-5.9	NO	NO
	2	14MAR97	15, .	1	0	0	0	1	1	1	2	1	1	0	1	1	0	0	0	0	10	-41.2	NO	NO
	3	21MAR97	22, .	2	0	0	0	0	0	0	0	1	1	0	1	0	0	0	2	0	7	-58.8	YES	YES
	4	27MAR97	28, .	3	0	0	2	1	0	2	2	1	1	0	1	0	0	0	0	0	13	-23.5	NO	NO
	5	03APR97	35, .	1	0	0	1	1	0	2	1	2	1	0	1	1	0	0	0	0	11	-35.3	NO	NO
	6	10APR97	42, .	1	1	0	2	2	0	0	2	1	0	0	1	0	0	0	0	0	10	-41.2	NO	NO
	7	17APR97	49, .	2	0	0	2	2	0	2	1	2	1	0	1	1	0	0	0	0	14	-17.6	NO	NO
	8	24APR97	56, .	2	0	0	2	2	0	1	2	2	1	0	1	1	0	0	0	0	14	-17.6	NO	NO
329.006.00040	SC	10FEB95	-6, .	3	2	1	2	2	1	3	0	2	3	1	2	0	0	1	0	1	24	.		
	BL	15FEB95	-1, .	3	2	0	2	2	1	1	0	1	2	1	0	1	0	0	0	1	17	.		
	1	22FEB95	7, .	3	1	1	0	0	0	2	0	0	3	0	1	2	2	0	0	0	15	-11.8	NO	NO
	2	01MAR95	14, .	1	0	0	0	0	0	3	1	1	2	2	2	2	0	1	0	0	15	-11.8	NO	NO
329.006.00041	SC	22MAR95	-14, -78	3	0	1	2	1	1	1	1	2	3	2	0	2	0	2	0	0	21	.		
	BL	05APR95	1, -64	1	0	0	2	0	0	2	1	0	1	2	0	2	0	1	0	0	12	.		
	1	10APR95	6, -59	1	0	0	0	0	0	2	1	0	0	2	0	2	0	2	0	0	10	-16.7	NO	NO
	2	19APR95	15, -50	3	0	0	2	1	0	3	2	0	3	2	1	1	0	2	0	0	20	66.7	NO	NO
	3	24APR95	20, -45	2	0	0	2	1	0	3	1	2	2	1	2	2	0	2	1	0	21	75.0	NO	NO

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Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.006.00041	4	01MAY95	27, -38	3	0	0	2	2	1	2	1	0	2	1	0	2	2	2	0	0	20	66.7	NO	NO
	5	08MAY95	34, -31	1	0	0	0	0	0	1	1	0	0	2	1	0	1	1	0	0	8	-33.3	YES	YES
	6	15MAY95	41, -24	3	0	0	2	0	0	2	2	1	3	1	2	2	1	3	0	0	22	83.3	NO	NO
	7	24MAY95	50, -15	1	0	0	2	0	0	3	0	0	1	1	1	1	1	1	0	0	12	0.0	NO	NO
	8	31MAY95	57, -8	1	0	0	2	2	0	1	1	0	2	2	0	1	1	2	0	0	15	25.0	NO	NO
	12	05JUL95	92, 28	2	0	0	0	0	0	0	0	0	0	2	0	1	1	1	0	0	7	-41.7	YES	YES
	16	31JUL95	118, 54	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-91.7	YES	YES
	20	24AUG95	142, 78	0	0	0	2	2	2	0	1	0	0	2	0	0	0	0	0	0	9	-25.0	NO	NO
	24	21SEP95	170, 106	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	28	24OCT95	203, 139	2	0	0	2	2	0	1	1	0	1	0	2	1	0	0	0	0	12	0.0	NO	NO
	32	21NOV95	231, 167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.007.00139	SC	04MAY95	-4, .	3	1	0	0	0	0	1	0	2	2	0	0	2	1	1	0	1	14	.		
	BL	05MAY95	-3, .	3	1	0	0	0	0	1	0	2	2	0	0	2	1	1	0	1	14	.		
	1	18MAY95	11, .	1	0	0	0	0	0	1	1	2	1	2	0	0	1	1	1	1	12	-14.3	NO	NO
	2	25MAY95	18, .	2	0	0	0	0	0	1	1	1	1	2	0	1	0	0	0	0	9	-35.7	NO	NO
	6	19JUN95	43, .	0	0	0	0	0	0	0	0	2	0	2	0	1	1	0	0	2	8	-42.9	YES	YES
329.007.00143	SC	26OCT95	-14, .	4	1	0	2	1	0	3	3	0	3	2	0	1	0	2	0	0	22	.		
	BL	09NOV95	1, .	4	2	0	2	1	0	3	3	1	1	0	0	1	0	0	0	1	19	.		
	1	16NOV95	8, .	3	0	0	2	0	0	1	3	0	1	0	0	1	0	0	0	0	11	-42.1	NO	NO
	2	22NOV95	14, .	3	2	0	1	1	0	2	3	1	1	1	0	0	0	0	0	2	17	-10.5	NO	NO
329.007.00146	SC	18JAN96	-7, -60	3	1	1	0	0	0	3	2	2	1	1	0	1	0	1	0	1	17	.		
	BL	25JAN96	1, -53	3	2	0	0	0	0	2	2	2	2	1	0	0	0	1	1	1	17	.		
	1	01FEB96	8, -46	3	0	0	0	0	0	2	1	1	1	0	0	1	0	0	0	1	10	-41.2	NO	NO
	2	05FEB96	12, -42	2	1	0	1	0	0	1	1	1	0	1	0	1	0	1	0	0	10	-41.2	NO	NO
	3	12FEB96	19, -35	2	0	0	0	0	0	1	1	1	0	0	0	0	0	1	0	0	6	-64.7	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.007.00146	4	19FEB96	26, -28	1	1	0	1	0	0	0	1	1	0	0	0	0	0	0	0	0	5	-70.6	YES	YES
	5	26FEB96	33, -21	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-94.1	YES	YES
	6	04MAR96	40, -14	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-94.1	YES	YES
	7	11MAR96	47, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	18MAR96	54, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	15APR96	82, 29	2	1	0	1	0	0	2	2	2	2	0	0	0	0	0	0	0	12	-29.4	NO	NO
	16	13MAY96	110, 57	1	0	0	0	0	0	1	0	2	0	0	0	0	0	0	0	0	4	-76.5	YES	YES
	20	06JUN96	134, 81	0	1	0	0	0	0	1	0	1	1	0	0	0	0	0	0	1	5	-70.6	YES	YES
	24	08JUL96	166, 113	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	28	05AUG96	194, 141	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	09SEP96	229, 176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.007.00269	SC	04APR96	-7, .	3	2	2	1	1	2	4	0	2	3	0	0	0	0	0	0	2	22	.		
	BL	11APR96	1, .	3	0	1	2	0	0	4	1	3	3	0	0	0	0	0	1	0	18	.		
	1	18APR96	8, .	3	1	0	1	1	0	3	1	2	2	0	0	1	0	0	1	2	18	0.0	NO	NO
	2	25APR96	15, .	2	1	0	0	0	0	2	0	1	0	0	0	0	0	0	0	2	8	-55.6	YES	YES
329.007.00270	SC	02MAY96	-7, .	3	2	0	0	1	0	3	2	0	2	0	0	1	0	0	0	0	14	.		
	BL	09MAY96	1, .	3	1	0	2	1	1	3	2	0	1	2	0	1	0	0	0	0	17	.		
	1	16MAY96	8, .	3	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1	8	-52.9	YES	YES
	2	23MAY96	15, .	1	0	0	0	0	0	1	1	0	0	1	0	0	0	0	0	0	4	-76.5	YES	YES
	3	30MAY96	22, .	1	0	0	1	0	0	1	1	0	0	0	0	2	0	0	1	0	7	-58.8	YES	YES
	4	06JUN96	29, .	0	0	0	0	0	1	0	0	0	1	1	1	0	0	0	0	0	4	-76.5	YES	YES
	5	13JUN96	36, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	6	20JUN96	43, .	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	-94.1	YES	YES
329.007.00307	SC	09MAY96	-7, .	3	2	0	2	2	1	3	1	1	3	1	1	1	0	2	0	0	23	.		
	BL	16MAY96	1, .	4	0	0	2	1	0	3	0	2	3	1	0	1	0	1	0	0	18	.		

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.007.00307	1	23MAY96	8, .	2	2	0	2	2	2	2	0	1	3	1	0	1	0	0	0	0	18	0.0	NO	NO
	2	30MAY96	15, .	2	0	0	2	2	1	0	0	2	1	2	0	1	0	0	0	0	13	-27.8	NO	NO
	3	06JUN96	22, .	1	1	0	2	2	2	1	0	2	2	1	0	1	0	0	0	0	15	-16.7	NO	NO
	4	13JUN96	29, .	0	0	0	1	1	0	1	0	1	0	0	0	0	0	0	0	0	4	-77.8	YES	YES
	5	20JUN96	36, .	0	0	0	0	1	0	0	0	2	0	0	0	0	0	0	0	0	3	-83.3	YES	YES
329.007.00308	SC	27JUN96	-5, .	3	1	0	1	0	0	2	3	0	1	0	0	0	0	0	0	2	13	.		
	BL	02JUL96	1, .	3	1	0	0	0	0	2	2	1	3	0	0	0	0	0	0	1	13	.		
329.008.00159	SC	06SEP95	-7, -69	2	1	2	2	1	0	2	1	1	1	1	1	1	0	0	1	0	17	.		
	BL	13SEP95	1, -62	2	0	1	2	1	1	3	2	0	1	0	0	1	0	0	0	0	14	.		
	1	19SEP95	7, -56	1	0	1	1	2	2	2	1	1	1	0	0	1	0	0	0	0	13	-7.1	NO	NO
	2	27SEP95	15, -48	1	0	0	0	0	1	1	1	0	0	0	0	1	0	1	0	0	6	-57.1	YES	YES
	3	03OCT95	21, -42	1	0	0	1	1	1	1	1	0	2	1	0	1	0	1	0	0	11	-21.4	NO	NO
	4	10OCT95	28, -35	2	1	0	0	2	2	1	1	1	2	1	0	1	0	1	0	0	15	7.1	NO	NO
	5	16OCT95	34, -29	1	0	2	0	1	1	0	0	1	0	1	0	1	0	1	0	0	9	-35.7	NO	NO
	6	24OCT95	42, -21	1	0	1	0	0	1	0	1	1	0	1	1	1	0	1	0	0	9	-35.7	NO	NO
	7	31OCT95	49, -14	1	1	1	1	1	1	0	1	0	0	1	0	1	0	1	0	0	10	-28.6	NO	NO
	8	14NOV95	63, 1	2	0	2	0	2	1	0	0	0	1	1	0	1	0	1	0	0	11	-21.4	NO	NO
	16	26DEC95	105, 43	1	1	0	1	0	0	1	1	1	0	0	0	0	0	1	0	0	7	-50.0	YES	YES
	20	23JAN96	133, 71	1	1	1	1	0	1	1	1	0	0	0	0	1	0	1	0	0	9	-35.7	NO	NO
329.008.00161	SC	31OCT95	-16, -71	1	2	2	2	1	0	3	2	1	2	0	0	1	0	0	0	0	17	.		
	BL	16NOV95	1, -55	1	2	0	0	0	0	3	0	3	2	0	0	1	0	1	0	0	13	.		
	1	22NOV95	7, -49	1	0	0	1	1	1	1	0	1	1	1	1	0	0	0	0	0	9	-30.8	NO	NO
	2	29NOV95	14, -42	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	3	-76.9	YES	YES
	3	07DEC95	22, -34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	4	15DEC95	30, -26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
\# Response is defined as a HAMD total of less than or equal to 8 OR a decrease from baseline in HAMD total score of 50% or greater.
\+ Remission is defined as a HAMD total of less than or equal to 8.

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.008.00161	6	27DEC95	42, -14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	-92.3	YES	YES
	7	03JAN96	49, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	10JAN96	56, 1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
329.008.00187	SC	15NOV95	-14, .	4	0	2	2	2	0	3	3	0	3	1	0	2	0	2	0	0	24	.		
	BL	29NOV95	1, .	3	0	2	2	2	0	3	3	0	1	0	1	1	0	1	0	0	19	.		
	1	07DEC95	9, .	1	2	2	0	1	1	3	1	1	2	2	0	1	0	2	0	0	19	0.0	NO	NO
	2	14DEC95	16, .	2	0	1	1	0	0	1	1	1	0	1	0	1	0	2	0	0	11	-42.1	NO	NO
	3	21DEC95	23, .	1	0	2	2	2	0	2	1	1	1	1	1	1	0	1	0	0	16	-15.8	NO	NO
	4	28DEC95	30, .	3	1	2	0	2	0	0	1	0	2	0	1	2	0	3	0	0	17	-10.5	NO	NO
	5	04JAN96	37, .	2	1	2	2	1	0	3	1	1	2	2	0	1	0	2	0	0	20	5.3	NO	NO
	6	11JAN96	44, .	1	0	2	2	1	0	2	1	0	2	2	0	2	0	2	0	0	17	-10.5	NO	NO
	7	18JAN96	51, .	1	0	2	2	2	1	1	1	0	1	2	1	2	0	2	0	0	18	-5.3	NO	NO
	8	26JAN96	59, .	1	1	1	2	1	0	1	1	0	2	1	0	1	0	2	0	0	14	-26.3	NO	NO
329.008.00192	SC	14FEB96	-20, .	2	1	0	1	0	0	3	1	1	1	2	1	1	0	0	0	0	14	.		
	BL	05MAR96	1, .	2	2	0	1	1	0	3	0	4	2	0	0	0	0	0	0	0	15	.		
	1	11MAR96	7, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	2	18MAR96	14, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	3	25MAR96	21, .	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0	0	0	3	-80.0	YES	YES
	4	03APR96	30, .	0	0	0	1	1	1	1	0	0	0	1	0	1	0	0	0	0	6	-60.0	YES	YES
	5	12APR96	39, .	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-93.3	YES	YES
329.008.00272	SC	19MAR96	-15, -71	2	1	0	0	0	0	3	2	1	1	1	0	1	0	0	0	0	12	.		
	BL	03APR96	1, -56	2	1	0	0	0	0	3	2	2	2	1	0	2	0	0	0	0	15	.		
	1	10APR96	8, -49	1	0	0	1	0	0	1	0	0	0	1	0	0	0	1	0	0	5	-66.7	YES	YES
	2	17APR96	15, -42	0	0	0	0	0	0	1	1	0	0	0	0	1	0	1	1	0	5	-66.7	YES	YES
	3	26APR96	24, -33	0	0	0	0	0	0	1	0	0	0	0	0	1	0	1	0	0	3	-80.0	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.008.00272	4	01MAY96	29, -28	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	2	-86.7	YES	YES
	5	07MAY96	35, -22	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	0	0	3	-80.0	YES	YES
	7	22MAY96	50, -7	0	2	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	5	-66.7	YES	YES
	8	29MAY96	57, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	-93.3	YES	YES
	12	26JUN96	85, 29	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	2	-86.7	YES	YES
	16	24JUL96	113, 57	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	20	21AUG96	141, 85	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	-86.7	YES	YES
	24	18SEP96	169, 113	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	2	-86.7	YES	YES
329.008.00273	SC	19APR96	-28, -91	2	0	0	2	1	0	1	1	0	3	3	0	2	0	0	0	0	15	.		
	BL	17MAY96	1, -63	2	2	1	2	0	0	3	2	0	3	1	0	2	0	0	0	0	18	.		
	1	24MAY96	8, -56	1	0	0	0	0	1	0	1	1	0	0	1	2	0	0	0	1	8	-55.6	YES	YES
	2	31MAY96	15, -49	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	1	5	-72.2	YES	YES
	3	10JUN96	25, -39	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	1	3	-83.3	YES	YES
	4	17JUN96	32, -32	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1	4	-77.8	YES	YES
	5	24JUN96	39, -25	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	1	3	-83.3	YES	YES
	6	01JUL96	46, -18	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	1	3	-83.3	YES	YES
	8	11JUL96	56, -8	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	1	3	-83.3	YES	YES
	8	19JUL96	64, 1	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	2	-88.9	YES	YES
	16	04SEP96	111, 48	0	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0	1	4	-77.8	YES	YES
329.009.00127	SC	03APR95	-7, .	3	2	3	2	2	1	4	3	1	4	3	1	1	1	3	1	0	35	.		
	BL	10APR95	1, .	4	2	2	2	2	0	4	2	1	2	3	1	1	0	2	0	1	29	.		
	1	17APR95	8, .	3	2	2	0	0	0	4	2	1	3	2	1	1	1	3	1	0	26	-10.3	NO	NO
	2	24APR95	15, .	2	0	0	2	0	0	2	1	0	1	1	0	1	1	2	0	0	13	-55.2	YES	NO
	3	01MAY95	22, .	2	0	0	2	0	0	3	1	0	2	2	1	2	1	2	0	0	18	-37.9	NO	NO
	4	08MAY95	29, .	1	0	0	0	2	1	2	1	0	2	1	1	1	0	1	0	0	13	-55.2	YES	NO
	5	15MAY95	36, .	1	0	0	0	1	1	2	2	0	2	1	1	1	0	1	0	0	13	-55.2	YES	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00132	SC	17MAY95	-6, -63	3	0	0	2	0	0	4	0	1	2	1	0	1	0	0	0	1	15	.		
	BL	23MAY95	1, -57	3	1	2	2	1	1	3	2	1	1	1	1	1	0	1	0	1	22	.		
	1	30MAY95	8, -50	1	1	1	1	1	1	3	1	1	1	1	1	1	0	1	0	1	17	-22.7	NO	NO
	2	06JUN95	15, -43	1	1	0	2	1	1	1	2	1	1	1	0	0	0	0	0	0	12	-45.5	NO	NO
	3	13JUN95	22, -36	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	-90.9	YES	YES
	4	20JUN95	29, -29	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.5	YES	YES
	5	27JUN95	36, -22	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.5	YES	YES
	6	05JUL95	44, -14	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.5	YES	YES
	7	11JUL95	50, -8	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.5	YES	YES
	8	19JUL95	58, 1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.5	YES	YES
	12	24AUG95	94, 37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	15SEP95	116, 59	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	3	-86.4	YES	YES
	20	24OCT95	155, 98	3	1	1	2	1	1	2	2	1	1	1	1	1	0	1	1	0	20	-9.1	NO	NO
329.009.00134	SC	28JUN95	-8, .	3	2	3	0	0	2	3	1	1	3	2	0	2	1	2	0	0	25	.		
	BL	06JUL95	1, .	4	2	1	2	2	1	3	2	1	3	2	0	1	0	2	0	0	26	.		
	1	14JUL95	9, .	3	2	2	1	1	0	3	2	2	2	2	1	1	0	1	0	0	23	-11.5	NO	NO
	2	19JUL95	14, .	3	2	2	1	1	0	3	2	2	2	2	1	1	0	1	0	0	23	-11.5	NO	NO
	3	26JUL95	21, .	2	1	1	0	0	0	2	2	1	1	1	0	1	0	1	0	0	13	-50.0	YES	NO
	4	03AUG95	29, .	2	1	0	0	0	0	3	1	1	1	2	1	1	0	1	0	0	14	-46.2	NO	NO
	5	08AUG95	34, .	2	0	0	0	0	0	2	1	1	1	1	0	1	0	0	0	0	9	-65.4	YES	NO
	6	15AUG95	41, .	1	0	0	1	1	0	0	1	1	0	1	0	1	0	0	0	0	7	-73.1	YES	YES
	7	24AUG95	50, .	1	0	0	0	0	0	1	1	0	1	2	0	0	0	0	0	0	6	-76.9	YES	YES
	8	29AUG95	55, .	3	1	2	0	1	0	0	1	1	2	1	0	1	0	1	0	0	14	-46.2	NO	NO
329.009.00137	SC	03OCT95	-7, .	1	1	3	2	0	0	4	0	3	1	0	0	0	1	0	0	2	18	.		
	BL	10OCT95	1, .	3	0	1	2	1	1	1	1	2	2	2	1	1	0	0	0	0	18	.		
	1	17OCT95	8, .	2	1	1	1	1	2	2	1	2	2	2	1	1	0	1	0	0	20	11.1	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00137	2	24OCT95	15, .	1	1	1	1	1	1	2	2	2	1	1	1	1	0	1	0	0	17	-5.6	NO	NO
	3	31OCT95	22, .	3	1	1	0	1	1	1	2	2	2	1	0	1	0	1	0	0	17	-5.6	NO	NO
	4	07NOV95	29, .	1	1	0	0	1	0	2	1	2	1	1	1	0	0	1	0	0	12	-33.3	NO	NO
	5	14NOV95	36, .	1	1	0	0	0	0	1	2	2	1	1	0	1	0	0	0	0	10	-44.4	NO	NO
	6	21NOV95	43, .	1	1	0	0	0	0	1	1	1	1	1	0	0	0	1	0	0	8	-55.6	YES	YES
	7	28NOV95	50, .	1	0	0	0	1	0	0	1	2	1	0	0	0	0	0	1	0	7	-61.1	YES	YES
	8	05DEC95	57, .	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	5	-72.2	YES	YES
329.009.00171	SC	31OCT95	-7, .	4	2	3	1	0	0	4	0	3	2	1	1	1	0	1	2	0	25	.		
	BL	07NOV95	1, .	3	1	1	1	1	0	3	2	2	3	2	1	1	0	2	2	0	25	.		
	1	14NOV95	8, .	3	1	2	1	1	1	2	1	2	2	2	1	1	0	1	0	0	21	-16.0	NO	NO
329.009.00172	SC	06NOV95	-7, -64	3	2	1	2	1	0	3	2	1	2	1	1	0	0	1	1	1	22	.		
	BL	13NOV95	1, -57	3	2	1	2	1	1	3	1	2	2	1	0	0	0	1	1	1	22	.		
	1	20NOV95	8, -50	3	1	0	1	1	1	3	1	0	2	1	0	0	0	1	1	1	17	-22.7	NO	NO
	2	27NOV95	15, -43	3	2	1	2	1	2	2	1	1	2	1	1	0	0	1	0	1	21	-4.5	NO	NO
	3	04DEC95	22, -36	3	2	0	1	1	0	2	1	1	2	1	0	2	0	0	0	0	16	-27.3	NO	NO
	4	11DEC95	29, -29	2	2	0	1	1	0	2	1	1	2	1	0	1	0	1	0	0	15	-31.8	NO	NO
	5	21DEC95	39, -19	1	1	0	0	0	0	1	1	1	2	2	0	1	0	0	0	0	10	-54.5	YES	NO
	6	27DEC95	45, -13	0	1	0	2	0	2	0	0	2	0	2	0	1	0	2	0	0	12	-45.5	NO	NO
	7	03JAN96	52, -6	1	1	0	0	0	0	1	0	1	2	1	0	0	0	1	0	0	8	-63.6	YES	YES
	8	09JAN96	58, 1	1	2	0	0	0	0	1	1	1	2	1	0	1	0	1	0	0	11	-50.0	YES	NO
	12	07FEB96	87, 30	0	1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	-86.4	YES	YES
	16	04MAR96	113, 56	1	2	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	5	-77.3	YES	YES
	20	01APR96	141, 84	0	1	0	0	2	0	1	0	1	0	0	0	0	0	0	0	0	5	-77.3	YES	YES
	24	29APR96	169, 112	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	-90.9	YES	YES
	28	10JUN96	211, 154	0	1	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	3	-86.4	YES	YES
	32	08JUL96	239, 182	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-95.5	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00194	SC	28NOV95	-7, -63	3	2	2	2	0	0	3	0	3	1	1	0	1	0	1	0	1	20	.		
	BL	05DEC95	1, -56	4	1	1	2	1	0	3	2	2	2	2	0	2	0	2	0	1	25	.		
	1	12DEC95	8, -49	4	1	1	2	1	0	3	2	1	2	2	0	1	0	2	0	1	23	-8.0	NO	NO
	2	19DEC95	15, -42	3	1	1	1	1	0	3	2	1	2	2	0	1	0	1	0	1	20	-20.0	NO	NO
	3	27DEC95	23, -34	3	1	1	0	1	0	2	2	1	2	2	1	1	0	1	0	1	19	-24.0	NO	NO
	4	02JAN96	29, -28	2	2	2	0	1	1	2	2	2	1	2	0	1	0	1	1	0	20	-20.0	NO	NO
	5	09JAN96	36, -21	3	1	1	1	2	1	2	1	1	1	1	0	2	0	2	0	2	21	-16.0	NO	NO
	6	16JAN96	43, -14	2	2	1	1	1	1	2	2	1	1	1	0	1	0	0	0	0	16	-36.0	NO	NO
	7	23JAN96	50, -7	1	1	1	1	1	0	1	2	1	1	1	0	0	0	0	0	0	11	-56.0	YES	NO
	8	30JAN96	57, 1	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	0	0	3	-88.0	YES	YES
	12	27FEB96	85, 29	0	0	0	2	0	0	0	1	0	1	0	0	0	0	0	0	0	4	-84.0	YES	YES
	16	02APR96	120, 64	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	-92.0	YES	YES
	20	30APR96	148, 92	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	-92.0	YES	YES
	24	04JUN96	183, 127	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-96.0	YES	YES
329.009.00195	SC	06DEC95	-9, .	4	2	3	2	1	0	2	0	3	2	2	2	0	0	2	2	0	27	.		
	BL	15DEC95	1, .	4	2	1	2	2	1	3	2	1	2	2	2	1	0	2	2	1	30	.		
	1	19DEC95	5, .	3	1	1	2	1	0	2	2	2	2	1	2	1	0	1	1	1	23	-23.3	NO	NO
	2	27DEC95	13, .	1	1	0	0	0	0	1	1	1	1	0	1	1	0	1	1	0	10	-66.7	YES	NO
	3	02JAN96	19, .	1	1	0	0	0	0	1	1	1	1	1	1	1	0	1	0	1	11	-63.3	YES	NO
	3	08JAN96	25, .	1	1	0	0	0	0	1	1	1	1	2	1	2	0	1	0	0	12	-60.0	YES	NO
329.009.00199	SC	10JAN96	-6, .	4	3	3	2	0	1	3	2	1	2	0	1	1	0	2	1	0	26	.		
	BL	16JAN96	1, .	3	2	3	1	2	0	3	0	2	2	1	1	1	0	0	1	0	22	.		
	1	23JAN96	8, .	2	2	1	1	0	2	2	0	2	2	2	1	1	0	1	0	0	19	-13.6	NO	NO
	2	29JAN96	14, .	3	2	2	2	1	0	2	0	2	2	1	1	0	0	0	0	0	18	-18.2	NO	NO
	3	07FEB96	23, .	2	2	1	1	0	2	2	1	2	1	1	1	1	1	1	0	0	19	-13.6	NO	NO
	4	14FEB96	30, .	3	2	0	2	2	0	2	2	2	2	2	1	1	0	1	1	0	23	4.5	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00199	5	21FEB96	37, .	2	2	0	1	1	0	1	1	2	2	1	0	0	0	1	1	0	15	-31.8	NO	NO
	6	28FEB96	44, .	3	1	0	2	1	0	2	1	2	2	2	0	1	0	0	0	0	17	-22.7	NO	NO
	7	06MAR96	51, .	3	1	0	0	0	0	3	2	2	1	1	1	0	0	0	0	0	14	-36.4	NO	NO
	8	13MAR96	58, .	3	2	0	1	0	2	2	1	2	1	2	0	0	0	0	1	0	17	-22.7	NO	NO
329.009.00203	SC	28FEB96	-5, .	3	1	0	2	2	0	4	2	0	2	1	2	1	0	0	1	1	22	.		
	BL	04MAR96	1, .	3	1	0	2	2	0	4	2	1	1	1	2	1	0	0	1	1	22	.		
	1	11MAR96	8, .	3	1	0	1	2	1	3	2	1	1	2	2	2	0	1	2	1	25	13.6	NO	NO
	2	19MAR96	16, .	3	1	0	1	1	1	3	2	1	1	1	2	1	0	1	1	0	20	-9.1	NO	NO
	3	26MAR96	23, .	2	1	0	0	0	0	2	1	0	1	0	1	1	0	0	0	0	9	-59.1	YES	NO
329.009.00236	SC	17DEC96	-13, .	2	1	2	0	0	0	3	1	3	1	2	0	2	0	0	0	0	17	.		
	BL	30DEC96	1, .	4	1	1	0	1	1	3	2	1	1	0	2	2	0	1	0	1	21	.		
	1	06JAN97	8, .	3	1	1	1	1	1	2	2	1	1	0	2	2	0	0	1	1	20	-4.8	NO	NO
	2	15JAN97	17, .	3	1	1	1	1	0	2	2	1	1	0	2	2	0	1	1	1	20	-4.8	NO	NO
	3	20JAN97	22, .	3	1	1	0	1	0	2	2	1	1	0	2	2	0	1	0	1	18	-14.3	NO	NO
	4	27JAN97	29, .	3	1	1	1	1	1	3	2	1	1	0	2	2	0	1	1	0	21	0.0	NO	NO
329.009.00239	SC	11NOV96	-8, -65	1	1	1	0	2	0	3	1	2	2	1	0	2	0	0	0	0	16	.		
	BL	18NOV96	-1, -58	3	1	1	0	1	1	2	2	1	1	1	0	2	0	1	0	0	17	.		
	1	25NOV96	7, -51	3	1	1	0	1	1	2	2	1	1	0	0	1	0	1	0	0	15	-11.8	NO	NO
	2	02DEC96	14, -44	0	0	0	1	1	0	1	1	1	1	1	1	2	0	0	1	2	13	-23.5	NO	NO
	3	09DEC96	21, -37	1	0	0	0	1	0	1	1	2	1	1	0	0	0	0	0	0	8	-52.9	YES	YES
	4	16DEC96	28, -30	0	0	0	0	0	0	0	1	0	1	0	0	1	0	0	0	0	3	-82.4	YES	YES
	5	23DEC96	35, -23	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-94.1	YES	YES
	6	30DEC96	42, -16	1	0	0	0	2	0	0	0	0	0	0	0	2	0	1	0	0	6	-64.7	YES	YES
	7	06JAN97	49, -9	2	0	0	0	0	0	1	1	0	1	0	0	1	0	1	0	0	7	-58.8	YES	YES
	8	15JAN97	58, 1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0	3	-82.4	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00239	12	18FEB97	92, 35	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-88.2	YES	YES
	16	17MAR97	119, 62	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-88.2	YES	YES
	20	14APR97	147, 90	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-94.1	YES	YES
	24	12MAY97	175, 118	3	2	1	1	1	0	2	2	2	1	1	2	2	0	0	0	1	21	23.5	NO	NO
329.009.00262	SC	07FEB97	-10, .	3	2	2	0	0	0	2	2	0	2	2	2	2	1	0	0	0	20	.		
	BL	17FEB97	1, .	3	1	2	1	0	0	2	2	1	2	1	0	1	0	0	0	1	17	.		
	1	24FEB97	8, .	3	1	0	0	0	0	2	2	0	1	0	2	2	0	0	0	1	14	-17.6	NO	NO
	2	03MAR97	15, .	2	1	0	0	1	1	1	1	1	1	0	1	0	0	1	0	1	12	-29.4	NO	NO
	3	07MAR97	19, .	1	0	0	0	0	0	1	1	1	1	1	1	2	0	0	1	0	10	-41.2	NO	NO
	4	17MAR97	29, .	2	1	0	0	0	0	1	2	0	1	0	1	2	0	1	1	1	13	-23.5	NO	NO
	5	24MAR97	36, .	3	1	1	0	0	0	2	2	1	3	0	1	1	0	0	1	0	16	-5.9	NO	NO
	6	31MAR97	43, .	3	1	0	0	0	0	2	2	1	1	0	1	1	0	0	1	1	14	-17.6	NO	NO
	7	07APR97	50, .	3	2	1	0	0	0	3	2	2	2	0	1	0	0	1	1	0	18	5.9	NO	NO
	8	14APR97	57, .	4	2	1	0	0	0	3	2	1	2	1	2	1	0	1	1	1	22	29.4	NO	NO
329.009.00264	SC	25OCT96	-7, .	1	1	0	0	1	1	4	1	0	2	2	1	2	0	0	0	1	17	.		
	BL	01NOV96	1, .	3	1	0	2	2	0	3	2	0	1	1	0	2	0	0	0	2	19	.		
	1	08NOV96	8, .	3	1	0	1	0	0	3	2	1	1	1	0	2	0	0	1	2	18	-5.3	NO	NO
	1	11NOV96	11, .	3	1	0	1	0	0	2	2	4	2	1	1	2	0	0	0	2	21	10.5	NO	NO
	2	18NOV96	18, .	2	1	0	0	1	0	2	1	1	2	1	0	2	0	1	0	2	16	-15.8	NO	NO
	3	25NOV96	25, .	3	0	0	0	0	0	2	2	2	1	2	0	1	0	1	0	2	16	-15.8	NO	NO
	4	02DEC96	32, .	1	1	0	0	0	0	2	2	1	2	1	0	1	0	1	0	2	14	-26.3	NO	NO
	6	11DEC96	41, .	3	0	0	2	1	0	2	2	1	1	0	0	1	0	1	1	0	15	-21.1	NO	NO
	6	16DEC96	46, .	3	0	0	0	0	0	3	2	2	1	0	0	1	0	1	0	2	15	-21.1	NO	NO
	7	23DEC96	53, .	3	1	0	0	0	0	3	2	1	1	0	1	1	0	1	0	2	16	-15.8	NO	NO
329.009.00301	SC	06MAR96	-13, -69	3	1	2	2	1	1	3	2	2	2	2	1	2	1	0	0	2	27	.		

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00301	BL	19MAR96	1, -56	3	1	1	1	2	1	2	2	1	1	0	2	1	0	0	1	2	21	.		
	1	26MAR96	8, -49	3	1	1	1	2	0	2	2	1	1	0	1	1	0	0	0	2	18	-14.3	NO	NO
	2	05APR96	18, -39	4	2	1	1	1	1	3	2	1	1	2	1	1	0	0	1	1	23	9.5	NO	NO
	3	12APR96	25, -32	3	1	1	1	1	0	4	2	1	2	2	2	2	0	2	0	1	25	19.0	NO	NO
	4	16APR96	29, -28	2	1	0	1	0	0	2	2	1	1	1	1	1	0	2	0	1	16	-23.8	NO	NO
	5	23APR96	36, -21	2	1	0	0	0	0	2	2	1	1	1	0	1	0	2	1	0	14	-33.3	NO	NO
	6	30APR96	43, -14	1	1	0	0	0	0	1	2	1	1	1	0	1	0	1	0	0	10	-52.4	YES	NO
	7	07MAY96	50, -7	1	1	0	0	0	0	1	1	0	0	0	0	0	0	1	0	1	6	-71.4	YES	YES
	8	14MAY96	57, 1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	0	3	-85.7	YES	YES
	12	11JUN96	85, 29	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.2	YES	YES
329.009.00305	SC	01MAY96	-6, -63	3	2	1	1	0	0	3	2	2	3	2	1	1	1	1	1	1	25	.		
	BL	07MAY96	1, -57	3	1	0	2	1	0	3	3	1	3	2	1	2	0	0	2	1	25	.		
	1	14MAY96	8, -50	3	1	0	2	0	0	3	2	1	3	1	1	1	0	1	1	1	21	-16.0	NO	NO
	2	21MAY96	15, -43	3	1	0	2	0	0	3	3	1	3	1	1	2	0	1	2	1	24	-4.0	NO	NO
	3	28MAY96	22, -36	3	1	0	2	0	0	3	3	0	3	1	0	2	0	1	0	1	20	-20.0	NO	NO
	4	04JUN96	29, -29	3	1	0	2	0	0	3	2	0	3	0	0	1	0	1	0	1	17	-32.0	NO	NO
	5	11JUN96	36, -22	3	1	0	1	0	0	3	2	1	1	0	0	2	0	1	0	1	16	-36.0	NO	NO
	6	19JUN96	44, -14	3	1	0	1	1	0	1	1	0	3	0	0	1	0	0	0	0	12	-52.0	YES	NO
	7	25JUN96	50, -8	1	1	0	1	0	0	1	1	0	1	0	0	1	0	0	0	0	7	-72.0	YES	YES
	8	03JUL96	58, 1	1	0	0	0	0	0	1	1	1	1	1	0	2	0	0	0	1	9	-64.0	YES	NO
	12	06AUG96	92, 35	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-96.0	YES	YES
	16	27AUG96	113, 56	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0	3	-88.0	YES	YES
	20	24SEP96	141, 84	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-96.0	YES	YES
	24	29OCT96	176, 119	1	1	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0	7	-72.0	YES	YES
	28	03DEC96	211, 154	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-96.0	YES	YES
	32	10JAN97	249, 192	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-96.0	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00325	SC	21AUG96	-6, -61	2	1	2	2	2	0	3	1	2	2	1	2	2	0	0	2	0	24	.		
	BL	27AUG96	1, -55	2	2	2	2	2	1	3	1	2	2	1	2	2	1	0	1	1	27	.		
	1	03SEP96	8, -48	3	1	1	2	1	2	2	1	1	1	2	2	2	1	2	1	1	26	-3.7	NO	NO
	2	09SEP96	14, -42	3	2	1	1	1	1	3	1	1	2	2	2	2	1	1	0	0	24	-11.1	NO	NO
	3	16SEP96	21, -35	2	1	1	2	1	1	3	1	1	2	1	0	0	1	1	0	1	19	-29.6	NO	NO
	4	23SEP96	28, -28	1	1	0	0	1	1	2	1	1	0	1	1	2	0	1	0	0	13	-51.9	YES	NO
	5	30SEP96	35, -21	1	0	0	0	1	1	1	0	1	1	0	0	0	0	0	1	0	7	-74.1	YES	YES
	6	10OCT96	45, -11	1	0	0	0	2	2	1	2	1	0	0	2	2	0	1	1	0	15	-44.4	NO	NO
	7	14OCT96	49, -7	1	0	0	0	2	2	1	1	1	1	0	1	1	0	1	0	1	13	-51.9	YES	NO
	8	21OCT96	56, 1	0	0	0	1	1	0	1	1	1	1	0	0	2	0	0	0	0	8	-70.4	YES	YES
	12	18NOV96	84, 29	1	0	1	0	2	1	2	1	1	1	0	0	0	0	0	0	0	10	-63.0	YES	NO
	16	16DEC96	112, 57	4	2	1	0	2	1	3	2	2	2	1	2	1	0	0	1	0	24	-11.1	NO	NO
329.009.00326	SC	26AUG96	-10, -63	3	2	2	2	2	2	3	2	1	2	1	0	2	1	0	0	0	25	.		
	BL	05SEP96	1, -53	3	2	2	2	1	1	3	1	1	2	2	0	2	0	1	0	1	24	.		
	1	09SEP96	5, -49	3	2	1	0	1	2	2	2	1	1	2	1	2	0	1	0	1	22	-8.3	NO	NO
	2	16SEP96	12, -42	1	1	0	0	1	0	2	1	1	0	1	1	0	0	1	1	1	12	-50.0	YES	NO
	3	23SEP96	19, -35	1	1	0	0	1	0	1	1	1	0	1	0	0	0	0	0	0	7	-70.8	YES	YES
	4	30SEP96	26, -28	1	0	0	0	0	1	1	1	1	0	1	0	1	0	0	1	0	8	-66.7	YES	YES
	5	07OCT96	33, -21	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	3	-87.5	YES	YES
	6	17OCT96	43, -11	1	0	0	1	0	0	0	1	1	1	1	0	2	0	0	0	0	8	-66.7	YES	YES
	7	24OCT96	50, -4	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	4	-83.3	YES	YES
	8	28OCT96	54, 1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	-91.7	YES	YES
	12	25NOV96	82, 29	3	1	0	2	0	1	2	2	0	1	0	1	0	0	0	1	0	14	-41.7	NO	NO
	16	16DEC96	103, 50	4	1	1	2	0	1	3	2	0	1	0	2	1	0	0	1	0	19	-20.8	NO	NO
329.010.00279	SC	08MAR96	-14, -70	3	0	0	0	1	0	3	2	0	1	0	2	2	0	0	1	0	15	.		
	BL	22MAR96	1, -56	3	0	0	1	0	0	3	2	0	1	0	2	2	0	0	1	0	15	.		

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.010.00279	1	29MAR96	8, -49	3	1	1	0	0	0	3	1	3	1	1	2	1	0	0	0	1	18	20.0	NO	NO
	2	05APR96	15, -42	3	0	0	0	0	0	3	0	2	0	0	2	0	0	1	0	1	12	-20.0	NO	NO
	3	12APR96	22, -35	3	1	2	1	0	0	3	1	2	1	1	2	0	0	0	0	1	18	20.0	NO	NO
	4	19APR96	29, -28	3	2	1	0	0	0	3	0	0	0	1	1	2	0	0	0	1	14	-6.7	NO	NO
	5	25APR96	35, -22	2	1	0	1	0	0	1	0	1	0	0	2	1	0	0	0	1	10	-33.3	NO	NO
	6	03MAY96	43, -14	3	0	0	2	0	0	2	0	1	2	1	2	1	0	0	0	1	15	0.0	NO	NO
	7	10MAY96	50, -7	1	0	0	1	0	0	2	0	1	0	0	1	0	0	0	0	0	6	-60.0	YES	YES
	8	17MAY96	57, 1	2	0	0	2	0	0	3	0	0	0	0	0	0	0	0	0	1	8	-46.7	YES	YES
	12	14JUN96	85, 29	3	0	0	0	0	0	3	0	1	0	0	0	0	0	0	0	1	8	-46.7	YES	YES
	16	11JUL96	112, 56	1	0	0	1	0	0	1	0	1	0	0	0	0	0	0	0	1	5	-66.7	YES	YES
	20	08AUG96	140, 84	3	0	0	2	0	0	3	1	1	1	0	0	0	0	0	0	1	12	-20.0	NO	NO
	24	05SEP96	168, 112	2	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1	7	-53.3	YES	YES
	28	02OCT96	195, 139	3	0	0	0	0	0	2	0	1	1	0	0	2	0	0	0	1	10	-33.3	NO	NO
	32	06NOV96	230, 174	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	3	-80.0	YES	YES
329.010.00281	SC	19JUL96	-7, -68	4	0	2	2	2	0	2	1	4	1	0	0	0	0	0	0	2	20	.		
	BL	26JUL96	1, -61	3	1	0	2	1	0	2	2	3	1	0	0	0	0	0	0	2	17	.		
	1	02AUG96	8, -54	3	0	0	2	1	0	2	2	2	0	0	0	0	0	0	0	2	14	-17.6	NO	NO
	2	09AUG96	15, -47	1	0	0	1	1	0	2	1	1	1	0	0	0	0	0	0	2	10	-41.2	NO	NO
	3	19AUG96	25, -37	1	0	0	1	1	0	1	1	1	0	0	0	0	0	0	1	2	9	-47.1	NO	NO
	4	26AUG96	32, -30	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1	2	7	-58.8	YES	YES
	6	04SEP96	41, -21	0	0	0	0	0	0	1	1	4	1	0	0	1	0	0	0	2	10	-41.2	NO	NO
	6	09SEP96	46, -16	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	2	6	-64.7	YES	YES
	8	18SEP96	55, -7	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1	4	-76.5	YES	YES
	8	25SEP96	62, 1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	2	-88.2	YES	YES
	12	25OCT96	92, 31	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	1	4	-76.5	YES	YES
	16	20NOV96	118, 57	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	1	3	-82.4	YES	YES
	20	20DEC96	148, 87	0	0	0	0	0	0	2	2	0	0	0	0	1	0	0	0	2	7	-58.8	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.010.00281	24	03JAN97	162, 101	0	0	0	0	0	0	3	2	2	0	0	0	2	0	0	0	2	11	-35.3	NO	NO
329.011.00163	SC	18NOV95	-7, .	2	0	3	1	0	0	2	0	0	2	2	0	1	0	3	1	0	17	.		
	BL	24NOV95	-1, .	2	0	1	1	0	0	3	0	1	2	2	0	1	0	3	1	0	17	.		
	1	01DEC95	7, .	2	0	2	0	0	0	2	0	2	2	2	0	2	0	3	1	0	18	5.9	NO	NO
	2	11DEC95	17, .	2	0	2	1	0	0	2	0	2	3	2	0	1	0	2	0	0	17	0.0	NO	NO
	3	18DEC95	24, .	2	0	0	1	0	0	2	0	2	2	1	1	1	0	2	2	0	16	-5.9	NO	NO
	5	27DEC95	33, .	2	0	0	1	0	0	2	0	3	3	2	1	2	0	3	0	0	19	11.8	NO	NO
329.011.00208	SC	22AUG96	-15, -74	3	2	3	2	2	0	1	0	0	4	2	1	2	0	2	0	0	24	.		
	BL	05SEP96	-1, -60	3	1	2	2	2	0	1	0	0	2	2	1	2	0	0	0	0	18	.		
	1	11SEP96	6, -54	3	2	2	1	1	0	2	0	1	2	1	1	2	0	0	0	0	18	0.0	NO	NO
	2	17SEP96	12, -48	3	0	0	2	2	1	1	0	0	2	1	1	1	0	0	0	0	14	-22.2	NO	NO
	3	26SEP96	21, -39	3	0	0	2	2	2	2	0	0	0	1	1	2	0	0	0	0	15	-16.7	NO	NO
	4	03OCT96	28, -32	3	0	1	0	0	0	2	0	0	2	0	1	1	0	0	1	0	11	-38.9	NO	NO
	5	10OCT96	35, -25	3	0	0	0	0	0	2	0	2	1	0	1	1	0	0	0	0	10	-44.4	NO	NO
	6	17OCT96	42, -18	0	0	0	0	0	0	2	0	0	1	1	0	1	0	0	0	0	5	-72.2	YES	YES
	7	24OCT96	49, -11	1	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	0	4	-77.8	YES	YES
	8	03NOV96	59, -1	0	0	0	0	0	0	1	1	0	1	0	1	1	0	0	0	0	5	-72.2	YES	YES
329.011.00209	SC	23AUG96	-19, -81	3	0	2	0	1	0	3	1	2	1	0	0	1	0	0	0	0	14	.		
	BL	10SEP96	-1, -63	3	0	1	0	0	0	2	2	2	1	1	0	1	0	0	0	0	13	.		
	1	19SEP96	9, -54	3	0	0	1	0	0	2	1	2	1	0	0	1	0	0	1	0	12	-7.7	NO	NO
	2	26SEP96	16, -47	3	0	0	0	0	0	1	1	2	0	0	0	1	0	1	1	0	10	-23.1	NO	NO
	3	03OCT96	23, -40	3	0	0	0	0	0	2	1	2	2	0	1	1	0	0	0	0	12	-7.7	NO	NO
	4	11OCT96	31, -32	0	0	0	0	0	0	1	1	1	0	0	1	1	0	0	0	0	5	-61.5	YES	YES
	5	17OCT96	37, -26	0	0	0	0	0	0	1	1	2	1	0	1	0	0	0	0	0	6	-53.8	YES	YES
	6	24OCT96	44, -19	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	3	-76.9	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.011.00209	7	01NOV96	52, -11	1	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0	0	6	-53.8	YES	YES
	8	11NOV96	62, -1	0	0	0	0	0	0	1	1	1	1	0	1	1	0	0	0	0	6	-53.8	YES	YES
	12	18DEC96	99, 37	1	0	0	1	1	0	1	1	1	1	0	1	1	0	0	1	0	10	-23.1	NO	NO
329.011.00284	SC	13MAR96	-9, -65	4	0	1	2	2	1	4	1	0	1	1	0	1	0	0	0	0	18	.		
	BL	21MAR96	-1, -57	3	0	0	2	0	0	4	2	0	2	1	1	1	0	0	1	0	17	.		
	1	28MAR96	7, -50	3	0	0	0	0	2	3	1	1	0	0	1	1	0	0	1	0	13	-23.5	NO	NO
	2	05APR96	15, -42	2	0	0	0	0	0	1	2	1	1	1	1	1	0	0	0	0	10	-41.2	NO	NO
	3	11APR96	21, -36	1	0	0	1	0	0	0	1	1	1	0	1	0	0	0	0	0	6	-64.7	YES	YES
	4	19APR96	29, -28	0	0	0	1	1	0	0	1	1	1	0	0	0	0	0	0	0	5	-70.6	YES	YES
	5	25APR96	35, -22	2	1	0	1	2	2	2	0	1	2	0	2	1	0	0	0	0	16	-5.9	NO	NO
	6	02MAY96	42, -15	1	1	0	0	0	2	1	1	0	1	0	0	1	0	0	1	0	9	-47.1	NO	NO
	7	09MAY96	49, -8	1	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	4	-76.5	YES	YES
	8	16MAY96	56, -1	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	1	0	3	-82.4	YES	YES
	12	10JUN96	81, 25	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	3	-82.4	YES	YES
	16	08JUL96	109, 53	1	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	4	-76.5	YES	YES
	20	05AUG96	137, 81	1	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0	0	6	-64.7	YES	YES
329.011.00286	SC	15MAY96	-22, -90	3	1	1	2	2	1	2	1	0	1	0	0	1	0	0	0	2	17	.		
	BL	05JUN96	-1, -69	3	0	0	2	1	0	3	1	2	1	1	0	1	0	0	0	1	16	.		
	1	14JUN96	9, -60	3	1	0	2	2	0	2	1	0	1	0	0	0	0	0	1	2	15	-6.3	NO	NO
	2	21JUN96	16, -53	3	1	0	0	0	0	2	1	1	2	0	0	1	0	0	0	2	13	-18.8	NO	NO
	3	28JUN96	23, -46	3	0	0	0	1	1	1	1	0	0	0	0	0	0	0	1	2	10	-37.5	NO	NO
	5	08JUL96	33, -36	3	0	0	0	0	0	1	1	2	2	0	0	1	0	0	0	2	12	-25.0	NO	NO
	6	17JUL96	42, -27	3	0	0	0	1	1	1	1	1	1	0	0	1	0	0	1	2	13	-18.8	NO	NO
	7	24JUL96	49, -20	3	0	0	0	0	0	1	1	1	1	0	0	1	0	0	1	2	11	-31.3	NO	NO
	8	02AUG96	58, -11	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	2	5	-68.8	YES	YES
	8	09AUG96	65, -4	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1	5	-68.8	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.011.00286	16	17SEP96	104, 36	0	0	0	1	1	1	1	0	1	0	0	0	0	0	0	0	0	5	-68.8	YES	YES
	20	24OCT96	141, 73	2	0	0	0	0	0	1	0	2	0	0	0	1	0	0	1	0	7	-56.3	YES	YES
	24	25NOV96	173, 105	0	0	0	0	0	0	1	1	2	1	0	0	1	0	0	0	1	7	-56.3	YES	YES
	28	30DEC96	208, 140	1	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	4	-75.0	YES	YES
329.012.00026	SC	09NOV95	-19, .	3	3	0	2	1	1	3	0	0	3	0	1	2	0	0	0	2	21	.		
	BL	28NOV95	1, .	4	3	0	2	1	0	3	0	0	4	0	2	0	0	0	0	2	21	.		
	1	05DEC95	8, .	2	2	1	2	1	0	2	0	1	1	0	0	1	0	0	0	2	15	-28.6	NO	NO
329.012.00219	SC	24MAY96	-7, -67	3	0	3	2	0	0	3	0	0	1	0	1	2	0	2	2	0	19	.		
	BL	31MAY96	1, -60	2	1	3	2	0	1	3	1	0	1	0	1	2	0	2	0	0	19	.		
	1	07JUN96	8, -53	2	0	0	1	0	1	1	0	2	1	0	0	1	0	0	0	0	9	-52.6	YES	NO
	2	14JUN96	15, -46	3	1	0	2	1	0	3	1	0	3	0	0	1	0	0	0	0	15	-21.1	NO	NO
	3	24JUN96	25, -36	1	1	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	4	-78.9	YES	YES
	5	02JUL96	33, -28	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	0	0	5	-73.7	YES	YES
	6	09JUL96	40, -21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	-94.7	YES	YES
	7	16JUL96	47, -14	0	2	0	2	2	0	0	0	0	3	0	0	0	0	0	0	0	9	-52.6	YES	NO
	8	23JUL96	54, -7	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	-89.5	YES	YES
	8	30JUL96	61, 1	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	-89.5	YES	YES
	12	30AUG96	92, 32	0	1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	-84.2	YES	YES
	16	26SEP96	119, 59	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-94.7	YES	YES
	20	25OCT96	148, 88	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	24	22NOV96	176, 116	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	-89.5	YES	YES
	28	20DEC96	204, 144	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	-89.5	YES	YES
	32	24JAN97	239, 179	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.012.00221	SC	18JUN96	-7, -70	4	3	2	2	2	1	4	0	4	4	0	2	1	0	0	0	0	29	.		
	BL	25JUN96	1, -63	4	3	3	2	2	1	4	0	4	4	0	2	2	0	0	0	0	31	.		

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.012.00221	1	02JUL96	8, -56	3	2	1	0	0	0	3	0	3	4	0	1	2	0	0	0	0	19	-38.7	NO	NO
	2	09JUL96	15, -49	3	2	2	1	2	0	2	1	3	3	1	0	2	0	0	1	0	23	-25.8	NO	NO
	3	16JUL96	22, -42	3	1	0	2	0	0	1	0	4	3	1	2	2	0	0	0	0	19	-38.7	NO	NO
	4	23JUL96	29, -35	3	2	0	0	2	2	1	0	4	4	0	0	1	0	0	0	0	19	-38.7	NO	NO
	5	30JUL96	36, -28	1	1	0	1	0	0	1	0	3	1	0	0	0	0	0	0	0	8	-74.2	YES	YES
	6	09AUG96	46, -18	1	2	0	0	0	0	0	0	3	4	0	0	2	0	0	0	0	12	-61.3	YES	NO
	8	19AUG96	56, -8	3	1	0	2	2	0	0	0	0	3	1	2	0	0	0	0	0	14	-54.8	YES	NO
	8	27AUG96	64, 1	3	1	0	2	0	0	0	0	2	2	2	0	0	1	0	0	0	13	-58.1	YES	NO
	12	23SEP96	91, 28	0	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	4	-87.1	YES	YES
	16	21OCT96	119, 56	1	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	5	-83.9	YES	YES
	20	04NOV96	133, 70	3	2	4	1	0	0	2	1	2	2	2	1	1	0	0	0	0	21	-32.3	NO	NO
329.012.00223	SC	23AUG96	-7, .	4	2	0	2	2	0	3	0	0	3	2	0	1	0	0	0	0	19	.		
	BL	30AUG96	1, .	4	2	0	2	2	0	3	0	0	4	3	0	1	0	0	0	0	21	.		
	1	06SEP96	8, .	4	2	1	2	2	0	3	1	0	2	0	2	2	0	0	0	0	21	0.0	NO	NO
	2	16SEP96	18, .	2	2	0	2	2	1	2	1	0	2	0	0	2	0	2	0	1	19	-9.5	NO	NO
	3	23SEP96	25, .	3	2	1	2	2	2	3	0	2	2	0	0	0	0	0	0	0	19	-9.5	NO	NO
	5	01OCT96	33, .	3	2	3	2	2	0	0	0	2	3	2	0	0	0	0	0	0	19	-9.5	NO	NO
329.012.00227	SC	12DEC96	-6, -75	4	2	3	1	0	0	2	2	2	3	1	1	1	1	0	1	0	24	.		
	BL	18DEC96	1, -69	3	2	2	1	1	0	1	2	2	1	0	0	0	0	0	1	0	16	.		
	1	27DEC96	10, -60	0	0	0	0	0	0	2	1	2	1	0	1	1	0	0	0	0	8	-50.0	YES	YES
	3	06JAN97	20, -50	3	0	0	2	0	0	1	1	1	3	0	1	1	0	0	0	0	13	-18.8	NO	NO
	4	15JAN97	29, -41	0	0	0	0	0	0	1	1	2	3	0	1	1	0	0	0	0	9	-43.7	NO	NO
	5	24JAN97	38, -32	2	0	0	1	1	0	3	1	2	1	0	0	2	0	0	0	0	13	-18.8	NO	NO
	7	04FEB97	49, -21	0	0	0	2	1	1	0	1	1	0	0	0	0	0	0	0	0	6	-62.5	YES	YES
	8	14FEB97	59, -11	1	1	0	1	0	2	1	1	0	1	1	1	1	0	0	0	0	11	-31.3	NO	NO
	8	20FEB97	65, -5	2	0	0	1	0	1	1	0	1	1	0	1	1	0	0	0	0	9	-43.7	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.012.00227	8	25FEB97	70, 1	1	0	1	0	1	0	1	1	1	1	1	0	1	0	0	0	0	9	-43.7	NO	NO
	16	27MAR97	100, 31	1	0	1	2	0	0	2	2	1	1	1	0	0	0	0	0	0	11	-31.3	NO	NO
	20	25APR97	129, 60	1	0	0	2	0	0	1	0	2	1	1	0	0	1	0	0	1	10	-37.5	NO	NO
	24	26MAY97	160, 91	1	1	0	0	0	0	1	0	2	1	1	0	0	0	0	0	1	8	-50.0	YES	YES
	28	25JUN97	190, 121	1	0	0	1	1	0	0	0	1	0	1	1	0	0	0	1	0	7	-56.3	YES	YES
	32	21JUL97	216, 147	1	1	0	1	0	0	1	0	1	0	0	0	0	0	0	0	0	5	-68.8	YES	YES
	32	19AUG97	245, 176	1	1	0	0	0	0	2	1	2	1	0	1	0	0	0	0	0	9	-43.7	NO	NO
329.012.00230	SC	20FEB97	-8, -77	4	1	2	2	0	1	3	1	0	4	0	0	1	0	0	0	1	20	.		
	BL	28FEB97	1, -69	4	2	2	2	0	0	3	1	0	4	0	0	2	0	0	0	1	21	.		
	1	07MAR97	8, -62	4	1	0	0	0	2	3	0	1	2	1	1	1	0	0	0	1	17	-19.0	NO	NO
	2	14MAR97	15, -55	3	0	1	0	0	2	4	0	1	1	1	1	1	0	0	1	0	16	-23.8	NO	NO
	3	24MAR97	25, -45	4	2	0	0	0	2	3	0	0	3	1	2	2	0	0	0	0	19	-9.5	NO	NO
	5	03APR97	35, -35	4	2	1	0	0	2	3	1	0	3	0	2	2	0	0	0	0	20	-4.8	NO	NO
	6	11APR97	43, -27	2	0	0	0	0	2	4	0	0	2	0	0	1	0	0	0	0	11	-47.6	NO	NO
	8	23APR97	55, -15	2	2	0	0	0	0	3	0	1	3	0	0	1	0	0	0	0	12	-42.9	NO	NO
	8	02MAY97	64, -6	1	0	0	0	0	0	3	1	0	0	1	0	1	0	0	0	0	7	-66.7	YES	YES
	8	08MAY97	70, 1	1	0	0	1	0	0	3	0	1	1	0	1	0	0	0	0	0	8	-61.9	YES	YES
	12	16MAY97	78, 9	3	0	0	0	0	0	3	1	0	1	1	1	0	0	0	1	0	11	-47.6	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.001.00062	SC	06OCT94	-14, .	4	3	1	2	2	2	4	3	3	3	2	2	2	1	0	1	0	35	.		
	BL	20OCT94	1, .	3	2	0	2	1	0	4	3	3	2	0	2	2	0	0	0	0	24	.		
	1	27OCT94	8, .	0	0	0	2	1	0	3	2	3	2	3	0	2	0	0	0	0	18	-25.0	NO	NO
	2	03NOV94	15, .	1	0	0	1	0	0	3	2	3	1	3	0	0	0	0	0	0	14	-41.7	NO	NO
	3	10NOV94	22, .	0	0	0	2	0	0	2	1	3	0	0	0	0	0	0	0	1	9	-62.5	YES	NO
329.001.00064	SC	04NOV94	-6, -60	4	0	0	1	0	0	4	3	1	0	0	1	2	0	0	0	0	16	.		
	BL	10NOV94	1, -54	2	0	0	1	0	0	4	3	1	0	1	1	2	0	0	0	0	15	.		
	1	16NOV94	7, -48	2	0	0	1	0	0	3	3	0	0	1	0	1	0	0	0	0	11	-26.7	NO	NO
	2	22NOV94	13, -42	1	0	0	1	0	0	2	2	0	0	0	0	1	0	0	0	1	8	-46.7	YES	YES
	3	29NOV94	20, -35	1	0	0	1	0	0	2	1	0	0	1	0	0	0	0	0	0	6	-60.0	YES	YES
	4	06DEC94	27, -28	0	0	0	1	0	0	2	1	0	0	0	0	0	0	0	0	2	6	-60.0	YES	YES
	5	13DEC94	34, -21	1	0	0	1	0	0	1	1	0	0	1	0	0	0	0	0	0	5	-66.7	YES	YES
	6	20DEC94	41, -14	1	0	0	1	0	0	2	2	0	0	0	0	1	0	0	0	0	7	-53.3	YES	YES
	7	27DEC94	48, -7	1	0	0	0	0	0	2	2	1	0	0	0	1	0	0	0	0	7	-53.3	YES	YES
	8	03JAN95	55, 1	1	0	0	1	0	0	3	2	0	0	0	0	1	0	0	0	0	8	-46.7	YES	YES
	12	31JAN95	83, 29	0	0	0	1	0	0	1	1	0	0	1	0	1	0	0	0	1	6	-60.0	YES	YES
	16	28FEB95	111, 57	0	0	0	1	0	0	2	2	0	0	1	0	1	0	0	0	0	7	-53.3	YES	YES
	20	28MAR95	139, 85	1	0	0	1	0	0	3	2	0	0	0	1	1	0	0	0	0	9	-40.0	NO	NO
329.001.00069	SC	07FEB95	-9, .	4	2	2	2	0	2	4	3	2	0	2	0	2	0	2	0	0	27	.		
	BL	16FEB95	1, .	3	0	0	1	0	2	4	3	3	1	2	0	2	0	1	0	0	22	.		
	1	23FEB95	8, .	2	0	0	1	0	2	4	2	0	0	1	0	2	0	0	0	0	14	-36.4	NO	NO
	2	02MAR95	15, .	2	0	0	1	1	0	3	2	1	0	0	0	1	0	0	0	1	12	-45.5	NO	NO
	3	09MAR95	22, .	1	1	0	1	0	2	3	2	1	0	0	0	1	0	0	1	0	13	-40.9	NO	NO
	4	16MAR95	29, .	0	0	0	0	0	0	1	2	2	0	0	0	1	0	0	0	0	6	-72.7	YES	YES
	5	23MAR95	36, .	0	0	0	0	0	1	2	0	1	1	1	2	1	0	0	1	0	10	-54.5	YES	NO
	6	30MAR95	43, .	3	1	2	1	0	2	2	2	1	1	1	1	1	0	0	0	0	18	-18.2	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.001.00069	7	06APR95	50,	.	3	0	1	1	1	0	4	3	1	2	1	1	2	0	0	0	0	20	-9.1	NO	NO
	8	13APR95	57,	.	1	0	2	0	0	0	3	2	2	1	0	0	1	0	0	0	0	12	-45.5	NO	NO
329.001.00071	SC	02FEB95	-21,	.	3	0	2	2	2	0	4	3	2	4	4	0	2	0	0	0	0	28	.		
	BL	23FEB95	1,	.	4	2	2	2	0	1	4	3	1	2	3	0	2	1	0	0	0	27	.		
	1	02MAR95	8,	.	3	2	0	2	0	0	3	3	2	2	4	0	2	0	0	1	0	24	-11.1	NO	NO
	2	09MAR95	15,	.	3	0	2	2	0	1	4	3	1	2	3	0	2	0	0	0	0	23	-14.8	NO	NO
	3	16MAR95	22,	.	2	0	1	2	0	0	3	2	1	2	1	0	2	2	1	0	0	19	-29.6	NO	NO
	4	23MAR95	29,	.	2	0	0	2	0	0	2	2	0	1	2	0	1	0	1	0	0	13	-51.9	YES	NO
	5	30MAR95	36,	.	1	0	0	2	0	0	2	2	0	0	1	0	1	0	0	0	0	9	-66.7	YES	NO
	6	06APR95	43,	.	3	0	2	2	0	0	4	3	0	2	3	0	2	1	0	0	0	22	-18.5	NO	NO
	7	13APR95	50,	.	3	0	0	2	0	0	4	2	1	2	0	0	2	0	0	0	0	16	-40.7	NO	NO
	8	20APR95	57,	.	2	0	0	2	0	0	4	3	1	2	4	0	2	0	0	0	0	20	-25.9	NO	NO
329.001.00123	SC	14DEC95	-21,	.	4	2	2	2	1	2	4	2	0	2	3	0	2	0	1	0	0	27	.		
	BL	04JAN96	1,	.	3	0	1	2	0	0	4	3	1	1	3	2	2	0	1	0	0	23	.		
	1	12JAN96	9,	.	1	0	0	2	0	0	3	1	1	1	0	0	1	0	1	0	0	11	-52.2	YES	NO
	2	18JAN96	15,	.	0	0	0	1	0	0	3	1	1	0	0	0	1	0	1	0	0	8	-65.2	YES	YES
	3	25JAN96	22,	.	3	0	1	0	0	0	3	2	1	2	3	0	2	0	0	0	0	17	-26.1	NO	NO
	4	01FEB96	29,	.	0	0	0	1	2	0	3	0	2	0	2	0	1	0	0	0	0	11	-52.2	YES	NO
	5	08FEB96	36,	.	1	0	0	0	0	0	3	2	1	0	0	0	1	0	0	0	0	8	-65.2	YES	YES
	6	15FEB96	43,	.	0	0	0	1	0	0	2	0	0	0	0	0	1	0	0	0	0	4	-82.6	YES	YES
	7	22FEB96	50,	.	3	1	2	0	0	0	4	3	2	1	2	0	2	0	2	0	0	22	-4.3	NO	NO
329.001.00207	SC	19FEB96	-9,	.	2	2	2	2	0	0	4	2	2	0	2	1	1	0	0	0	0	20	.		
	BL	28FEB96	1,	.	3	1	2	1	0	0	4	2	3	0	0	0	2	0	0	0	0	18	.		
	1	06MAR96	8,	.	1	0	0	0	0	0	3	0	3	2	0	0	1	0	0	0	1	11	-38.9	NO	NO
	2	13MAR96	15,	.	0	0	0	1	1	0	2	0	1	0	0	0	1	0	0	0	0	6	-66.7	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.001.00207	3	20MAR96	22, .	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	-88.9	YES	YES
	4	26MAR96	28, .	0	0	0	0	0	0	2	0	0	0	0	1	0	0	0	0	0	3	-83.3	YES	YES
	5	03APR96	36, .	1	0	0	0	0	0	2	0	1	0	0	0	0	0	0	0	0	4	-77.8	YES	YES
	6	10APR96	43, .	2	0	0	0	0	0	4	1	1	1	0	0	0	0	0	0	0	9	-50.0	YES	NO
	7	17APR96	50, .	2	1	0	0	0	0	3	0	1	0	1	0	0	0	0	0	2	10	-44.4	NO	NO
	8	24APR96	57, .	3	1	0	2	0	0	3	2	1	1	1	0	0	0	0	1	0	15	-16.7	NO	NO
329.002.00049	SC	03MAR95	-6, .	4	0	0	0	2	1	3	1	0	1	3	0	2	2	0	0	2	21	.		
	BL	08MAR95	-1, .	4	0	0	0	0	2	3	1	0	1	0	1	2	2	0	0	1	17	.		
	1	15MAR95	7, .	4	0	0	0	0	0	3	1	0	0	0	0	2	2	0	0	1	13	-23.5	NO	NO
	2	22MAR95	14, .	4	0	0	0	1	0	3	1	0	0	0	1	2	2	0	0	1	15	-11.8	NO	NO
	3	29MAR95	21, .	2	0	0	0	1	0	3	0	0	1	0	1	2	2	0	0	0	12	-29.4	NO	NO
	4	05APR95	28, .	4	0	0	0	1	1	3	2	0	0	0	1	1	2	0	0	0	15	-11.8	NO	NO
	5	12APR95	35, .	3	0	0	0	1	1	3	0	0	0	0	1	1	0	0	0	0	10	-41.2	NO	NO
	6	19APR95	42, .	4	0	0	0	0	0	3	1	0	0	0	1	1	2	0	0	0	12	-29.4	NO	NO
	7	27APR95	50, .	2	0	0	1	0	0	3	0	0	0	0	1	1	2	0	1	0	11	-35.3	NO	NO
	8	05MAY95	58, .	3	0	0	0	0	0	3	1	0	0	0	1	1	2	0	0	1	12	-29.4	NO	NO
329.002.00059	SC	03NOV94	-7, .	2	0	0	2	1	0	3	2	0	3	2	1	2	0	2	0	1	21	.		
	BL	10NOV94	1, .	2	0	0	0	0	0	2	1	0	3	2	1	2	0	1	0	1	15	.		
	1	17NOV94	8, .	2	0	0	1	0	0	3	1	1	2	1	1	2	0	2	0	1	17	13.3	NO	NO
	2	23NOV94	14, .	1	0	0	0	0	0	3	0	0	2	0	1	1	0	1	0	1	10	-33.3	NO	NO
	3	01DEC94	22, .	2	0	0	2	0	0	3	1	0	2	1	0	1	0	1	0	1	14	-6.7	NO	NO
	4	08DEC94	29, .	1	0	0	2	0	0	3	1	0	1	1	0	1	0	2	0	1	13	-13.3	NO	NO
	5	15DEC94	36, .	0	0	0	0	0	0	3	1	0	2	0	0	1	0	2	0	0	9	-40.0	NO	NO
	6	22DEC94	43, .	1	0	0	1	0	0	3	2	0	2	1	0	1	0	2	0	0	13	-13.3	NO	NO
	7	29DEC94	50, .	1	0	0	0	0	0	3	2	0	2	1	0	1	0	1	0	0	11	-26.7	NO	NO
	8	05JAN95	57, .	3	0	0	2	0	0	3	2	0	3	0	0	1	0	2	0	0	16	6.7	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00060	SC	24JAN95	-7, -63	3	2	1	2	0	0	3	2	1	3	2	1	2	0	0	2	0	24	.		
	BL	31JAN95	1, -56	1	0	0	1	0	1	3	1	0	2	2	1	2	0	0	2	0	16	.		
	1	07FEB95	8, -49	2	0	0	0	1	1	3	1	0	2	2	1	2	0	0	0	0	15	-6.3	NO	NO
	2	14FEB95	15, -42	2	0	0	0	1	0	3	1	0	2	0	0	1	0	0	0	0	10	-37.5	NO	NO
	3	21FEB95	22, -35	2	0	0	0	1	0	3	1	0	3	2	0	1	0	0	0	0	13	-18.8	NO	NO
	4	28FEB95	29, -28	2	1	0	1	1	0	3	1	0	3	2	1	1	0	0	0	0	16	0.0	NO	NO
	5	07MAR95	36, -21	1	0	0	0	0	0	3	0	0	1	2	1	2	0	0	0	0	10	-37.5	NO	NO
	6	14MAR95	43, -14	0	0	0	0	0	0	2	0	0	0	1	0	1	0	0	0	0	4	-75.0	YES	YES
	7	21MAR95	50, -7	0	0	0	0	1	0	2	0	0	0	2	0	1	0	0	0	0	6	-62.5	YES	YES
	8	28MAR95	57, 1	1	0	0	0	1	0	3	0	0	1	2	0	1	0	0	0	0	9	-43.7	NO	NO
	12	25APR95	85, 29	3	1	1	1	1	0	3	1	0	2	2	2	2	0	0	1	0	20	25.0	NO	NO
329.002.00097	SC	20DEC94	-14, -72	3	2	1	2	0	2	3	2	1	3	2	0	2	0	0	0	0	23	.		
	BL	03JAN95	1, -58	3	2	1	2	0	2	3	2	1	3	2	0	2	0	0	0	0	23	.		
	1	10JAN95	8, -51	3	1	0	0	0	0	1	1	1	2	2	0	1	0	0	0	0	12	-47.8	NO	NO
	2	18JAN95	16, -43	2	0	0	1	0	2	3	0	1	1	1	1	1	1	0	0	0	14	-39.1	NO	NO
	3	24JAN95	22, -37	2	1	0	1	0	0	1	1	1	1	1	0	1	0	0	0	0	10	-56.5	YES	NO
	4	31JAN95	29, -30	2	1	0	2	0	1	1	1	1	2	2	0	2	0	0	0	0	15	-34.8	NO	NO
	5	07FEB95	36, -23	3	1	0	0	2	1	2	1	1	2	1	0	1	0	0	0	0	15	-34.8	NO	NO
	6	14FEB95	43, -16	2	1	0	1	1	1	2	0	1	1	1	0	1	0	0	0	0	12	-47.8	NO	NO
	7	21FEB95	50, -9	2	1	0	1	0	0	1	0	1	1	0	0	1	0	0	0	0	8	-65.2	YES	YES
	8	02MAR95	59, 1	2	0	1	1	0	1	1	1	1	2	1	0	1	0	0	0	0	12	-47.8	NO	NO
	12	30MAR95	87, 29	2	1	1	2	0	2	1	0	0	3	1	0	0	0	0	0	0	13	-43.5	NO	NO
	16	27APR95	115, 57	0	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0	4	-82.6	YES	YES
	20	23MAY95	141, 83	2	0	0	2	0	0	1	1	1	2	2	0	1	0	0	0	0	12	-47.8	NO	NO
	24	29JUN95	178, 120	2	0	0	0	0	0	1	0	1	3	2	0	2	0	0	0	0	11	-52.2	YES	NO
	28	01AUG95	211, 153	3	0	0	1	0	1	0	2	2	3	1	0	0	1	0	0	0	14	-39.1	NO	NO
	32	05SEP95	246, 188	0	0	0	1	0	0	1	0	1	1	0	0	1	0	0	0	0	5	-78.3	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00101	SC	20MAR95	-8, -66	3	1	1	1	1	0	3	0	1	4	2	0	1	0	0	1	0	19	.		
	BL	28MAR95	1, -58	3	1	1	1	1	0	3	0	1	4	2	0	1	0	0	1	0	19	.		
	1	04APR95	8, -51	2	1	0	2	2	1	3	0	1	2	2	1	1	0	0	1	0	19	0.0	NO	NO
	2	13APR95	17, -42	1	0	0	1	2	0	2	0	0	2	1	0	1	0	0	0	0	10	-47.4	NO	NO
	3	20APR95	24, -35	1	1	1	0	2	0	3	0	1	2	1	0	1	0	0	0	0	13	-31.6	NO	NO
	4	27APR95	31, -28	1	1	0	0	0	0	2	0	0	1	2	0	1	0	0	0	0	8	-57.9	YES	YES
	5	04MAY95	38, -21	1	1	0	0	0	0	2	0	0	1	1	0	1	0	0	0	0	7	-63.2	YES	YES
	6	11MAY95	45, -14	2	1	1	0	0	0	2	1	0	1	1	0	1	0	0	0	0	10	-47.4	NO	NO
	7	18MAY95	52, -7	1	1	0	0	0	0	2	0	0	1	1	0	0	0	0	0	0	6	-68.4	YES	YES
	8	25MAY95	59, 1	1	1	0	0	1	0	1	0	0	1	0	0	1	0	0	0	0	6	-68.4	YES	YES
	12	22JUN95	87, 29	2	1	0	0	0	0	1	0	0	4	0	0	0	0	0	1	0	9	-52.6	YES	NO
	12	27JUN95	92, 34	0	0	0	0	2	0	0	0	0	1	0	0	0	0	0	1	0	4	-78.9	YES	YES
329.002.00107	SC	18JAN96	-7, -63	3	1	0	2	0	0	4	1	0	1	1	0	2	0	1	0	0	16	.		
	BL	25JAN96	1, -56	3	1	1	1	0	0	4	1	0	3	2	0	2	0	1	0	0	19	.		
	1	01FEB96	8, -49	1	0	0	0	0	0	4	1	0	3	2	0	2	0	1	0	0	14	-26.3	NO	NO
	2	08FEB96	15, -42	2	1	0	1	0	0	4	0	0	3	1	0	1	0	0	0	0	13	-31.6	NO	NO
	3	13FEB96	20, -37	1	0	0	0	0	0	4	0	0	3	1	0	1	0	0	0	0	10	-47.4	NO	NO
	4	20FEB96	27, -30	1	0	0	1	0	0	1	0	0	0	2	0	0	0	0	0	0	5	-73.7	YES	YES
	5	27FEB96	34, -23	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	3	-84.2	YES	YES
	6	05MAR96	41, -16	3	1	0	0	1	0	0	0	0	1	2	0	0	0	0	0	0	8	-57.9	YES	YES
	7	15MAR96	51, -6	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	3	-84.2	YES	YES
	8	21MAR96	57, 1	2	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	3	-84.2	YES	YES
	12	23APR96	90, 34	1	1	0	0	0	0	0	1	0	1	1	0	0	1	1	0	0	7	-63.2	YES	YES
	16	21MAY96	118, 62	1	1	1	2	0	0	1	0	1	1	1	0	1	1	1	0	0	12	-36.8	NO	NO
	20	20JUN96	148, 92	1	1	1	0	0	0	0	0	0	2	1	0	0	0	0	1	0	7	-63.2	YES	YES
	24	18JUL96	176, 120	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-94.7	YES	YES
	32	29AUG96	218, 162	0	0	0	2	0	0	1	0	0	1	0	0	0	0	0	0	0	4	-78.9	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00107	32	26SEP96	246, 190	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	1	0	3	-84.2	YES	YES
329.002.00241	SC	25JAN96	-12, -68	2	2	3	1	1	1	2	0	2	1	0	1	1	0	0	0	0	17	.		
	BL	06FEB96	1, -56	2	0	3	0	1	1	2	3	4	1	0	1	2	0	0	0	0	20	.		
	1	13FEB96	8, -49	2	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	3	-85.0	YES	YES
	2	22FEB96	17, -40	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	-85.0	YES	YES
	3	27FEB96	22, -35	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-95.0	YES	YES
	4	05MAR96	29, -28	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	-90.0	YES	YES
	5	12MAR96	36, -21	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-95.0	YES	YES
	6	19MAR96	43, -14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	7	26MAR96	50, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	02APR96	57, 1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-95.0	YES	YES
	12	30APR96	85, 29	3	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	0	7	-65.0	YES	YES
329.002.00246	SC	01APR96	-17, .	4	2	2	0	1	0	3	1	3	4	2	0	2	1	1	0	0	26	.		
	BL	18APR96	1, .	3	2	3	1	0	0	3	1	4	4	2	0	2	0	1	0	0	26	.		
	1	25APR96	8, .	3	1	1	0	1	0	2	2	3	4	1	1	2	0	1	0	0	22	-15.4	NO	NO
	2	02MAY96	15, .	1	0	0	1	0	0	2	0	3	1	2	0	1	0	1	0	0	12	-53.8	YES	NO
	3	09MAY96	22, .	3	1	2	1	0	0	2	0	4	3	2	0	2	0	1	0	0	21	-19.2	NO	NO
	4	16MAY96	29, .	2	1	1	1	0	0	1	1	3	3	2	0	2	0	1	0	0	18	-30.8	NO	NO
	5	23MAY96	36, .	1	1	1	0	0	0	2	0	2	3	2	0	2	0	1	0	0	15	-42.3	NO	NO
	6	30MAY96	43, .	0	1	1	0	0	0	3	0	1	3	2	0	2	0	1	0	0	14	-46.2	NO	NO
	7	04JUN96	48, .	2	1	0	0	0	0	1	1	3	3	1	0	2	0	1	0	0	15	-42.3	NO	NO
	8	18JUN96	62, .	3	1	1	0	0	0	3	2	1	4	2	0	2	0	1	0	0	20	-23.1	NO	NO
329.002.00320	SC	09MAY96	-7, -68	3	2	1	2	2	2	2	1	2	3	3	0	1	0	1	0	0	25	.		
	BL	16MAY96	1, -61	2	2	0	2	2	2	2	1	2	1	3	0	1	0	1	0	0	21	.		
	1	23MAY96	8, -54	4	1	2	0	2	0	2	1	2	3	2	0	1	0	0	0	0	20	-4.8	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.002.00320	2	30MAY96	15, -47	4	1	1	2	2	2	3	2	1	3	0	0	2	0	0	0	0	23	9.5	NO	NO
	3	04JUN96	20, -42	3	1	0	2	2	1	1	0	2	2	2	0	0	0	0	0	0	16	-23.8	NO	NO
	5	18JUN96	34, -28	3	2	1	2	1	1	2	0	2	2	2	0	2	0	0	0	0	20	-4.8	NO	NO
	6	25JUN96	41, -21	2	1	0	1	1	2	1	0	1	1	1	0	0	0	0	0	0	11	-47.6	NO	NO
	7	02JUL96	48, -14	3	2	2	0	2	1	2	0	1	1	1	0	2	0	0	0	0	17	-19.0	NO	NO
	8	09JUL96	55, -7	3	1	2	1	2	0	0	0	0	1	0	0	0	0	0	0	0	10	-52.4	YES	NO
	8	16JUL96	62, 1	2	1	0	1	1	1	0	0	1	1	0	0	1	0	0	0	0	9	-57.1	YES	NO
	12	13AUG96	90, 29	2	1	1	1	2	1	0	0	1	1	0	0	0	0	0	0	0	10	-52.4	YES	NO
	16	17SEP96	125, 64	3	1	1	2	1	0	0	0	1	2	1	0	1	0	1	0	0	14	-33.3	NO	NO
329.002.00323	SC	04NOV96	-8, -66	3	1	1	1	0	0	2	1	0	4	1	1	2	0	1	0	0	18	.		
	BL	12NOV96	1, -58	3	1	1	1	0	0	2	1	0	3	1	1	2	0	1	0	0	17	.		
	1	19NOV96	8, -51	1	1	0	1	0	0	1	1	0	3	1	0	2	0	1	0	0	12	-29.4	NO	NO
	2	26NOV96	15, -44	2	1	0	0	0	0	1	1	0	2	1	1	2	0	1	0	0	12	-29.4	NO	NO
	3	05DEC96	24, -35	1	0	0	0	0	0	1	1	0	3	1	0	2	0	0	0	0	9	-47.1	NO	NO
	4	10DEC96	29, -30	1	0	0	0	0	0	2	1	0	3	1	0	2	0	1	0	0	11	-35.3	NO	NO
	5	17DEC96	36, -23	0	1	0	0	0	0	2	1	0	1	1	0	2	0	0	0	0	8	-52.9	YES	YES
	6	26DEC96	45, -14	0	0	0	0	0	0	0	0	0	2	1	0	0	0	1	0	0	4	-76.5	YES	YES
	7	02JAN97	52, -7	0	0	0	0	0	0	1	1	0	2	1	0	1	0	0	0	0	6	-64.7	YES	YES
	8	09JAN97	59, 1	0	0	0	1	0	0	1	0	0	2	2	0	2	0	0	0	0	8	-52.9	YES	YES
	12	04FEB97	85, 27	2	0	0	0	0	0	1	1	0	1	1	0	2	0	0	0	0	8	-52.9	YES	YES
	16	04MAR97	113, 55	1	0	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0	6	-64.7	YES	YES
	20	03APR97	143, 85	1	0	0	0	0	0	1	0	0	1	0	0	2	0	0	0	0	5	-70.6	YES	YES
	24	30APR97	170, 112	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	-88.2	YES	YES
	28	27MAY97	197, 139	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	-88.2	YES	YES
	32	12JUN97	213, 155	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	-88.2	YES	YES
329.003.00074	SC	18JAN95	-7, -63	3	0	1	0	0	0	3	2	3	4	2	0	2	0	1	0	0	21	.		

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00074	BL	25JAN95	1, -56	3	1	2	0	0	0	3	0	3	3	0	0	2	0	0	0	0	17	.		
	1	01FEB95	8, -49	2	1	1	0	0	0	3	1	3	3	2	0	0	0	0	0	0	16	-5.9	NO	NO
	2	08FEB95	15, -42	3	0	1	0	0	0	3	1	3	3	2	0	1	0	0	0	0	17	0.0	NO	NO
	3	15FEB95	22, -35	2	0	0	0	0	0	3	0	2	4	1	0	1	0	0	0	0	13	-23.5	NO	NO
	4	21FEB95	28, -29	3	0	0	0	0	0	1	1	1	3	1	0	1	0	0	0	0	11	-35.3	NO	NO
	5	01MAR95	36, -21	2	1	0	0	0	0	1	0	2	3	2	0	1	0	0	0	0	12	-29.4	NO	NO
	7	15MAR95	50, -7	2	0	0	0	0	0	1	0	1	2	1	0	0	0	0	0	0	7	-58.8	YES	YES
	8	22MAR95	57, 1	2	0	0	0	0	0	1	0	1	2	1	0	0	0	0	0	0	7	-58.8	YES	YES
	12	19APR95	85, 29	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	3	-82.4	YES	YES
	16	17MAY95	113, 57	1	0	0	0	0	0	1	0	0	2	0	0	0	0	0	0	0	4	-76.5	YES	YES
	20	19JUN95	146, 90	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	2	-88.2	YES	YES
	24	24JUL95	181, 125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	30AUG95	218, 162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	32	11OCT95	260, 204	0	0	0	0	0	0	1	0	0	2	1	0	0	0	0	0	0	4	-76.5	YES	YES
329.003.00078	SC	11APR95	-15, .	2	1	0	0	0	0	4	1	0	2	0	0	2	0	0	0	0	12	.		
	BL	26APR95	1, .	2	1	0	0	0	0	4	1	1	1	0	0	2	0	0	0	0	12	.		
	1	02MAY95	7, .	1	0	0	0	0	0	3	1	1	1	0	0	1	0	0	0	0	8	-33.3	YES	YES
	2	10MAY95	15, .	1	0	0	0	0	0	3	1	0	2	2	0	2	0	0	0	0	11	-8.3	NO	NO
	3	17MAY95	22, .	2	1	0	0	0	0	3	1	0	2	0	0	2	0	0	0	0	11	-8.3	NO	NO
	4	24MAY95	29, .	2	0	0	0	0	0	3	1	0	1	0	0	2	0	0	0	0	9	-25.0	NO	NO
	5	30MAY95	35, .	2	0	0	0	0	0	3	0	0	1	0	0	2	0	0	0	0	8	-33.3	YES	YES
	6	07JUN95	43, .	2	0	0	0	0	0	3	1	0	0	0	0	2	0	0	0	0	8	-33.3	YES	YES
	7	15JUN95	51, .	2	0	0	0	0	0	3	0	0	0	0	0	2	0	0	0	0	7	-41.7	YES	YES
	8	21JUN95	57, .	2	0	0	0	0	0	2	0	0	0	0	0	2	0	0	0	0	6	-50.0	YES	YES
329.003.00080	BL	27NOV95	1, .	4	2	1	2	0	0	3	1	0	1	0	0	1	1	0	0	0	16	.		
	1	04DEC95	8, .	4	0	1	2	0	2	3	2	0	0	0	0	2	1	0	0	1	18	12.5	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00080	1	07DEC95	11, .	4	2	0	2	0	0	3	1	0	0	0	0	1	1	0	0	0	14	-12.5	NO	NO
	3	18DEC95	22, .	2	0	2	2	0	0	3	2	0	0	1	0	1	2	0	1	0	16	0.0	NO	NO
	5	04JAN96	39, .	3	0	2	2	0	0	3	2	0	0	0	0	2	1	0	0	0	15	-6.3	NO	NO
	6	10JAN96	45, .	2	0	1	2	0	0	3	1	0	0	0	0	0	1	0	0	0	10	-37.5	NO	NO
	7	17JAN96	52, .	2	0	1	2	0	0	3	2	0	0	0	0	2	1	0	0	0	13	-18.8	NO	NO
	8	24JAN96	59, .	3	0	1	2	0	0	3	2	0	0	0	0	2	1	0	0	0	14	-12.5	NO	NO
329.003.00085	SC	26OCT94	-13, .	3	0	3	0	2	1	2	1	1	2	0	1	0	0	0	0	0	16	.		
	BL	07NOV94	-1, .	2	0	3	2	2	2	3	2	2	1	0	0	0	2	0	0	0	21	.		
	1	14NOV94	7, .	3	0	0	0	2	2	3	1	2	1	0	0	0	0	0	0	0	14	-33.3	NO	NO
	2	21NOV94	14, .	3	0	1	0	2	2	3	1	2	2	0	0	0	0	0	0	0	16	-23.8	NO	NO
	3	28NOV94	21, .	3	0	0	0	2	1	2	1	1	2	0	0	0	0	0	0	0	12	-42.9	NO	NO
	4	05DEC94	28, .	4	0	0	0	2	2	2	2	0	1	0	0	0	0	0	0	0	13	-38.1	NO	NO
	5	12DEC94	35, .	3	0	0	0	2	2	1	2	2	2	0	0	0	0	0	0	0	14	-33.3	NO	NO
	6	19DEC94	42, .	2	0	0	0	2	2	2	2	0	2	0	0	0	0	0	1	0	13	-38.1	NO	NO
	7	27DEC94	50, .	2	0	0	0	2	0	2	1	2	2	0	0	0	0	0	0	0	11	-47.6	NO	NO
	8	03JAN95	57, .	2	0	0	0	2	2	2	1	2	0	0	0	0	0	0	0	0	11	-47.6	NO	NO
329.003.00086	SC	09NOV94	-19, -76	2	1	3	1	0	0	3	1	2	2	2	0	1	0	0	0	0	18	.		
	BL	21NOV94	-7, -64	3	0	3	0	0	0	3	2	0	0	1	1	1	1	0	0	0	15	.		
	1	05DEC94	8, -50	2	1	0	2	0	0	2	2	2	3	1	1	1	0	0	0	0	17	13.3	NO	NO
	2	12DEC94	15, -43	2	2	0	0	0	0	2	1	2	2	2	1	1	2	2	0	0	19	26.7	NO	NO
	3	19DEC94	22, -36	2	3	0	0	0	0	2	2	1	2	1	1	1	0	1	0	0	16	6.7	NO	NO
	4	27DEC94	30, -28	2	2	0	0	2	0	2	2	2	2	2	0	1	0	0	0	0	17	13.3	NO	NO
	5	03JAN95	37, -21	1	1	0	0	0	0	2	1	0	1	1	0	1	0	0	0	0	8	-46.7	YES	YES
	6	09JAN95	43, -15	1	1	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0	6	-60.0	YES	YES
	7	17JAN95	51, -7	1	1	0	0	0	0	0	0	0	0	0	1	1	0	0	1	0	5	-66.7	YES	YES
	8	23JAN95	57, -1	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	3	-80.0	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
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Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00086	12	13FEB95	78, 21	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-93.3	YES	YES
	16	28MAR95	121, 64	1	1	0	1	1	0	0	0	1	0	0	0	1	0	0	0	0	6	-60.0	YES	YES
	20	25APR95	149, 92	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	-86.7	YES	YES
	28	30MAY95	184, 127	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-86.7	YES	YES
	32	11JUL95	226, 169	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	2	-86.7	YES	YES
	32	17AUG95	263, 206	0	0	0	0	0	0	1	0	0	1	0	1	1	0	0	1	0	5	-66.7	YES	YES
329.003.00094	BL	24OCT95	1, .	3	0	3	0	0	0	3	2	0	1	0	0	2	0	0	0	0	14	.		
	1	31OCT95	8, .	3	1	3	0	0	0	3	0	2	0	0	0	2	0	0	0	0	14	0.0	NO	NO
	2	07NOV95	15, .	3	1	3	0	0	0	3	0	2	0	0	0	2	0	0	0	0	14	0.0	NO	NO
	3	14NOV95	22, .	2	1	2	1	0	0	2	1	1	1	0	0	2	0	0	0	0	13	-7.1	NO	NO
	4	21NOV95	29, .	1	1	0	0	0	0	2	0	1	2	0	0	1	0	0	0	0	8	-42.9	YES	YES
	5	28NOV95	36, .	2	2	2	1	0	0	2	1	1	2	0	0	2	0	0	0	0	15	7.1	NO	NO
	6	05DEC95	43, .	2	1	2	1	0	0	1	1	1	2	0	0	1	0	0	0	0	12	-14.3	NO	NO
	7	12DEC95	50, .	3	2	3	0	0	0	3	3	1	3	0	1	2	0	0	0	0	21	50.0	NO	NO
	8	19DEC95	57, .	2	1	2	2	0	0	3	1	1	3	1	0	2	0	0	0	0	18	28.6	NO	NO
329.003.00251	BL	27MAR96	-1, .	2	2	2	2	0	1	3	1	1	3	0	1	2	0	0	0	0	20	.		
	1	04APR96	8, .	2	2	2	2	0	0	3	0	0	2	0	0	2	0	0	0	0	15	-25.0	NO	NO
	2	09APR96	13, .	1	0	0	2	0	0	3	0	0	1	0	0	2	0	0	0	0	9	-55.0	YES	NO
329.003.00252	SC	19MAR96	-22, .	3	1	1	0	0	0	3	2	1	3	0	0	2	0	0	0	0	16	.		
	BL	09APR96	-1, .	3	0	0	0	0	0	4	1	1	3	0	1	2	0	0	0	0	15	.		
	1	16APR96	7, .	2	0	0	0	0	0	3	2	1	3	0	0	2	0	0	0	0	13	-13.3	NO	NO
	2	23APR96	14, .	1	0	0	0	0	0	3	1	0	0	0	0	2	0	0	0	0	7	-53.3	YES	YES
	3	30APR96	21, .	2	1	0	0	0	0	3	1	1	1	0	0	2	0	0	0	0	11	-26.7	NO	NO
	4	09MAY96	30, .	1	0	0	0	0	0	2	1	1	1	0	0	2	0	0	0	0	8	-46.7	YES	YES
	5	14MAY96	35, .	1	0	0	0	0	0	1	1	0	0	0	0	1	0	0	0	0	4	-73.3	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00252	6	21MAY96	42, .	2	1	0	0	0	0	1	0	1	1	0	0	2	0	0	0	0	8	-46.7	YES	YES
	7	28MAY96	49, .	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	3	-80.0	YES	YES
	8	04JUN96	56, .	2	1	1	0	0	0	2	1	0	2	0	0	2	0	0	0	0	11	-26.7	NO	NO
329.003.00291	BL	03JUL96	1, -65	4	2	2	2	1	1	3	3	2	4	2	2	2	2	3	2	0	37	.		
	2	15JUL96	13, -53	3	2	1	1	1	1	3	2	1	3	2	1	2	1	2	0	0	26	-29.7	NO	NO
	3	24JUL96	22, -44	1	2	2	0	0	1	1	1	1	1	1	2	1	1	1	0	0	16	-56.8	YES	NO
	4	31JUL96	29, -37	1	1	1	2	0	0	1	1	1	1	1	0	0	0	0	0	0	10	-73.0	YES	NO
	5	07AUG96	36, -30	1	1	1	2	0	0	1	1	1	1	0	0	0	0	0	0	0	9	-75.7	YES	NO
	6	14AUG96	43, -23	1	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	3	-91.9	YES	YES
	7	21AUG96	50, -16	0	0	0	2	2	0	0	0	1	1	1	0	1	0	0	0	0	8	-78.4	YES	YES
	8	28AUG96	57, -9	0	0	0	1	0	0	0	0	1	1	0	0	0	0	0	0	0	3	-91.9	YES	YES
	8	04SEP96	64, -2	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	3	-91.9	YES	YES
	12	02OCT96	92, 27	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	-94.6	YES	YES
	16	30OCT96	120, 55	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-97.3	YES	YES
329.003.00315	BL	05NOV96	-7, .	3	1	0	2	0	0	3	3	0	0	0	0	2	0	0	0	0	14	.		
	1	21NOV96	10, .	3	2	1	0	0	0	3	2	0	0	0	0	0	0	0	0	0	11	-21.4	NO	NO
	2	26NOV96	15, .	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	3	-78.6	YES	YES
	3	03DEC96	22, .	1	0	0	0	.	0	1	0	0	0	0	0	0	0	0	0	0	2	-84.8	YES	YES
	4	12DEC96	31, .	1	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	3	-78.6	YES	YES
	5	17DEC96	36, .	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-85.7	YES	YES
	6	23DEC96	42, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	07JAN97	57, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.003.00316	BL	17DEC96	1, .	3	1	1	2	0	0	3	2	2	2	0	1	2	0	0	1	0	20	.		
	1	23DEC96	7, .	3	1	0	0	0	0	3	2	2	0	0	1	2	0	0	0	0	14	-30.0	NO	NO
	3	07JAN97	22, .	2	0	0	1	0	0	2	0	0	1	1	0	0	0	0	1	0	8	-60.0	YES	YES

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Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.003.00316	4	14JAN97	29,	.	3	1	2	1	1	0	3	2	1	3	0	0	2	0	0	0	0	19	-5.0	NO	NO
	5	21JAN97	36,	.	3	1	1	2	2	2	2	2	1	2	0	0	2	0	0	0	0	20	0.0	NO	NO
	6	28JAN97	43,	.	3	2	2	2	2	0	3	2	1	3	1	0	2	0	0	0	0	23	15.0	NO	NO
	7	04FEB97	50,	.	3	1	2	2	2	0	2	2	1	3	0	0	2	0	0	0	0	20	0.0	NO	NO
	8	11FEB97	57,	.	3	2	2	2	2	0	2	1	1	3	0	0	2	0	0	0	0	20	0.0	NO	NO
329.004.00016	SC	01MAR95	-12,	.	3	0	0	2	0	0	3	2	1	1	1	1	2	0	0	2	0	18	.		
	BL	13MAR95	1,	.	3	0	0	2	0	0	3	2	1	1	2	1	2	0	0	1	0	18	.		
	1	20MAR95	8,	.	3	0	0	2	0	0	3	2	1	2	0	1	2	0	0	2	0	18	0.0	NO	NO
	2	29MAR95	17,	.	3	0	0	2	0	0	2	0	2	1	0	0	2	0	0	0	0	12	-33.3	NO	NO
	3	05APR95	24,	.	3	0	0	2	0	0	3	2	1	1	0	1	2	0	0	0	0	15	-16.7	NO	NO
	4	12APR95	31,	.	3	0	0	2	0	0	3	2	1	1	0	1	2	0	0	0	0	15	-16.7	NO	NO
	5	19APR95	38,	.	3	0	0	2	0	0	2	2	1	1	0	1	2	0	0	0	0	14	-22.2	NO	NO
329.004.00018	SC	19APR95	-14,	.	3	2	2	2	2	0	2	0	1	2	0	0	2	1	0	0	0	19	.		
	BL	03MAY95	1,	.	3	1	2	2	2	1	2	0	2	2	2	0	2	0	1	0	0	22	.		
	1	11MAY95	9,	.	3	1	1	2	2	2	3	0	2	2	2	1	2	0	0	0	0	23	4.5	NO	NO
	2	18MAY95	16,	.	2	0	0	2	0	2	1	0	2	1	2	0	1	0	0	0	0	13	-40.9	NO	NO
	3	25MAY95	23,	.	3	1	1	1	1	2	2	0	1	1	1	0	2	0	0	0	0	16	-27.3	NO	NO
	4	01JUN95	30,	.	3	0	0	0	0	2	3	0	2	1	2	0	2	0	0	0	0	15	-31.8	NO	NO
	5	08JUN95	37,	.	3	1	2	0	0	1	2	0	1	1	2	1	0	0	1	0	0	15	-31.8	NO	NO
	7	19JUN95	48,	.	3	1	1	1	1	0	3	0	1	1	1	0	2	0	0	0	0	15	-31.8	NO	NO
	7	22JUN95	51,	.	3	0	1	0	0	1	2	0	1	1	1	0	2	0	0	0	0	12	-45.5	NO	NO
	8	29JUN95	58,	.	1	0	0	1	0	2	1	0	1	1	2	0	1	0	0	0	0	10	-54.5	YES	NO
329.004.00020	SC	02NOV95	-7,	.	3	2	2	1	1	0	3	0	2	1	0	0	2	1	0	0	0	18	.		
	BL	09NOV95	1,	.	3	2	2	2	0	0	2	0	2	1	1	0	2	1	1	0	0	19	.		
	1	16NOV95	8,	.	2	2	3	2	0	0	1	0	2	1	1	2	2	0	0	1	0	19	0.0	NO	NO

* days relative to start of acute phase, days relative to start of continuation phase
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\+ Remission is defined as a HAMD total of less than or equal to 8.

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.004.00020	2	24NOV95	16, .	2	1	2	2	0	0	2	0	2	2	1	1	2	0	0	0	0	17	-10.5	NO	NO
329.004.00213	SC	18JUL96	-15, -69	2	2	1	2	1	0	3	0	2	1	2	1	2	0	1	0	0	20	.		
	BL	01AUG96	-1, -55	2	0	2	0	0	0	3	0	1	1	1	2	1	0	0	1	0	14	.		
	1	08AUG96	7, -48	2	0	3	2	0	0	3	0	0	1	2	1	2	0	0	0	0	16	14.3	NO	NO
	2	15AUG96	14, -41	4	0	2	2	0	0	3	0	0	1	0	1	2	0	0	0	0	15	7.1	NO	NO
	3	21AUG96	20, -35	1	0	1	1	0	0	1	0	1	1	0	1	0	0	0	0	0	7	-50.0	YES	YES
	4	29AUG96	28, -27	1	0	0	1	0	0	1	0	1	1	1	0	1	0	0	0	0	7	-50.0	YES	YES
	5	03SEP96	33, -22	0	0	0	0	0	0	1	0	1	1	1	0	1	0	0	0	0	5	-64.3	YES	YES
	6	10SEP96	40, -15	1	0	0	0	0	0	0	0	1	1	1	0	1	0	0	1	0	6	-57.1	YES	YES
	7	17SEP96	47, -8	1	0	0	0	0	0	0	0	1	1	1	1	1	0	0	1	0	7	-50.0	YES	YES
	8	24SEP96	54, -1	3	0	3	0	0	0	0	0	0	1	0	0	0	0	0	0	0	7	-50.0	YES	YES
	12	22OCT96	82, 28	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-85.7	YES	YES
	16	19NOV96	110, 56	1	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	4	-71.4	YES	YES
	20	20DEC96	141, 87	2	0	3	0	0	0	0	0	0	1	1	0	1	0	0	0	0	8	-42.9	YES	YES
	24	21JAN97	173, 119	1	0	2	0	0	0	0	0	0	1	0	0	0	0	0	0	0	4	-71.4	YES	YES
	28	18FEB97	201, 147	2	0	3	0	0	0	0	0	0	1	1	0	0	0	0	0	0	7	-50.0	YES	YES
	32	19MAR97	230, 176	0	0	0	0	0	0	1	0	1	1	1	0	1	0	0	0	0	5	-64.3	YES	YES
329.005.00001	SC	11APR94	-9, .	3	0	2	2	1	0	2	0	0	3	2	1	2	0	0	0	0	18	.		
	BL	20APR94	1, .	3	0	2	2	0	0	2	1	0	4	2	1	2	0	0	0	0	19	.		
	1	27APR94	8, .	3	0	2	1	0	0	2	2	0	2	0	1	2	0	0	1	0	16	-15.8	NO	NO
	2	04MAY94	15, .	3	0	2	0	0	0	3	2	1	1	2	1	1	0	0	0	0	16	-15.8	NO	NO
	3	11MAY94	22, .	3	0	2	0	0	0	3	1	0	2	0	1	1	0	0	0	0	13	-31.6	NO	NO
	4	18MAY94	29, .	2	0	2	2	0	0	3	1	0	3	0	1	1	0	0	0	0	15	-21.1	NO	NO
	5	25MAY94	36, .	2	0	2	2	0	0	3	1	0	3	3	1	1	0	0	0	0	18	-5.3	NO	NO
	6	01JUN94	43, .	2	0	0	2	0	0	1	1	0	1	1	0	1	0	0	0	0	9	-52.6	YES	NO
	7	08JUN94	50, .	2	0	0	0	0	0	1	1	0	3	3	0	2	0	0	0	1	13	-31.6	NO	NO

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Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00001	8	15JUN94	57, .	3	0	2	1	0	0	0	1	0	1	0	0	1	0	1	0	0	10	-47.4	NO	NO
329.005.00005	SC	24OCT94	-8, .	3	0	2	2	1	0	3	2	0	1	2	0	1	0	0	0	1	18	.		
	BL	01NOV94	1, .	2	0	2	2	0	1	2	1	0	0	2	0	0	0	0	0	0	12	.		
	1	08NOV94	8, .	1	0	2	2	1	0	0	0	0	1	0	0	0	0	0	0	0	7	-41.7	YES	YES
329.005.00010	SC	07DEC94	-6, -63	2	2	2	2	2	2	2	1	1	1	0	1	1	0	0	0	0	19	.		
	BL	13DEC94	1, -57	2	2	1	2	2	2	2	1	1	1	0	1	1	0	0	0	0	18	.		
	1	20DEC94	8, -50	2	1	0	2	0	2	1	1	1	1	0	0	0	0	0	1	0	12	-33.3	NO	NO
	2	27DEC94	15, -43	0	2	0	0	0	0	0	0	2	1	0	0	0	0	0	1	0	6	-66.7	YES	YES
	3	04JAN95	23, -35	1	0	0	0	1	0	0	0	1	1	1	0	1	0	0	0	0	6	-66.7	YES	YES
	4	11JAN95	30, -28	0	0	0	2	2	2	1	0	1	1	0	0	1	0	0	0	0	10	-44.4	NO	NO
	5	18JAN95	37, -21	1	0	0	2	0	2	1	0	1	1	0	1	2	1	0	0	0	12	-33.3	NO	NO
	6	25JAN95	44, -14	1	0	0	0	0	0	1	1	1	1	0	1	1	0	0	2	0	9	-50.0	YES	NO
	7	02FEB95	52, -6	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
	8	08FEB95	58, 1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
	12	10MAR95	88, 31	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	3	-83.3	YES	YES
	16	13APR95	122, 65	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	2	-88.9	YES	YES
	20	10MAY95	149, 92	1	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	3	-83.3	YES	YES
	24	06JUN95	176, 119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	-94.4	YES	YES
	32	12JUL95	212, 155	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2	-88.9	YES	YES
	32	09AUG95	240, 183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00012	SC	12DEC94	-7, -66	3	1	1	0	0	0	2	2	3	1	0	0	2	0	0	1	0	16	.		
	BL	19DEC94	1, -59	3	1	0	0	0	0	3	2	3	1	0	0	1	0	0	1	0	15	.		
	1	27DEC94	9, -51	1	0	0	0	1	2	3	2	4	0	1	1	1	0	0	0	0	16	6.7	NO	NO
	2	05JAN95	18, -42	2	0	1	0	1	2	1	1	2	1	0	0	1	0	0	0	0	12	-20.0	NO	NO
	3	12JAN95	25, -35	1	0	0	0	0	0	1	1	2	0	0	0	1	0	0	0	0	6	-60.0	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00012	4	18JAN95	31, -29	1	0	0	0	0	0	1	1	2	1	0	0	0	0	0	0	0	6	-60.0	YES	YES
	5	25JAN95	38, -22	1	0	0	0	0	1	1	0	1	0	0	0	1	0	0	0	0	5	-66.7	YES	YES
	6	31JAN95	44, -16	2	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1	0	7	-53.3	YES	YES
	7	08FEB95	52, -8	1	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	4	-73.3	YES	YES
	8	16FEB95	60, 1	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-86.7	YES	YES
	12	27MAR95	99, 40	1	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	5	-66.7	YES	YES
	20	04MAY95	137, 78	1	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	4	-73.3	YES	YES
	24	31MAY95	164, 105	2	0	0	2	0	0	1	0	0	0	0	0	0	0	0	1	0	6	-60.0	YES	YES
329.005.00111	SC	05JAN95	-6, -62	2	0	1	2	1	0	2	3	1	1	0	0	1	0	1	0	0	15	.		
	BL	11JAN95	1, -56	2	0	0	2	1	1	2	1	2	1	0	0	1	0	0	0	0	13	.		
	1	18JAN95	8, -49	2	0	2	0	1	1	1	2	1	2	0	1	0	0	0	1	0	14	7.7	NO	NO
	2	25JAN95	15, -42	2	0	0	0	0	1	1	3	3	1	0	0	1	0	0	0	0	12	-7.7	NO	NO
	3	01FEB95	22, -35	2	0	0	0	2	2	2	1	1	1	0	1	2	0	0	1	0	15	15.4	NO	NO
	4	08FEB95	29, -28	0	0	0	0	0	1	1	0	3	0	0	1	0	0	0	1	0	7	-46.2	YES	YES
	5	15FEB95	36, -21	1	0	0	0	2	1	1	1	2	0	0	1	0	0	0	0	0	9	-30.8	NO	NO
	6	22FEB95	43, -14	0	0	0	0	1	0	0	0	1	1	0	1	0	0	0	1	0	5	-61.5	YES	YES
	7	01MAR95	50, -7	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	-84.6	YES	YES
	8	08MAR95	57, 1	1	0	0	0	1	0	2	0	1	0	0	0	1	0	0	0	0	6	-53.8	YES	YES
	12	05APR95	85, 29	0	0	0	0	1	0	1	0	1	0	0	1	0	0	1	1	0	6	-53.8	YES	YES
	12	19APR95	99, 43	0	0	0	0	2	2	1	0	0	0	0	0	2	0	0	1	0	8	-38.5	YES	YES
	16	03MAY95	113, 57	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-92.3	YES	YES
329.005.00114	SC	23JAN95	-8, -65	3	0	1	1	0	0	2	2	0	1	0	1	2	1	0	1	0	15	.		
	BL	31JAN95	1, -57	1	0	0	1	1	2	2	1	2	1	0	1	0	0	0	1	0	13	.		
	1	07FEB95	8, -50	3	0	0	1	0	0	0	3	2	1	0	1	0	0	0	0	0	11	-15.4	NO	NO
	2	14FEB95	15, -43	3	0	0	1	1	0	0	2	2	0	0	1	0	0	0	0	0	10	-23.1	NO	NO
	3	21FEB95	22, -36	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-84.6	YES	YES

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Paroxetine - Protocol 329
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Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00114	4	28FEB95	29, -29	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	-84.6	YES	YES
	5	09MAR95	38, -20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	6	15MAR95	44, -14	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	1	0	3	-76.9	YES	YES
	7	22MAR95	51, -7	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	-84.6	YES	YES
	8	29MAR95	58, 1	3	1	1	1	0	0	1	0	2	0	0	0	0	0	0	1	0	10	-23.1	NO	NO
	12	26APR95	86, 29	3	0	1	0	0	0	2	1	1	1	0	0	0	0	0	0	0	9	-30.8	NO	NO
	16	17MAY95	107, 50	3	0	0	2	0	0	2	1	0	1	0	0	0	1	0	0	0	10	-23.1	NO	NO
329.005.00115	SC	27JAN95	-10, -81	3	1	0	2	2	1	2	1	1	1	0	1	2	2	2	2	0	23	.		
	BL	06FEB95	1, -71	2	0	1	2	2	1	2	1	1	1	0	1	2	2	2	1	0	21	.		
	1	13FEB95	8, -64	1	1	0	0	1	2	0	0	3	1	1	2	2	2	2	1	0	19	-9.5	NO	NO
	2	20FEB95	15, -57	0	0	0	2	0	0	1	0	2	1	2	1	2	0	1	1	0	13	-38.1	NO	NO
	3	02MAR95	25, -47	2	0	0	0	1	0	3	1	0	1	0	1	2	0	2	0	0	13	-38.1	NO	NO
	5	10MAR95	33, -39	0	0	0	0	1	0	0	0	1	0	0	0	2	0	1	1	0	6	-71.4	YES	YES
	6	17MAR95	40, -32	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	-90.5	YES	YES
	7	28MAR95	51, -21	0	0	0	0	0	0	0	0	4	0	0	0	2	0	0	0	0	6	-71.4	YES	YES
	8	10APR95	64, -8	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-95.2	YES	YES
	8	18APR95	72, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	-90.5	YES	YES
	12	27APR95	81, 10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00120	SC	22AUG95	-8, .	3	0	2	0	0	0	3	1	0	1	0	0	2	0	0	0	2	14	.		
	BL	30AUG95	1, .	3	0	0	1	0	0	3	2	0	2	0	0	0	0	0	0	1	12	.		
	1	07SEP95	9, .	3	0	0	0	0	0	3	0	4	3	0	0	0	0	0	0	1	14	16.7	NO	NO
	2	14SEP95	16, .	2	0	0	0	0	0	3	0	0	0	0	0	1	0	0	0	1	7	-41.7	YES	YES
	3	21SEP95	23, .	1	0	0	0	0	0	1	0	0	2	0	0	1	0	0	0	1	6	-50.0	YES	YES
	4	28SEP95	30, .	2	1	0	1	0	0	1	0	0	2	0	0	0	0	0	0	1	8	-33.3	YES	YES
	5	05OCT95	37, .	2	0	0	1	0	0	2	0	0	2	1	0	0	0	0	0	0	8	-33.3	YES	YES
	6	12OCT95	44, .	2	1	1	1	0	0	1	0	0	3	0	0	1	0	0	0	0	10	-16.7	NO	NO

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Paroxetine - Protocol 329
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Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00120	7	19OCT95	51, .	3	0	0	2	0	0	2	0	0	2	0	1	0	0	0	0	0	10	-16.7	NO	NO
	8	26OCT95	58, .	1	0	0	2	0	0	1	0	0	2	0	0	0	0	0	0	0	6	-50.0	YES	YES
329.005.00253	SC	31JAN96	-8, .	3	0	2	2	2	0	1	0	2	1	1	1	1	0	0	1	1	18	.		
	BL	08FEB96	1, .	3	1	1	2	2	0	2	0	1	0	0	1	0	0	0	0	0	13	.		
	1	14FEB96	7, .	3	0	1	2	1	0	2	1	1	0	0	1	1	0	0	0	0	13	0.0	NO	NO
	2	21FEB96	14, .	3	0	1	2	1	0	2	0	1	0	0	1	1	0	0	0	0	12	-7.7	NO	NO
	3	28FEB96	21, .	3	0	2	2	1	0	3	1	1	1	0	1	1	0	0	0	0	16	23.1	NO	NO
	4	06MAR96	28, .	3	1	2	2	0	0	3	0	1	1	0	1	1	0	0	0	0	15	15.4	NO	NO
	5	14MAR96	36, .	3	1	2	1	1	0	2	0	1	1	0	0	1	0	0	0	0	13	0.0	NO	NO
	6	20MAR96	42, .	3	1	2	1	1	0	2	0	1	1	0	0	1	0	0	0	0	13	0.0	NO	NO
	7	28MAR96	50, .	3	0	2	2	2	0	1	1	2	1	0	0	1	0	0	0	0	15	15.4	NO	NO
	8	03APR96	56, .	3	1	1	1	1	0	2	0	1	1	1	1	1	0	0	0	0	14	7.7	NO	NO
329.005.00254	SC	08FEB96	-7, -62	3	2	2	0	0	0	3	2	0	2	2	1	1	0	0	1	0	19	.		
	BL	14FEB96	-1, -56	3	2	2	0	0	1	1	2	0	2	1	0	1	0	0	2	0	17	.		
	1	21FEB96	7, -49	2	0	2	0	0	1	1	2	2	1	0	0	2	0	0	0	0	13	-23.5	NO	NO
	2	28FEB96	14, -42	3	2	2	0	0	0	0	2	0	2	2	0	2	0	0	1	0	16	-5.9	NO	NO
	3	06MAR96	21, -35	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	3	-82.4	YES	YES
	4	13MAR96	28, -28	1	0	0	0	0	0	0	1	0	1	0	1	2	0	0	1	0	7	-58.8	YES	YES
	5	20MAR96	35, -21	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	3	-82.4	YES	YES
	6	27MAR96	42, -14	1	0	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0	4	-76.5	YES	YES
	7	03APR96	49, -7	2	0	1	0	0	0	1	0	0	1	0	0	0	1	0	1	0	7	-58.8	YES	YES
	8	10APR96	56, 1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	-88.2	YES	YES
	12	22MAY96	98, 43	1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1	0	4	-76.5	YES	YES
	16	12JUN96	119, 64	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2	-88.2	YES	YES
	20	10JUL96	147, 92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	24	07AUG96	175, 120	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES

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Paroxetine - Protocol 329
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Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00254	28	12SEP96	211, 156	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	-94.1	YES	YES
	32	16OCT96	245, 190	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.005.00293	SC	06MAR97	-6, .	4	0	1	0	0	1	3	2	1	1	0	1	1	2	0	0	0	17	.		
	BL	12MAR97	1, .	3	1	1	0	0	0	3	2	0	1	0	0	1	0	0	0	0	12	.		
	1	19MAR97	8, .	4	1	0	0	0	0	3	2	0	1	0	0	2	0	0	0	0	13	8.3	NO	NO
	2	25MAR97	14, .	3	1	0	0	0	0	2	2	0	1	0	0	0	0	0	0	0	9	-25.0	NO	NO
	3	02APR97	22, .	2	0	0	0	0	0	0	2	0	1	0	0	0	0	0	0	0	5	-58.3	YES	YES
	4	09APR97	29, .	2	0	0	2	0	0	0	2	0	1	0	0	0	0	0	0	0	7	-41.7	YES	YES
	5	16APR97	36, .	3	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	6	-50.0	YES	YES
	6	23APR97	43, .	2	0	0	0	0	0	2	2	0	1	0	0	0	0	0	0	0	7	-41.7	YES	YES
	7	30APR97	50, .	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	3	-75.0	YES	YES
	8	07MAY97	57, .	1	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	4	-66.7	YES	YES
329.005.00298	SC	15MAY96	-7, -63	3	0	2	1	1	1	2	2	1	1	0	0	1	0	0	0	0	15	.		
	BL	22MAY96	1, -56	3	0	1	0	0	0	2	2	2	1	1	0	2	0	0	0	0	14	.		
	1	30MAY96	9, -48	1	0	0	2	0	0	1	2	2	1	0	1	0	0	0	0	0	10	-28.6	NO	NO
	2	06JUN96	16, -41	3	0	0	0	0	0	2	2	2	1	0	1	1	0	0	1	0	13	-7.1	NO	NO
	3	12JUN96	22, -35	3	0	1	0	0	0	1	2	1	1	0	1	1	0	0	0	0	11	-21.4	NO	NO
	4	19JUN96	29, -28	0	0	0	0	0	0	1	1	2	1	0	0	0	0	0	0	0	5	-64.3	YES	YES
	5	26JUN96	36, -21	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	3	-78.6	YES	YES
	6	03JUL96	43, -14	2	0	0	0	0	0	1	1	1	1	0	0	2	0	0	0	0	8	-42.9	YES	YES
	7	10JUL96	50, -7	0	0	0	0	0	0	2	1	0	0	0	0	0	1	0	1	0	5	-64.3	YES	YES
	8	17JUL96	57, 1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
	12	07AUG96	78, 22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	19SEP96	121, 65	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	0	0	3	-78.6	YES	YES
	20	17OCT96	149, 93	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	-78.6	YES	YES
	24	14NOV96	177, 121	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-85.7	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.005.00298	28	12DEC96	205, 149	1	1	0	0	0	0	0	0	0	1	0	0	2	0	0	0	0	5	-64.3	YES	YES
	32	13JAN97	237, 181	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	-85.7	YES	YES
329.005.00331	SC	14NOV96	-7, .	4	2	2	2	2	2	3	2	3	2	2	1	2	0	1	0	0	30	.		
	BL	21NOV96	1, .	3	2	0	2	2	2	1	2	3	2	2	1	2	0	0	0	0	24	.		
	1	27NOV96	7, .	3	2	0	2	2	2	2	1	3	2	0	1	2	0	1	0	0	23	-4.2	NO	NO
	2	04DEC96	14, .	3	2	3	2	2	2	2	1	2	2	0	1	2	0	0	0	0	24	0.0	NO	NO
	3	12DEC96	22, .	2	1	1	2	2	2	1	1	2	1	0	1	0	0	0	0	0	16	-33.3	NO	NO
	4	19DEC96	29, .	1	1	0	2	1	1	1	0	1	1	0	1	0	0	0	1	0	11	-54.2	YES	NO
	5	26DEC96	36, .	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-91.7	YES	YES
	6	02JAN97	43, .	1	1	1	1	1	2	1	1	1	2	0	0	0	0	0	0	0	12	-50.0	YES	NO
	7	10JAN97	51, .	1	0	0	2	1	0	0	1	1	1	0	1	0	0	0	1	0	9	-62.5	YES	NO
	8	16JAN97	57, .	2	0	1	0	1	1	1	1	1	1	0	1	1	0	0	0	0	11	-54.2	YES	NO
329.005.00334	SC	24JAN97	-7, .	3	1	3	2	0	0	2	1	2	1	0	1	0	0	0	0	0	16	.		
	BL	29JAN97	-2, .	2	0	1	2	1	0	3	1	2	1	0	1	1	0	0	1	0	16	.		
	1	06FEB97	7, .	3	0	1	0	2	0	2	1	2	1	0	1	1	0	0	0	0	14	-12.5	NO	NO
	2	13FEB97	14, .	1	0	2	0	0	0	1	0	1	1	0	1	1	0	0	0	0	8	-50.0	YES	YES
	3	21FEB97	22, .	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	-87.5	YES	YES
	4	26FEB97	27, .	1	0	1	1	1	1	0	1	3	1	0	2	0	0	0	2	0	14	-12.5	NO	NO
	5	06MAR97	35, .	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	3	-81.3	YES	YES
	6	13MAR97	42, .	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	3	-81.3	YES	YES
	7	21MAR97	50, .	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	2	0	3	-81.3	YES	YES
	8	27MAR97	56, .	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	-93.8	YES	YES
329.006.00037	SC	20JAN95	-8, .	1	0	0	0	0	0	0	2	2	3	1	0	1	1	0	0	1	12	.		
	BL	27JAN95	-1, .	2	1	1	0	0	0	2	0	1	0	0	0	1	0	3	0	1	12	.		
	1	03FEB95	7, .	0	0	0	0	1	2	0	0	3	0	1	1	1	1	0	0	1	11	-8.3	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.006.00037	2	13FEB95	17, .	1	1	0	2	1	1	1	0	3	1	2	1	1	1	2	1	1	20	66.7	NO	NO
	4	22FEB95	26, .	3	2	1	2	2	0	2	0	0	2	0	0	1	1	0	0	0	16	33.3	NO	NO
329.006.00042	SC	01DEC95	-6, -63	1	2	2	0	1	0	2	1	4	2	2	0	2	0	2	0	0	21	.		
	BL	06DEC95	-1, -58	1	2	2	1	2	0	2	0	4	2	1	0	2	0	1	0	0	20	.		
	1	13DEC95	7, -51	1	2	0	1	1	2	1	1	3	0	2	0	1	0	0	0	0	15	-25.0	NO	NO
	2	20DEC95	14, -44	1	2	2	1	1	0	2	1	1	0	1	0	0	0	0	0	0	12	-40.0	NO	NO
	3	27DEC95	21, -37	3	2	2	1	1	0	1	1	2	1	2	0	1	0	0	0	0	17	-15.0	NO	NO
	4	03JAN96	28, -30	1	3	1	1	1	0	1	1	0	3	2	0	1	0	0	1	0	16	-20.0	NO	NO
	5	10JAN96	35, -23	1	3	1	1	1	0	1	0	2	1	2	0	2	0	1	0	0	16	-20.0	NO	NO
	6	17JAN96	42, -16	1	3	1	1	0	0	2	0	2	0	2	0	1	0	0	2	0	15	-25.0	NO	NO
	7	23JAN96	48, -10	1	2	1	1	0	1	0	0	1	2	1	0	0	0	1	0	0	11	-45.0	NO	NO
	8	02FEB96	58, 1	1	1	2	0	0	0	0	0	1	1	1	1	0	0	0	0	0	8	-60.0	YES	YES
	12	29FEB96	85, 28	1	1	2	0	0	0	0	0	1	2	1	0	1	0	0	0	0	9	-55.0	YES	NO
	16	26MAR96	111, 54	1	0	0	0	0	0	0	0	1	2	1	0	1	0	0	0	0	6	-70.0	YES	YES
	20	23APR96	139, 82	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	-90.0	YES	YES
	24	21MAY96	167, 110	1	2	0	0	0	0	0	4	0	0	1	0	0	0	0	0	0	8	-60.0	YES	YES
	28	18JUN96	195, 138	1	0	0	1	0	2	0	0	4	1	1	0	1	0	0	0	0	11	-45.0	NO	NO
	32	16JUL96	223, 166	1	2	1	0	0	1	0	0	2	0	3	0	0	0	0	2	0	12	-40.0	NO	NO
329.006.00259	SC	22APR96	-32, .	3	0	1	1	1	1	3	0	0	1	0	1	2	0	0	1	0	15	.		
	BL	22MAY96	-2, .	3	0	1	1	0	1	3	0	1	0	0	0	2	0	1	2	1	16	.		
	1	30MAY96	7, .	1	0	0	2	0	0	3	0	2	0	0	0	2	0	1	1	1	13	-18.8	NO	NO
	2	06JUN96	14, .	0	0	0	2	1	2	3	1	1	1	0	0	2	0	1	0	1	15	-6.3	NO	NO
	3	13JUN96	21, .	0	0	0	0	0	0	2	0	0	1	0	0	1	0	3	2	1	10	-37.5	NO	NO
	4	20JUN96	28, .	1	0	1	0	0	1	2	0	2	1	0	0	2	0	0	1	1	12	-25.0	NO	NO
	5	27JUN96	35, .	1	0	0	0	1	1	0	0	2	0	0	0	2	0	3	0	1	11	-31.3	NO	NO
	6	03JUL96	41, .	1	0	1	0	0	0	1	0	4	1	0	0	1	0	0	0	1	10	-37.5	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.006.00259	7	10JUL96	48, .	1	0	1	1	1	1	0	0	4	1	0	0	1	0	0	0	1	12	-25.0	NO	NO
	8	17JUL96	55, .	0	0	0	0	1	1	1	0	2	0	0	0	2	0	0	0	0	7	-56.3	YES	YES
329.007.00141	SC	14SEP95	-7, .	3	2	0	2	1	0	2	3	2	2	1	0	1	0	0	1	2	22	.		
	BL	21SEP95	1, .	3	1	1	1	0	2	3	2	1	3	2	1	1	0	2	0	0	23	.		
	1	28SEP95	8, .	3	1	0	0	0	0	1	3	0	3	0	0	0	0	0	0	2	13	-43.5	NO	NO
	2	05OCT95	15, .	2	1	0	0	1	0	1	2	1	1	0	0	0	0	0	0	1	10	-56.5	YES	NO
	3	12OCT95	22, .	3	1	0	0	1	0	1	1	1	3	0	0	0	0	0	0	2	13	-43.5	NO	NO
329.007.00144	SC	30NOV95	-7, -63	4	2	2	0	1	0	2	2	1	3	0	0	0	0	0	0	1	18	.		
	BL	07DEC95	1, -56	3	2	2	0	1	0	2	2	1	2	1	0	1	0	2	0	1	20	.		
	1	14DEC95	8, -49	3	2	2	0	2	0	3	0	2	3	2	1	2	0	1	0	0	23	15.0	NO	NO
	2	21DEC95	15, -42	2	1	0	1	0	0	1	0	2	2	1	0	0	0	0	0	1	11	-45.0	NO	NO
	3	28DEC95	22, -35	1	1	2	0	1	0	2	1	2	2	2	0	2	0	2	1	0	19	-5.0	NO	NO
	4	04JAN96	29, -28	1	1	0	1	0	0	0	0	2	1	1	0	0	0	0	0	1	8	-60.0	YES	YES
	5	11JAN96	36, -21	1	1	0	0	2	0	1	0	1	0	0	1	0	0	2	0	0	9	-55.0	YES	NO
	6	18JAN96	43, -14	1	0	0	0	0	0	0	0	1	1	1	0	1	0	0	0	1	6	-70.0	YES	YES
	7	25JAN96	50, -7	1	1	0	0	0	0	0	0	1	2	0	0	0	0	0	0	1	6	-70.0	YES	YES
	8	01FEB96	57, 1	1	1	0	0	0	0	1	0	1	1	1	1	0	0	0	0	1	8	-60.0	YES	YES
329.007.00266	SC	29FEB96	-7, .	4	2	0	2	0	0	3	0	2	3	0	0	0	0	0	2	2	20	.		
	BL	07MAR96	1, .	3	1	0	2	1	0	3	1	2	3	0	1	1	0	0	0	2	20	.		
	1	14MAR96	8, .	1	1	0	0	0	0	1	0	2	2	0	0	0	0	0	0	1	8	-60.0	YES	YES
	3	25MAR96	19, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	3	28MAR96	22, .	1	0	0	0	0	0	2	0	2	1	0	0	0	0	0	0	0	6	-70.0	YES	YES
	4	04APR96	29, .	3	2	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	7	-65.0	YES	YES
	5	11APR96	36, .	2	0	0	2	0	0	1	1	2	1	0	0	0	0	0	0	0	9	-55.0	YES	NO
	6	18APR96	43, .	2	0	0	1	0	0	1	0	2	1	0	0	0	0	0	0	0	7	-65.0	YES	YES

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Paroxetine - Protocol 329
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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.007.00266	8	29APR96	54, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	8	02MAY96	57, .	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-95.0	YES	YES
329.007.00267	SC	29FEB96	-7, .	4	1	0	1	0	0	3	3	1	3	0	0	0	0	0	0	2	18	.		
	BL	07MAR96	1, .	4	1	0	2	0	0	3	3	1	3	0	0	0	0	0	0	1	18	.		
	1	14MAR96	8, .	3	0	0	0	0	0	2	2	1	1	0	0	0	0	0	0	2	11	-38.9	NO	NO
	2	21MAR96	15, .	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	3	28MAR96	22, .	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	-88.9	YES	YES
	4	04APR96	29, .	2	0	0	2	0	0	1	1	0	0	0	0	0	0	0	1	0	7	-61.1	YES	YES
	5	11APR96	36, .	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	6	18APR96	43, .	2	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	4	-77.8	YES	YES
	7	25APR96	50, .	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	0	0	3	-83.3	YES	YES
	8	02MAY96	57, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.007.00311	SC	26SEP96	-7, -67	4	2	0	0	2	0	3	1	0	3	0	0	0	0	0	0	0	15	.		
	BL	03OCT96	1, -60	3	1	0	0	2	2	3	0	2	3	0	0	0	0	0	0	0	16	.		
	1	10OCT96	8, -53	0	0	0	0	2	0	2	0	0	1	1	1	0	0	0	1	0	8	-50.0	YES	YES
	2	17OCT96	15, -46	2	0	0	0	2	0	0	0	1	2	0	0	0	0	0	0	0	7	-56.3	YES	YES
	4	28OCT96	26, -35	1	0	0	0	2	0	0	0	1	2	0	1	0	0	0	0	0	7	-56.3	YES	YES
	4	31OCT96	29, -32	1	0	0	0	2	0	1	0	0	1	0	0	0	0	0	0	0	5	-68.8	YES	YES
	5	07NOV96	36, -25	0	0	0	0	2	0	0	0	1	2	0	0	0	0	0	0	0	5	-68.8	YES	YES
	6	14NOV96	43, -18	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	2	-87.5	YES	YES
	7	22NOV96	51, -10	2	1	0	0	2	0	1	1	0	2	0	1	0	0	0	0	0	10	-37.5	NO	NO
	8	02DEC96	61, 1	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	3	-81.3	YES	YES
	12	02JAN97	92, 32	2	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	0	5	-68.8	YES	YES
	16	30JAN97	120, 60	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	3	-81.3	YES	YES
	24	13MAR97	162, 102	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	3	-81.3	YES	YES
	28	11APR97	191, 131	3	1	0	1	2	0	2	0	1	2	0	0	0	0	0	0	0	12	-25.0	NO	NO

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Paroxetine - Protocol 329
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Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.008.00158	SC	06SEP95	-7, -69	2	1	2	2	1	0	3	2	0	3	0	1	1	0	0	0	0	18	.		
	BL	13SEP95	1, -62	3	0	0	2	1	1	3	3	0	0	1	0	1	0	1	1	0	17	.		
	1	19SEP95	7, -56	3	1	2	2	1	0	0	2	0	0	1	0	1	0	0	0	0	13	-23.5	NO	NO
	2	27SEP95	15, -48	3	0	0	2	2	1	2	2	0	2	0	0	2	0	1	1	0	18	5.9	NO	NO
	3	03OCT95	21, -42	2	0	0	1	0	0	2	1	0	1	0	0	0	0	1	0	0	8	-52.9	YES	YES
	4	10OCT95	28, -35	1	0	0	0	0	0	2	0	0	1	0	1	0	0	1	0	0	6	-64.7	YES	YES
	5	16OCT95	34, -29	2	0	0	1	0	0	1	2	0	1	0	0	2	0	1	0	0	10	-41.2	NO	NO
	6	24OCT95	42, -21	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	-88.2	YES	YES
	7	31OCT95	49, -14	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-88.2	YES	YES
	8	14NOV95	63, 1	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	2	-88.2	YES	YES
	16	26DEC95	105, 43	2	0	0	1	0	0	3	1	0	1	0	0	1	0	0	0	0	9	-47.1	NO	NO
	20	23JAN96	133, 71	2	0	3	2	0	0	3	1	0	0	0	0	2	0	3	0	0	16	-5.9	NO	NO
329.008.00162	SC	26OCT95	-6, -71	4	2	3	2	2	0	3	2	0	3	0	0	2	0	1	2	0	26	.		
	BL	01NOV95	1, -65	1	2	1	2	2	1	2	2	1	1	0	0	1	0	1	0	0	17	.		
	1	10NOV95	10, -56	4	1	2	2	2	0	3	2	1	1	2	1	2	1	1	1	0	26	52.9	NO	NO
	3	20NOV95	20, -46	3	2	2	2	0	0	3	2	1	2	1	0	2	0	0	0	0	20	17.6	NO	NO
	4	29NOV95	29, -37	2	2	2	2	1	0	3	2	0	2	0	0	0	0	0	0	0	16	-5.9	NO	NO
	5	07DEC95	37, -29	1	2	0	2	0	0	3	2	0	0	0	1	1	0	0	0	0	12	-29.4	NO	NO
	6	14DEC95	44, -22	0	2	0	2	1	0	0	0	0	2	1	0	0	0	0	0	0	8	-52.9	YES	YES
	7	20DEC95	50, -16	0	2	0	2	0	0	3	0	0	0	0	1	0	0	0	0	0	8	-52.9	YES	YES
	8	27DEC95	57, -9	1	2	0	2	0	0	3	0	0	2	2	0	0	0	2	0	0	14	-17.6	NO	NO
	8	05JAN96	66, 1	1	1	1	2	1	0	3	1	0	1	0	0	1	0	0	0	0	12	-29.4	NO	NO
	16	09FEB96	101, 36	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	3	-82.4	YES	YES
	20	08MAR96	129, 64	1	0	0	2	0	0	0	1	0	1	2	1	0	0	0	0	0	8	-52.9	YES	YES
	24	11APR96	163, 98	0	0	0	1	1	0	1	0	0	0	0	0	0	0	0	0	0	3	-82.4	YES	YES
	24	01MAY96	183, 118	0	0	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	3	-82.4	YES	YES
	32	05JUN96	218, 153	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0	0	0	3	-82.4	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.008.00162	32	02JUL96	245, 180	0	0	0	2	0	1	3	0	0	1	2	0	1	0	0	0	0	10	-41.2	NO	NO
329.008.00191	SC	12JAN96	-20, -81	4	2	3	2	2	0	3	2	0	2	0	0	0	0	1	2	0	23	.		
	BL	01FEB96	1, -61	4	2	2	2	2	0	3	2	0	2	0	0	0	0	1	0	0	20	.		
	2	12FEB96	12, -50	0	2	2	0	0	0	1	1	0	2	0	1	1	0	0	0	0	10	-50.0	YES	NO
	3	20FEB96	20, -42	1	1	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	5	-75.0	YES	YES
	4	27FEB96	27, -35	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	2	-90.0	YES	YES
	5	05MAR96	34, -28	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-90.0	YES	YES
	6	12MAR96	41, -21	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-90.0	YES	YES
	7	18MAR96	47, -15	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	-95.0	YES	YES
	8	26MAR96	55, -7	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	-95.0	YES	YES
	8	02APR96	62, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	01MAY96	91, 30	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-90.0	YES	YES
	16	05JUN96	126, 65	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	2	-90.0	YES	YES
	20	12JUN96	133, 72	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.009.00128	SC	05APR95	-6, .	3	2	2	2	0	0	2	1	2	3	2	0	2	0	2	0	0	23	.		
	BL	11APR95	1, .	3	1	2	2	1	0	2	1	2	3	2	1	2	0	2	0	0	24	.		
	1	18APR95	8, .	3	2	1	1	1	0	2	2	2	3	2	1	1	0	2	0	1	24	0.0	NO	NO
	2	25APR95	15, .	3	1	1	2	1	0	2	2	2	2	2	1	1	0	2	0	1	23	-4.2	NO	NO
329.009.00129	SC	22MAR95	-20, .	4	3	2	1	2	2	3	2	2	2	2	0	2	1	1	0	0	29	.		
	BL	11APR95	1, .	3	1	1	2	1	1	3	2	3	3	2	1	2	1	1	0	0	27	.		
	1	18APR95	8, .	4	2	1	2	2	0	2	2	2	2	2	1	1	0	1	0	0	24	-11.1	NO	NO
	2	25APR95	15, .	3	2	1	2	1	0	2	1	2	2	2	1	1	0	1	0	0	21	-22.2	NO	NO
	3	02MAY95	22, .	3	2	1	2	1	1	2	1	1	2	2	1	1	0	1	0	1	22	-18.5	NO	NO
	4	09MAY95	29, .	4	2	2	2	1	1	2	2	3	2	2	1	1	0	1	1	0	27	0.0	NO	NO
	5	16MAY95	36, .	4	2	1	2	1	0	2	2	2	1	2	0	1	0	1	0	0	21	-22.2	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00135	SC	25SEP95	-7, .	4	2	0	1	0	1	4	3	0	2	2	2	2	1	3	0	0	27	.		
	BL	02OCT95	1, .	4	3	1	1	0	0	4	3	1	3	2	1	2	1	1	0	0	27	.		
	1	09OCT95	8, .	4	3	1	1	0	0	4	3	1	3	2	1	2	1	1	0	0	27	0.0	NO	NO
	2	16OCT95	15, .	4	3	1	1	0	0	4	3	2	1	3	1	2	1	1	0	0	27	0.0	NO	NO
	3	23OCT95	22, .	4	2	1	1	0	0	4	3	1	2	2	1	2	1	1	0	0	25	-7.4	NO	NO
	4	30OCT95	29, .	4	3	1	1	0	0	4	3	1	1	2	1	2	1	1	0	0	25	-7.4	NO	NO
	5	06NOV95	36, .	4	2	1	1	0	0	4	3	0	3	0	1	2	1	2	0	0	24	-11.1	NO	NO
329.009.00136	SC	26SEP95	-7, .	4	0	3	2	2	1	4	1	0	2	3	0	2	0	0	0	0	24	.		
	BL	03OCT95	1, .	4	2	1	2	2	1	3	2	1	1	1	0	1	0	1	0	0	22	.		
	1	10OCT95	8, .	4	2	1	2	2	1	3	2	2	1	2	0	1	0	1	0	0	24	9.1	NO	NO
	2	17OCT95	15, .	3	2	1	2	2	1	2	2	1	2	2	0	1	0	2	0	0	23	4.5	NO	NO
	3	24OCT95	22, .	3	2	1	2	2	1	2	2	1	1	2	1	1	0	0	0	0	21	-4.5	NO	NO
	4	03NOV95	32, .	3	1	0	2	2	0	2	2	2	2	1	0	1	0	1	0	0	19	-13.6	NO	NO
	5	07NOV95	36, .	3	1	0	2	1	0	1	1	2	1	1	0	0	0	2	0	0	15	-31.8	NO	NO
	6	14NOV95	43, .	3	1	2	2	1	2	2	2	2	2	1	0	1	0	1	0	0	22	0.0	NO	NO
	7	21NOV95	50, .	3	2	1	2	2	0	2	2	2	2	1	0	1	0	1	0	0	21	-4.5	NO	NO
	8	28NOV95	57, .	3	2	1	2	2	0	3	2	2	2	1	0	1	0	1	0	1	23	4.5	NO	NO
329.009.00169	SC	25OCT95	-6, -71	4	3	3	1	2	2	3	0	3	3	1	1	0	0	0	1	0	27	.		
	BL	31OCT95	1, -65	3	2	2	2	2	1	2	2	1	2	1	2	1	0	1	1	0	25	.		
	1	07NOV95	8, -58	3	2	2	1	2	1	2	2	2	2	1	2	1	0	1	1	0	25	0.0	NO	NO
	2	14NOV95	15, -51	1	1	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	4	-84.0	YES	YES
	3	21NOV95	22, -44	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	2	-92.0	YES	YES
	4	28NOV95	29, -37	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-92.0	YES	YES
	5	05DEC95	36, -30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	6	12DEC95	43, -23	1	1	0	0	0	0	1	0	2	1	1	0	0	0	0	0	0	7	-72.0	YES	YES
	7	19DEC95	50, -16	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	2	-92.0	YES	YES

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Paroxetine - Protocol 329
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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00169	8	27DEC95	58, -8	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	2	-92.0	YES	YES
	12	23JAN96	85, 20	0	0	0	0	0	0	1	0	2	0	0	0	0	0	0	0	0	3	-88.0	YES	YES
329.009.00174	SC	14NOV95	-7, -64	1	1	2	2	1	0	3	0	2	1	0	0	1	0	0	0	0	14	.		
	BL	21NOV95	1, -57	2	1	2	2	1	0	3	0	3	1	0	1	2	0	1	0	1	20	.		
	1	28NOV95	8, -50	2	1	0	2	0	0	3	0	2	1	0	0	2	0	1	0	1	15	-25.0	NO	NO
	2	05DEC95	15, -43	3	1	0	2	0	0	3	1	1	1	1	2	2	0	2	0	1	20	0.0	NO	NO
	3	12DEC95	22, -36	3	1	0	1	0	0	3	1	1	1	1	1	2	0	1	0	1	17	-15.0	NO	NO
	4	19DEC95	29, -29	1	0	0	0	0	0	2	0	1	1	0	0	1	0	0	0	1	7	-65.0	YES	YES
	5	27DEC95	37, -21	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-90.0	YES	YES
	6	02JAN96	43, -15	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-95.0	YES	YES
	7	09JAN96	50, -8	1	0	0	1	0	0	1	1	0	1	0	0	0	0	0	0	0	5	-75.0	YES	YES
	8	17JAN96	58, 1	2	1	0	0	0	0	1	0	2	1	0	0	1	0	0	0	0	8	-60.0	YES	YES
	12	31JAN96	72, 15	2	1	0	0	0	0	4	1	1	1	2	1	2	0	1	0	1	17	-15.0	NO	NO
329.009.00197	SC	20DEC95	-9, -63	4	2	1	1	0	0	3	2	2	2	2	1	2	0	0	0	2	24	.		
	BL	29DEC95	1, -54	4	2	2	1	1	0	3	2	2	1	2	0	2	0	1	0	1	24	.		
	1	02JAN96	5, -50	3	2	2	1	1	0	3	2	2	1	2	0	2	0	1	0	1	23	-4.2	NO	NO
	1	08JAN96	11, -44	2	2	2	0	1	0	2	2	2	1	2	0	2	0	1	0	1	20	-16.7	NO	NO
	3	16JAN96	19, -36	3	2	0	0	0	0	2	2	1	1	1	0	1	0	1	0	2	16	-33.3	NO	NO
	4	23JAN96	26, -29	1	1	0	1	0	0	1	1	2	1	1	1	2	0	1	0	1	14	-41.7	NO	NO
	5	30JAN96	33, -22	1	0	0	0	0	0	1	1	1	1	1	0	0	0	1	0	1	8	-66.7	YES	YES
	6	06FEB96	40, -15	0	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	4	-83.3	YES	YES
	7	13FEB96	47, -8	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	-95.8	YES	YES
	8	20FEB96	54, -1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	19MAR96	82, 28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	23APR96	117, 63	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.8	YES	YES
	20	21MAY96	145, 91	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00197	24	25JUN96	180, 126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	28	16JUL96	201, 147	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	-95.8	YES	YES
	32	20AUG96	236, 182	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.009.00198	SC	19DEC95	-14, .	4	1	2	2	2	2	3	0	2	2	2	2	2	2	1	2	0	31	.		
	BL	02JAN96	1, .	4	2	2	2	2	1	3	2	1	3	2	2	1	0	1	2	1	31	.		
	1	08JAN96	7, .	4	2	2	1	2	1	3	2	1	3	2	2	2	0	2	1	1	31	0.0	NO	NO
	2	16JAN96	15, .	4	2	1	2	2	1	3	1	3	2	2	2	2	0	1	0	1	29	-6.5	NO	NO
	3	23JAN96	22, .	4	2	1	2	2	1	3	1	3	2	2	2	2	0	1	0	1	29	-6.5	NO	NO
	4	30JAN96	29, .	4	2	1	2	0	0	3	2	2	2	2	2	2	0	2	1	0	27	-12.9	NO	NO
	5	06FEB96	36, .	3	2	0	2	1	1	3	2	2	2	1	1	2	0	2	0	0	24	-22.6	NO	NO
	6	13FEB96	43, .	3	2	1	2	1	1	3	2	1	2	1	1	2	0	2	1	0	25	-19.4	NO	NO
	7	20FEB96	50, .	4	2	1	2	1	1	3	2	1	2	1	2	1	0	2	1	0	26	-16.1	NO	NO
	8	27FEB96	57, .	4	2	1	2	1	1	3	2	2	2	2	2	2	1	1	1	0	29	-6.5	NO	NO
329.009.00200	SC	17JAN96	-6, .	4	0	2	2	0	0	4	2	2	1	0	0	2	2	0	0	1	22	.		
	BL	23JAN96	1, .	4	2	1	2	2	1	3	2	1	2	2	1	2	0	2	0	2	29	.		
	1	02FEB96	11, .	4	1	1	1	1	0	4	2	1	2	1	1	2	0	0	0	2	23	-20.7	NO	NO
	2	06FEB96	15, .	4	1	1	2	1	0	3	2	2	2	1	1	2	0	0	0	1	23	-20.7	NO	NO
	3	13FEB96	22, .	4	1	1	2	1	0	4	2	2	2	1	1	1	0	0	1	1	24	-17.2	NO	NO
	4	20FEB96	29, .	4	1	1	2	1	0	3	2	2	2	1	1	2	0	0	1	1	24	-17.2	NO	NO
	5	28FEB96	37, .	4	1	1	2	1	0	4	2	2	2	1	1	2	0	1	0	1	25	-13.8	NO	NO
	6	08MAR96	46, .	4	1	1	2	1	1	4	2	3	2	1	1	2	0	2	0	1	28	-3.4	NO	NO
329.009.00202	SC	14FEB96	-6, .	2	2	2	2	2	2	3	1	3	2	1	2	2	0	0	2	0	28	.		
	BL	20FEB96	1, .	4	2	1	2	2	1	3	2	2	2	2	2	2	0	2	2	2	33	.		
	1	27FEB96	8, .	4	2	1	2	1	1	3	1	2	2	2	2	2	0	3	0	1	29	-12.1	NO	NO
	2	08MAR96	18, .	4	2	1	2	1	0	2	1	1	2	2	2	2	0	2	0	1	25	-24.2	NO	NO

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Paroxetine - Protocol 329
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Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00202	4	19MAR96	29,	.	2	1	1	2	1	1	2	1	1	1	0	0	0	0	0	0	1	14	-57.6	YES	NO
	5	26MAR96	36,	.	1	1	0	1	1	0	2	1	2	2	1	0	0	0	0	0	0	12	-63.6	YES	NO
329.009.00237	SC	04NOV96	-7,	.	1	2	0	2	1	0	3	1	1	1	0	0	0	0	0	0	2	14	.		
	BL	11NOV96	1,	.	3	1	0	2	0	0	3	2	0	1	0	1	2	0	0	1	0	16	.		
	1	18NOV96	8,	.	3	1	0	2	1	0	3	2	1	1	0	1	2	0	0	0	0	17	6.3	NO	NO
329.009.00238	SC	28OCT96	-15,	.	2	2	1	2	2	0	3	1	1	2	2	0	2	1	0	2	0	23	.		
	BL	12NOV96	1,	.	2	2	3	2	1	0	2	1	1	2	1	0	2	0	1	0	0	20	.		
	1	19NOV96	8,	.	3	2	2	1	0	0	2	1	1	1	0	0	1	1	0	0	0	15	-25.0	NO	NO
	2	26NOV96	15,	.	2	1	1	2	2	1	2	0	1	1	0	0	0	0	0	0	0	13	-35.0	NO	NO
	3	03DEC96	22,	.	3	1	0	2	0	0	2	1	1	2	1	1	2	0	0	0	0	16	-20.0	NO	NO
	4	10DEC96	29,	.	1	0	0	0	0	0	1	0	1	1	0	1	0	0	0	1	0	6	-70.0	YES	YES
	5	17DEC96	36,	.	1	1	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	6	-70.0	YES	YES
	6	23DEC96	42,	.	2	1	0	0	0	0	1	0	0	0	0	0	2	0	0	0	0	6	-70.0	YES	YES
	7	31DEC96	50,	.	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	-90.0	YES	YES
	8	07JAN97	57,	.	3	1	0	2	0	0	1	2	0	1	0	0	2	0	0	0	0	12	-40.0	NO	NO
329.009.00276	SC	17JAN97	-4,	.	2	0	3	1	2	0	4	2	2	2	2	1	2	0	0	1	0	24	.		
	BL	21JAN97	1,	.	4	1	3	2	2	1	3	1	3	2	2	1	2	0	0	0	1	28	.		
	1	28JAN97	8,	.	3	1	1	2	2	1	2	0	1	1	0	1	1	0	0	2	1	19	-32.1	NO	NO
	2	04FEB97	15,	.	3	1	1	2	1	0	3	1	1	2	0	1	2	0	0	0	0	18	-35.7	NO	NO
	3	11FEB97	22,	.	3	1	2	2	0	0	3	0	1	1	0	1	2	1	0	1	1	19	-32.1	NO	NO
	4	18FEB97	29,	.	2	0	1	1	1	0	2	1	0	0	0	0	2	0	0	0	1	11	-60.7	YES	NO
	5	25FEB97	36,	.	2	0	1	2	0	0	2	0	1	1	0	0	1	0	0	0	0	10	-64.3	YES	NO
	6	04MAR97	43,	.	2	0	0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	6	-78.6	YES	YES
	7	13MAR97	52,	.	2	0	0	2	0	0	1	0	0	1	0	0	1	0	0	0	0	7	-75.0	YES	YES
	8	18MAR97	57,	.	2	0	0	2	0	0	2	1	0	1	0	1	2	0	0	1	0	12	-57.1	YES	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00302	SC	20MAR96	-7,	.	3	1	1	2	0	0	3	2	0	2	0	0	1	1	0	0	1	17	.		
	BL	27MAR96	1,	.	3	1	1	0	0	0	3	2	1	1	1	1	2	1	0	1	0	18	.		
	1	03APR96	8,	.	3	2	0	1	0	0	3	0	1	2	0	1	1	0	0	0	0	14	-22.2	NO	NO
	2	10APR96	15,	.	2	2	0	0	0	0	2	1	1	1	0	1	0	0	0	0	0	10	-44.4	NO	NO
329.009.00306	SC	03JUN96	-8,	.	3	0	2	2	1	0	3	2	0	2	0	0	1	0	0	0	1	17	.		
	BL	11JUN96	1,	.	3	2	2	2	1	1	3	2	1	2	1	1	0	0	0	0	1	22	.		
	1	18JUN96	8,	.	3	2	2	2	1	1	3	2	0	2	1	1	0	0	0	0	1	21	-4.5	NO	NO
	2	25JUN96	15,	.	4	2	1	2	1	1	4	3	2	2	0	2	1	0	0	1	1	27	22.7	NO	NO
	3	02JUL96	22,	.	3	2	1	2	2	2	2	2	2	2	1	1	2	0	1	0	1	26	18.2	NO	NO
	4	09JUL96	29,	.	2	2	1	1	1	1	2	2	1	2	1	1	1	0	0	0	0	18	-18.2	NO	NO
	5	16JUL96	36,	.	1	1	0	1	1	0	2	1	2	1	1	1	2	0	0	0	0	14	-36.4	NO	NO
	6	23JUL96	43,	.	1	1	0	0	0	0	2	1	0	1	1	0	2	0	0	0	0	9	-59.1	YES	NO
	7	30JUL96	50,	.	3	1	0	1	0	0	3	2	0	0	0	0	2	0	0	0	1	13	-40.9	NO	NO
	8	06AUG96	57,	.	2	1	0	0	0	0	2	1	0	0	0	1	1	0	0	0	1	9	-59.1	YES	NO
329.009.00312	SC	30OCT96	-5,	.	2	1	1	0	2	0	3	1	0	4	2	0	2	1	1	0	0	20	.		
	BL	04NOV96	1,	.	4	2	1	0	1	1	3	2	1	2	2	0	2	0	1	0	0	22	.		
	2	15NOV96	12,	.	4	2	0	0	1	1	3	2	1	1	1	0	2	0	1	0	1	20	-9.1	NO	NO
	2	18NOV96	15,	.	3	2	0	1	1	0	2	2	1	1	1	0	1	0	0	0	1	16	-27.3	NO	NO
	4	02DEC96	29,	.	3	2	0	2	1	1	4	2	1	1	2	0	2	0	1	0	1	23	4.5	NO	NO
	5	09DEC96	36,	.	3	1	0	2	2	1	2	2	1	1	1	1	2	0	1	0	1	21	-4.5	NO	NO
	6	16DEC96	43,	.	3	1	0	0	0	0	3	2	0	1	0	0	1	0	1	0	1	13	-40.9	NO	NO
	8	27DEC96	54,	.	3	2	0	1	1	0	3	2	1	2	1	0	2	0	1	0	1	20	-9.1	NO	NO
	8	30DEC96	57,	.	3	1	1	0	0	0	3	2	1	1	0	0	2	0	0	0	2	16	-27.3	NO	NO
	8	06JAN97	64,	.	3	2	0	0	1	0	3	2	0	2	1	0	2	0	1	0	1	18	-18.2	NO	NO
329.009.00327	SC	09SEP96	-7,	.	3	2	2	2	2	1	3	2	3	2	2	1	2	1	1	1	0	30	.		

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.009.00327	BL	16SEP96	1,	.	4	2	1	2	2	0	3	2	2	3	2	1	2	0	1	0	0	27	.		
	1	23SEP96	8,	.	4	2	1	2	2	1	3	2	1	2	2	2	1	0	1	1	0	27	0.0	NO	NO
	2	30SEP96	15,	.	4	2	1	2	1	1	3	2	1	2	2	2	2	0	1	1	0	27	0.0	NO	NO
	3	07OCT96	22,	.	4	2	1	2	2	1	3	2	1	2	2	2	2	0	1	1	0	28	3.7	NO	NO
	4	14OCT96	29,	.	4	2	1	2	1	1	3	1	1	2	2	1	2	0	1	1	0	25	-7.4	NO	NO
	5	21OCT96	36,	.	4	1	1	2	2	1	3	2	1	2	2	1	2	0	1	1	0	26	-3.7	NO	NO
329.009.00330	SC	15OCT96	-6,	.	3	2	3	1	2	1	3	1	4	4	2	1	1	0	0	1	0	29	.		
	BL	21OCT96	1,	.	3	1	2	2	1	1	2	2	1	1	0	1	1	0	0	1	2	21	.		
	1	28OCT96	8,	.	2	0	1	0	1	1	1	2	1	1	0	1	2	0	0	1	2	16	-23.8	NO	NO
	2	04NOV96	15,	.	2	1	1	1	1	1	2	1	2	2	1	1	2	0	2	0	1	21	0.0	NO	NO
329.010.00183	SC	21NOV95	-12,	.	3	0	3	0	0	0	3	0	2	0	0	1	2	0	0	2	1	17	.		
	BL	28NOV95	-5,	.	3	0	0	0	2	0	3	0	2	1	1	1	2	0	0	0	1	16	.		
	1	05DEC95	3,	.	2	0	0	0	2	0	2	0	3	2	0	0	1	0	0	0	1	13	-18.8	NO	NO
	2	19DEC95	17,	.	1	0	0	0	0	0	2	0	3	1	0	0	0	0	0	0	1	8	-50.0	YES	YES
329.010.00263	SC	24JUL96	-16,	.	4	2	0	2	0	0	3	2	0	2	1	0	0	0	1	1	0	18	.		
	BL	09AUG96	1,	.	3	1	0	2	0	0	3	1	0	2	2	0	1	0	2	0	1	18	.		
	1	14AUG96	6,	.	3	1	0	1	0	0	2	1	0	2	0	0	1	0	2	0	1	14	-22.2	NO	NO
	2	21AUG96	13,	.	1	1	0	1	0	0	2	1	0	2	0	0	1	0	2	0	1	12	-33.3	NO	NO
	3	28AUG96	20,	.	1	0	0	0	0	0	1	1	0	2	0	0	0	0	2	0	1	8	-55.6	YES	YES
	4	04SEP96	27,	.	0	0	0	0	0	0	1	0	0	1	0	0	1	0	1	0	1	5	-72.2	YES	YES
	5	11SEP96	34,	.	1	0	0	0	0	0	1	1	0	1	0	0	1	0	2	0	0	7	-61.1	YES	YES
	6	18SEP96	41,	.	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	0	0	3	-83.3	YES	YES
	7	25SEP96	48,	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	-94.4	YES	YES
	8	09OCT96	62,	.	1	0	0	1	0	0	2	1	0	1	0	0	0	0	1	0	0	7	-61.1	YES	YES

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.010.00277	SC	23FEB96	-7, -63	2	0	0	0	0	0	3	1	4	0	3	0	2	1	0	0	1	17	.		
	BL	01MAR96	1, -56	2	1	0	0	0	0	3	1	4	0	2	0	2	1	0	0	1	17	.		
	1	08MAR96	8, -49	1	0	0	0	0	0	3	1	4	0	0	0	2	1	0	0	1	13	-23.5	NO	NO
	2	18MAR96	18, -39	1	0	0	0	0	0	3	1	2	0	1	2	0	1	0	0	1	12	-29.4	NO	NO
	3	22MAR96	22, -35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	-94.1	YES	YES
	4	29MAR96	29, -28	1	0	0	0	0	0	2	0	1	0	0	1	1	1	0	0	1	8	-52.9	YES	YES
	6	15APR96	46, -11	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	-88.2	YES	YES
	7	19APR96	50, -7	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	2	-88.2	YES	YES
	8	26APR96	57, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	12	24MAY96	85, 29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	16	21JUN96	113, 57	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
	24	07AUG96	160, 104	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-100.0	YES	YES
329.010.00282	SC	19JUL96	-7, .	3	0	0	0	0	0	2	1	3	1	0	0	1	0	3	0	1	15	.		
	BL	26JUL96	1, .	3	0	0	0	0	0	2	0	3	1	0	0	1	0	3	0	1	14	.		
	1	02AUG96	8, .	3	0	0	0	0	0	2	0	2	1	0	0	0	0	2	0	1	11	-21.4	NO	NO
	2	09AUG96	15, .	2	0	0	0	0	0	2	0	2	1	0	0	0	0	2	0	1	10	-28.6	NO	NO
	3	16AUG96	22, .	2	0	0	0	0	0	3	0	1	1	0	0	1	0	2	0	1	11	-21.4	NO	NO
	4	26AUG96	32, .	1	0	0	0	0	0	2	0	0	1	0	0	0	0	2	0	1	7	-50.0	YES	YES
	6	03SEP96	40, .	1	0	0	0	0	0	2	0	1	1	0	0	1	0	1	0	1	8	-42.9	YES	YES
	7	13SEP96	50, .	0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	3	-78.6	YES	YES
	8	19SEP96	56, .	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	3	-78.6	YES	YES
	8	27SEP96	64, .	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-92.9	YES	YES
329.011.00164	SC	15DEC95	-7, .	3	0	0	1	1	0	3	1	1	2	1	1	1	0	0	1	0	16	.		
	BL	21DEC95	-1, .	3	0	0	2	2	0	4	1	2	3	1	0	1	0	0	0	0	19	.		
	1	28DEC95	7, .	3	0	0	0	2	1	3	1	3	1	2	0	2	0	0	0	0	18	-5.3	NO	NO
	2	04JAN96	14, .	2	0	0	2	1	0	4	0	3	1	1	0	1	0	0	0	0	15	-21.1	NO	NO

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.011.00164	3	11JAN96	21, .	2	0	0	2	1	0	3	1	2	1	0	0	1	0	0	0	0	13	-31.6	NO	NO
	4	18JAN96	28, .	3	0	0	2	1	0	3	1	2	1	0	0	2	0	0	0	0	15	-21.1	NO	NO
	5	25JAN96	35, .	2	0	0	2	1	0	3	0	2	1	1	0	1	0	0	0	0	13	-31.6	NO	NO
329.011.00210	SC	13SEP96	-15, -81	3	0	2	2	1	2	1	0	1	2	1	1	1	0	0	0	1	18	.		
	BL	27SEP96	-1, -67	3	0	1	2	2	1	2	0	2	1	0	1	1	0	0	0	2	18	.		
	1	03OCT96	6, -61	2	0	1	1	1	0	2	0	2	1	0	0	1	0	0	0	0	11	-38.9	NO	NO
	2	09OCT96	12, -55	4	2	2	0	0	0	3	0	2	3	2	0	2	0	1	0	0	21	16.7	NO	NO
	3	17OCT96	20, -47	3	0	0	1	1	0	2	1	2	2	1	1	1	0	0	1	0	16	-11.1	NO	NO
	4	24OCT96	27, -40	0	0	0	2	1	0	1	0	2	1	0	0	1	0	0	0	0	8	-55.6	YES	YES
	5	04NOV96	38, -29	1	0	0	1	0	0	1	0	1	1	1	0	1	1	0	0	0	8	-55.6	YES	YES
	6	12NOV96	46, -21	0	2	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	4	-77.8	YES	YES
	8	22NOV96	56, -11	0	1	0	0	0	0	0	0	2	1	0	1	0	0	0	0	0	5	-72.2	YES	YES
	8	02DEC96	66, -1	0	1	0	0	0	0	1	0	2	1	0	1	1	0	0	1	0	8	-55.6	YES	YES
329.011.00285	SC	08MAY96	-10, .	3	2	2	2	2	2	3	1	0	3	1	1	1	0	2	0	0	25	.		
	BL	17MAY96	-1, .	3	1	2	2	2	2	3	1	0	3	1	1	1	0	2	0	0	24	.		
	1	27MAY96	10, .	3	0	0	2	2	2	3	1	2	2	1	1	1	0	0	0	0	20	-16.7	NO	NO
	2	03JUN96	17, .	3	2	2	2	1	2	3	1	0	3	1	0	1	0	1	0	0	22	-8.3	NO	NO
	3	10JUN96	24, .	3	0	2	2	2	1	3	0	1	2	1	1	1	0	0	0	0	19	-20.8	NO	NO
	5	21JUN96	35, .	4	0	1	2	1	0	2	1	2	2	0	1	1	0	1	0	0	18	-25.0	NO	NO
	6	28JUN96	42, .	3	0	2	2	0	0	2	1	2	3	1	1	1	0	0	1	0	19	-20.8	NO	NO
	7	08JUL96	52, .	3	1	2	2	2	0	3	1	2	1	1	1	1	0	0	0	0	20	-16.7	NO	NO
	8	18JUL96	62, .	3	0	0	2	1	0	1	1	2	2	0	0	1	0	0	1	0	14	-41.7	NO	NO
	8	24JUL96	68, .	3	0	0	2	1	0	1	1	2	2	0	0	1	0	0	0	0	13	-45.8	NO	NO
329.011.00287	SC	25JUN96	-8, .	3	2	2	2	1	0	2	0	2	2	1	0	1	0	0	0	0	18	.		
	BL	02JUL96	-1, .	3	1	2	1	0	0	1	1	2	1	0	1	1	0	0	0	1	15	.		

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.011.00287	1	09JUL96	7, .	2	0	2	2	1	0	1	0	2	1	1	0	1	0	0	0	0	13	-13.3	NO	NO
	2	17JUL96	15, .	1	1	1	2	1	0	1	0	2	2	0	1	1	0	0	1	0	14	-6.7	NO	NO
	3	23JUL96	21, .	2	0	0	2	1	0	1	0	2	1	0	1	1	0	0	1	1	13	-13.3	NO	NO
	4	30JUL96	28, .	2	0	2	1	1	0	2	0	2	1	0	1	1	0	0	0	0	13	-13.3	NO	NO
	5	06AUG96	35, .	1	0	1	1	1	1	1	0	2	1	0	1	1	0	0	0	0	11	-26.7	NO	NO
	6	13AUG96	42, .	1	1	1	1	1	0	1	0	2	1	0	0	0	0	0	0	0	9	-40.0	NO	NO
	7	20AUG96	49, .	1	0	0	1	0	1	1	0	2	1	0	1	1	0	0	0	0	9	-40.0	NO	NO
	8	27AUG96	56, .	2	0	0	1	1	1	1	0	1	1	0	0	1	0	0	0	0	9	-40.0	NO	NO
329.012.00027	SC	23NOV95	-13, .	4	2	1	2	1	2	3	2	0	1	0	2	2	0	0	0	0	22	.		
	BL	06DEC95	1, .	4	1	1	2	1	1	3	2	0	1	0	2	2	0	0	0	0	20	.		
	1	12DEC95	7, .	2	2	0	0	1	1	3	2	1	1	0	0	2	0	0	0	0	15	-25.0	NO	NO
	2	19DEC95	14, .	3	2	1	0	2	2	3	0	0	4	2	1	1	0	1	0	0	22	10.0	NO	NO
	3	27DEC95	22, .	4	1	1	2	1	1	3	0	1	4	2	1	2	0	3	0	0	26	30.0	NO	NO
	4	02JAN96	28, .	3	1	0	2	2	1	3	0	0	2	1	1	2	0	3	0	1	22	10.0	NO	NO
329.012.00217	SC	14MAY96	-7, .	4	2	2	2	2	1	3	1	4	1	3	2	2	1	0	1	0	31	.		
	BL	21MAY96	1, .	4	2	2	2	2	1	3	1	1	1	3	2	2	1	0	0	0	27	.		
	1	31MAY96	11, .	4	2	1	2	2	2	3	2	0	1	1	1	1	0	0	0	0	22	-18.5	NO	NO
	2	07JUN96	18, .	3	2	1	2	1	1	3	0	0	2	1	1	1	0	0	0	0	18	-33.3	NO	NO
	3	14JUN96	25, .	3	0	1	2	0	1	1	1	0	1	0	2	2	0	0	0	0	14	-48.1	NO	NO
	4	19JUN96	30, .	4	2	2	2	2	0	4	0	2	3	0	1	1	0	0	0	0	23	-14.8	NO	NO
329.012.00218	SC	04JUN96	-12, -70	4	1	2	2	1	0	3	2	0	2	0	2	2	0	1	0	0	22	.		
	BL	14JUN96	-2, -60	3	2	1	2	1	0	2	1	0	2	0	2	1	0	1	0	0	18	.		
	1	21JUN96	6, -53	2	2	1	2	0	0	2	0	0	2	0	1	2	0	0	0	0	14	-22.2	NO	NO
	2	28JUN96	13, -46	1	2	2	1	0	0	1	0	0	3	0	2	0	0	0	0	0	12	-33.3	NO	NO
	3	05JUL96	20, -39	0	1	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	6	-66.7	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
\# Response is defined as a HAMD total of less than or equal to 8 OR a decrease from baseline in HAMD total score of 50% or greater.
\+ Remission is defined as a HAMD total of less than or equal to 8.

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.012.00218	4	12JUL96	27, -32	0	0	0	0	0	0	1	0	0	1	0	1	1	0	0	0	0	4	-77.8	YES	YES
	5	19JUL96	34, -25	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2	-88.9	YES	YES
	6	29JUL96	44, -15	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-88.9	YES	YES
	7	06AUG96	52, -7	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-94.4	YES	YES
	8	13AUG96	59, 1	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	3	-83.3	YES	YES
	12	18SEP96	95, 37	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	-88.9	YES	YES
329.012.00224	SC	30AUG96	-17, -83	4	2	2	2	2	2	3	2	0	3	0	2	1	0	0	0	0	25	.		
	BL	16SEP96	1, -66	3	2	2	2	2	1	2	1	0	3	0	2	1	0	0	0	0	21	.		
	1	24SEP96	9, -58	3	2	1	2	2	1	2	0	2	3	0	1	1	0	0	0	0	20	-4.8	NO	NO
	2	03OCT96	18, -49	1	1	0	0	0	1	0	0	2	2	0	0	0	0	0	0	0	7	-66.7	YES	YES
	3	10OCT96	25, -42	1	1	0	0	0	1	0	0	1	1	0	0	0	0	0	0	0	5	-76.2	YES	YES
	4	17OCT96	32, -35	0	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	4	-81.0	YES	YES
	6	25OCT96	40, -27	0	2	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	5	-76.2	YES	YES
	7	04NOV96	50, -17	0	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	4	-81.0	YES	YES
	8	12NOV96	58, -9	1	2	0	1	0	0	0	0	0	2	0	0	0	0	0	0	0	6	-71.4	YES	YES
	8	20NOV96	66, -1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-95.2	YES	YES
	12	19DEC96	95, 29	1	1	0	0	0	0	1	0	1	2	0	0	0	0	0	1	0	7	-66.7	YES	YES
	16	20JAN97	127, 61	0	2	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	6	-71.4	YES	YES
	24	18FEB97	156, 90	0	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	3	-85.7	YES	YES
329.012.00225	SC	19NOV96	-7, -71	4	2	0	1	0	0	3	2	2	1	1	1	0	0	0	1	1	19	.		
	BL	26NOV96	1, -64	4	0	0	0	1	0	4	2	0	3	0	2	2	0	0	1	1	20	.		
	1	03DEC96	8, -57	4	2	0	0	0	0	3	2	2	2	1	1	1	0	0	0	1	19	-5.0	NO	NO
	2	10DEC96	15, -50	2	1	0	0	0	1	2	1	0	0	0	1	0	0	0	0	0	8	-60.0	YES	YES
	3	20DEC96	25, -40	0	0	0	1	0	0	1	1	0	0	0	0	1	0	0	0	0	4	-80.0	YES	YES
	4	27DEC96	32, -33	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	2	-90.0	YES	YES
	6	06JAN97	42, -23	2	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	1	6	-70.0	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
\# Response is defined as a HAMD total of less than or equal to 8 OR a decrease from baseline in HAMD total score of 50% or greater.
\+ Remission is defined as a HAMD total of less than or equal to 8.

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Paroxetine - Protocol 329
Appendix C.1
Listing of HAMD Scores and Responders by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	% Change From Baseline	Responder#	Remission+
329.012.00225	7	13JAN97	49, -16	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0	0	3	-85.0	YES	YES
	8	21JAN97	57, -8	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-95.0	YES	YES
	8	29JAN97	65, 1	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	3	-85.0	YES	YES
	12	24FEB97	91, 27	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-95.0	YES	YES
	16	20MAR97	115, 51	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	1	0	3	-85.0	YES	YES
	20	21APR97	147, 83	1	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	5	-75.0	YES	YES
	24	26MAY97	182, 118	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	3	-85.0	YES	YES
	32	30JUN97	217, 153	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	0	3	-85.0	YES	YES
	32	30JUL97	247, 183	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	-90.0	YES	YES

* days relative to start of acute phase, days relative to start of continuation phase
\# Response is defined as a HAMD total of less than or equal to 8 OR a decrease from baseline in HAMD total score of 50% or greater.
\+ Remission is defined as a HAMD total of less than or equal to 8.

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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.001.00063	SC	02NOV94	-6,	.	3	2	0	0	2	2	4	3	2	0	4	2	2	0	2	0	0	28	10	4	4	10
	BL	08NOV94	1,	.	3	2	2	1	0	0	4	2	2	0	4	1	1	0	1	0	0	23	7	6	1	9
	1	15NOV94	8,	.	0	0	0	1	1	0	3	1	0	0	3	2	1	0	0	0	0	12	6	0	2	4
	2	22NOV94	15,	.	0	0	0	0	0	0	4	0	0	0	4	1	2	0	0	0	0	11	7	0	0	4
	3	29NOV94	22,	.	0	0	0	0	0	0	1	0	1	0	1	0	1	1	0	0	0	5	2	1	0	2
	4	06DEC94	29,	.	0	0	0	0	2	0	0	0	1	0	3	0	0	1	0	0	0	7	3	1	2	1
	5	13DEC94	36,	.	3	0	0	0	0	0	2	0	1	3	4	0	2	0	0	0	0	15	9	1	0	5
329.001.00065	SC	07NOV94	-10,	.	3	3	2	2	1	2	4	2	3	2	3	1	2	0	0	0	0	30	8	8	5	9
	BL	17NOV94	1,	.	4	1	0	2	1	1	3	2	4	2	3	1	2	0	0	0	0	26	8	5	4	9
	1	21NOV94	5,	.	3	1	0	2	2	0	4	2	2	2	4	1	2	0	0	0	0	25	9	3	4	9
329.001.00068	SC	01FEB95	-7,	.	4	1	2	2	1	0	4	3	2	0	3	1	2	0	1	0	0	26	7	5	3	11
	BL	08FEB95	1,	.	4	1	0	2	0	1	4	3	2	1	3	1	2	0	0	0	0	24	7	3	3	11
	1	15FEB95	8,	.	2	0	2	2	2	0	4	2	2	0	2	0	2	0	0	0	0	20	4	4	4	8
	2	22FEB95	15,	.	4	0	2	2	1	1	4	3	2	1	1	0	2	0	0	0	0	23	4	4	4	11
	3	01MAR95	22,	.	3	0	0	2	2	0	3	3	2	0	3	0	2	0	0	0	0	20	5	2	4	9
	4	08MAR95	29,	.	1	0	0	2	1	0	3	2	2	0	1	0	1	0	0	0	0	13	2	2	3	6
	5	15MAR95	36,	.	1	0	0	2	1	0	3	1	2	1	2	0	1	0	0	0	0	14	4	2	3	5
	6	22MAR95	43,	.	2	0	0	2	2	0	3	2	2	2	1	0	2	0	0	0	1	19	6	2	4	7
	7	29MAR95	50,	.	1	0	0	1	2	0	3	1	2	0	2	0	1	0	0	0	0	13	3	2	3	5
	8	05APR95	57,	.	2	0	0	2	2	0	4	2	2	2	3	0	1	0	0	0	0	20	6	2	4	8
329.001.00072	SC	07MAR95	-13,	.	3	0	0	2	0	0	4	2	2	0	0	0	2	0	0	0	1	16	3	2	2	9
	BL	20MAR95	1,	.	2	0	0	2	1	0	4	3	2	0	0	0	2	0	0	0	1	17	3	2	3	9
	1	27MAR95	8,	.	0	0	0	1	0	0	3	2	1	0	1	0	1	0	0	0	0	9	2	1	1	5
	2	03APR95	15,	.	0	0	0	0	0	0	2	1	2	0	0	1	0	0	0	1	0	7	1	2	0	3
	3	10APR95	22,	.	0	0	0	0	0	0	3	1	1	0	0	1	0	0	0	0	0	6	1	1	0	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.001.00121	SC	22MAR95	-13, -69	4	1	2	1	0	0	4	3	3	1	2	0	2	0	1	0	0	24	6	6	1	11
	BL	04APR95	1, -56	3	0	0	1	0	0	4	2	3	1	3	0	2	0	0	0	0	19	6	3	1	9
	1	11APR95	8, -49	2	0	0	0	0	0	3	2	3	0	3	0	1	0	0	0	0	14	4	3	0	7
	2	18APR95	15, -42	1	0	0	1	0	0	4	2	1	0	1	0	2	0	0	0	2	14	5	1	1	7
	3	26APR95	23, -34	2	1	1	1	0	0	3	2	2	0	3	1	2	0	0	1	1	20	7	4	1	7
	4	02MAY95	29, -28	2	0	0	0	0	0	3	2	2	0	0	0	2	0	0	0	2	13	4	2	0	7
	5	09MAY95	36, -21	0	0	1	0	0	0	3	1	2	0	0	0	1	0	0	0	0	8	1	3	0	4
	6	16MAY95	43, -14	0	0	0	0	0	0	2	1	2	0	0	0	1	0	0	0	0	6	1	2	0	3
	7	23MAY95	50, -7	0	0	0	0	0	0	3	1	1	0	0	0	1	0	0	0	0	6	1	1	0	4
	8	30MAY95	57, 1	0	0	0	0	0	0	2	1	1	0	0	1	1	0	0	0	0	6	2	1	0	3
	12	27JUN95	85, 29	0	0	0	0	0	0	1	1	1	0	0	0	1	0	0	0	2	6	3	1	0	2
	16	24JUL95	112, 56	2	0	0	0	0	0	3	1	1	0	0	0	1	0	0	0	2	10	3	1	0	6
	20	21AUG95	140, 84	2	1	0	1	0	0	3	2	1	0	0	0	1	0	0	0	2	13	3	2	1	7
329.001.00205	SC	29JAN96	-9, .	3	1	0	1	0	0	4	2	1	2	1	0	1	0	0	0	0	16	4	2	1	9
	BL	07FEB96	1, .	3	0	0	0	0	0	4	2	2	0	0	0	2	0	0	0	2	15	4	2	0	9
	1	14FEB96	8, .	0	0	0	2	2	0	4	0	3	0	0	1	0	0	0	0	0	12	1	3	4	4
329.001.00206	SC	12FEB96	-9, .	4	2	2	1	1	0	4	3	0	1	3	0	1	0	0	0	0	22	5	4	2	11
	BL	21FEB96	1, .	4	0	0	2	0	0	4	3	0	0	0	0	2	0	0	0	0	15	2	0	2	11
	1	28FEB96	8, .	2	0	0	2	0	0	4	3	1	0	0	0	1	0	0	0	0	13	1	1	2	9
	2	06MAR96	15, .	4	0	0	1	0	0	4	3	0	0	0	0	2	0	0	0	0	14	2	0	1	11
	3	13MAR96	22, .	1	0	0	0	0	0	3	2	0	0	0	0	0	0	0	0	0	6	0	0	0	6
	4	20MAR96	29, .	2	2	0	0	0	0	4	3	0	0	0	0	2	0	0	0	0	13	2	2	0	9
	5	26MAR96	35, .	2	0	0	2	0	0	4	3	0	0	0	0	2	0	0	0	0	13	2	0	2	9
	6	03APR96	43, .	1	0	0	2	0	0	4	2	0	0	0	0	1	0	0	1	0	11	1	0	2	7
	7	10APR96	50, .	2	0	0	1	0	0	4	2	0	0	0	0	1	0	0	0	0	10	1	0	1	8
	8	17APR96	57, .	3	0	0	2	0	0	4	3	1	0	0	0	1	0	0	0	0	14	1	1	2	10

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00055	SC	09JUN94	-15, -70	3	2	3	2	2	0	3	2	1	1	2	1	2	0	0	1	0	25	6	6	4	8
	BL	23JUN94	-1, -56	3	1	2	1	0	0	3	2	0	1	1	0	2	0	0	0	2	18	6	3	1	8
	1	30JUN94	7, -49	3	2	1	2	0	0	3	2	0	2	1	0	1	0	0	0	1	18	5	3	2	8
	2	07JUL94	14, -42	2	1	0	2	1	0	2	1	0	1	0	0	1	0	0	0	1	12	3	1	3	5
	3	14JUL94	21, -35	1	0	0	0	1	0	1	1	0	0	1	0	1	0	0	0	1	7	3	0	1	3
	4	21JUL94	28, -28	1	1	0	0	0	0	2	2	0	1	0	0	1	0	0	0	1	9	3	1	0	5
	5	28JUL94	35, -21	2	0	0	0	0	0	3	2	0	3	1	1	2	0	0	1	1	16	8	0	0	7
	6	04AUG94	42, -14	2	0	0	0	0	0	1	1	0	1	1	0	0	0	0	0	1	7	3	0	0	4
	7	11AUG94	49, -7	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1	5	2	1	0	2
	8	18AUG94	56, 1	0	0	0	0	2	0	1	1	1	1	0	1	1	0	0	1	1	10	4	1	2	2
	12	15SEP94	84, 29	0	0	0	1	1	0	1	1	0	1	1	0	1	0	0	0	2	9	5	0	2	2
	16	13OCT94	112, 57	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	3	2	0	1	0
	20	10NOV94	140, 85	3	2	2	2	1	0	3	2	0	1	3	1	2	0	0	0	0	22	7	4	3	8
329.002.00058	SC	08SEP94	-12, -70	1	2	3	0	1	2	0	0	4	2	2	0	2	0	2	1	1	23	9	9	3	1
	BL	20SEP94	1, -58	3	2	0	2	2	0	3	2	0	2	2	0	1	0	2	0	0	21	7	2	4	8
	1	29SEP94	10, -49	1	1	0	0	1	0	2	2	3	2	1	1	1	0	1	1	1	18	7	4	1	5
	2	07OCT94	18, -41	2	1	0	0	0	0	3	1	1	2	1	0	1	0	1	0	0	13	5	2	0	6
	3	13OCT94	24, -35	1	1	0	0	0	0	1	1	1	1	1	0	1	0	1	0	0	9	4	2	0	3
	4	20OCT94	31, -28	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	4	1	1	0	2
	5	27OCT94	38, -21	0	0	0	0	0	0	1	2	3	1	0	0	1	0	0	0	0	8	2	3	0	3
	6	03NOV94	45, -14	0	0	0	0	0	0	1	0	2	1	1	0	0	0	0	0	0	5	2	2	0	1
	7	10NOV94	52, -7	0	0	0	1	1	0	0	1	1	1	1	0	0	0	0	0	1	7	3	1	2	1
	8	17NOV94	59, 1	1	0	0	0	0	0	1	0	3	1	0	0	0	0	1	0	0	7	2	3	0	2
	12	15DEC94	87, 29	0	0	0	0	0	0	3	0	3	1	0	0	1	0	0	0	1	9	3	3	0	3
	16	13JAN95	116, 58	1	0	0	0	0	0	0	0	3	0	0	0	0	0	1	0	0	5	1	3	0	1
	20	27JAN95	130, 72	3	0	0	0	0	0	0	0	2	3	0	0	1	0	0	1	0	10	4	2	0	3
329.002.00099	SC	23FEB95	-7, -62	2	1	1	0	1	0	2	0	1	2	2	0	1	0	1	0	0	14	6	3	1	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00099	BL	02MAR95	1, -55	3	2	2	1	0	0	3	1	0	1	2	0	1	0	2	0	0	18	6	4	1	7
	1	07MAR95	6, -50	3	1	0	0	1	0	1	1	1	3	1	0	1	0	0	1	0	14	5	2	1	5
	2	14MAR95	13, -43	1	1	0	0	0	0	1	1	1	1	1	0	1	0	1	0	0	9	4	2	0	3
	3	21MAR95	20, -36	1	0	0	2	1	0	0	0	1	1	1	0	0	0	1	0	0	8	3	1	3	1
	4	28MAR95	27, -29	0	0	0	1	0	0	0	0	1	1	1	0	0	0	0	0	0	4	2	1	1	0
	5	04APR95	34, -22	0	0	0	1	0	0	0	0	1	1	1	0	1	0	0	0	0	5	3	1	1	0
	6	11APR95	41, -15	0	0	0	0	0	0	1	0	1	1	1	0	1	0	0	0	0	5	3	1	0	1
	7	18APR95	48, -8	2	0	0	0	0	0	0	0	1	1	1	0	0	0	1	0	0	6	3	1	0	2
	8	25APR95	55, -1	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	3	1	1	0	1
	12	23MAY95	83, 28	0	0	0	0	0	0	1	0	1	0	0	0	2	0	0	0	0	4	2	1	0	1
	16	27JUN95	118, 63	0	0	0	2	0	0	0	0	1	1	0	0	0	0	0	0	0	4	1	1	2	0
	20	01AUG95	153, 98	0	0	0	0	0	0	0	0	1	0	3	0	2	0	1	0	2	9	8	1	0	0
	24	31AUG95	183, 128	0	0	0	1	0	0	0	0	1	0	0	0	1	0	0	0	0	3	1	1	1	0
	28	28SEP95	211, 156	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	32	26OCT95	239, 184	3	1	2	1	0	0	2	2	1	3	0	0	1	1	0	0	0	17	4	4	1	8
329.002.00102	SC	03APR95	-10, -64	3	1	2	2	0	0	3	0	4	1	2	0	2	0	1	1	0	22	6	7	2	6
	BL	13APR95	1, -54	3	0	1	2	0	0	3	0	3	2	2	0	1	0	1	0	0	18	6	4	2	6
	1	18APR95	6, -49	1	0	0	2	0	0	1	0	3	3	1	1	1	0	1	1	0	15	7	3	2	2
	2	25APR95	13, -42	2	0	0	2	0	0	3	0	4	3	1	1	1	0	0	0	0	17	6	4	2	5
	3	02MAY95	20, -35	1	0	0	2	1	0	1	0	1	2	1	0	1	0	0	0	0	10	4	1	3	2
	4	09MAY95	27, -28	2	0	0	2	0	0	1	0	3	2	1	1	1	0	0	0	0	13	5	3	2	3
	5	16MAY95	34, -21	0	0	0	0	0	0	1	0	3	0	1	0	1	0	0	0	0	6	2	3	0	1
	6	23MAY95	41, -14	0	0	0	0	0	0	0	0	3	0	1	1	0	0	0	0	0	5	2	3	0	0
	7	30MAY95	48, -7	0	0	0	0	0	0	0	0	3	0	0	1	0	0	0	0	0	4	1	3	0	0
	8	06JUN95	55, 1	0	0	0	0	0	0	0	0	2	0	1	0	0	0	0	0	0	3	1	2	0	0
	12	13JUL95	92, 38	0	0	0	0	0	0	0	0	3	0	1	0	0	0	0	0	0	4	1	3	0	0
	16	10AUG95	120, 66	0	0	0	0	0	1	0	0	2	0	1	1	2	0	0	1	0	8	4	2	1	0
	20	12SEP95	153, 99	0	0	0	0	0	0	0	0	3	0	1	0	0	0	0	0	0	4	1	3	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00102	24	10OCT95	181, 127	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	3	0	3	0	0
	28	09NOV95	211, 157	0	0	0	0	0	0	1	0	3	0	1	0	1	0	0	0	0	6	2	3	0	1
	32	05DEC95	237, 183	0	0	0	0	0	0	0	0	3	0	1	0	0	0	0	0	0	4	1	3	0	0
329.002.00105	SC	20JUL95	-7, .	2	0	2	2	2	0	2	2	0	3	0	0	2	0	0	0	0	17	5	2	4	6
	BL	27JUL95	1, .	3	2	3	0	0	0	1	2	1	1	2	0	2	0	1	0	0	18	6	6	0	6
	1	03AUG95	8, .	2	0	1	2	0	2	3	2	1	1	2	0	0	0	1	0	0	17	4	2	4	7
	2	10AUG95	15, .	0	0	0	1	0	0	2	1	0	1	1	0	1	0	1	0	0	8	4	0	1	3
	3	17AUG95	22, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.002.00106	SC	20JUL95	-7, .	3	1	1	1	1	0	3	1	0	3	1	1	1	1	0	2	0	20	6	2	2	8
	BL	27JUL95	1, .	3	1	1	0	1	0	2	1	0	1	2	0	1	0	0	0	0	13	4	2	1	6
	1	03AUG95	8, .	1	1	1	2	0	0	2	1	0	2	1	0	1	0	0	0	0	12	4	2	2	4
	2	08AUG95	13, .	0	0	2	1	0	1	2	1	0	3	2	0	1	0	0	0	0	13	6	2	2	3
	3	17AUG95	22, .	0	0	0	2	0	0	3	2	0	4	0	0	1	0	0	0	0	12	5	0	2	5
	4	24AUG95	29, .	0	1	0	2	0	1	1	1	0	1	0	0	1	0	0	0	0	8	2	1	3	2
	5	31AUG95	36, .	2	1	0	2	0	0	2	1	0	3	1	0	0	0	0	0	0	12	4	1	2	5
	6	05SEP95	41, .	1	1	2	0	1	0	0	1	0	3	0	0	0	0	0	0	0	9	3	3	1	2
	7	12SEP95	48, .	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	3	1	0	0	2
329.002.00242	SC	26JAN96	-12, -70	4	2	0	0	2	2	0	2	0	3	1	1	2	0	3	2	0	24	10	2	4	6
	1	14FEB96	8, -51	1	0	0	0	2	1	3	2	0	1	1	2	1	0	0	0	0	14	5	0	3	6
	2	21FEB96	15, -44	0	0	0	0	1	0	1	0	0	2	0	2	1	0	2	0	0	9	7	0	1	1
	3	29FEB96	23, -36	1	0	0	0	0	0	2	1	0	0	0	1	1	0	0	0	0	6	2	0	0	4
	4	06MAR96	29, -30	0	0	0	0	0	0	0	1	0	1	0	1	1	0	0	0	0	4	3	0	0	1
	5	14MAR96	37, -22	0	0	0	0	0	0	2	1	0	1	0	1	1	0	0	0	0	6	3	0	0	3
	6	20MAR96	43, -16	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0	0	0	3	2	0	0	1
	7	28MAR96	51, -8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	05APR96	59, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.002.00242	12	08MAY96	92, 34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	05JUN96	120, 62	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	3	2	0	0	1
	20	10JUL96	155, 97	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
329.002.00245	SC	21MAR96	-7, .	3	1	2	0	2	2	3	0	1	3	1	0	1	0	0	0	2	21	7	4	4	6
	BL	28MAR96	1, .	3	1	2	0	2	2	1	0	3	1	1	0	2	0	0	0	0	18	4	6	4	4
	1	04APR96	8, .	1	2	0	2	1	2	2	0	2	3	1	0	1	0	0	0	1	18	6	4	5	3
329.002.00319	SC	23APR96	-7, -63	4	1	1	2	2	1	2	2	0	4	0	1	2	0	0	0	0	22	7	2	5	8
	BL	30APR96	1, -56	4	0	1	1	1	0	2	2	0	3	2	0	2	0	0	0	0	18	7	1	2	8
	1	07MAY96	8, -49	0	1	0	2	1	1	1	2	0	3	1	1	2	0	0	0	0	15	7	1	4	3
	2	14MAY96	15, -42	1	0	0	0	1	0	1	1	0	0	1	1	0	0	0	0	0	6	2	0	1	3
	3	21MAY96	22, -35	3	0	0	1	0	0	1	2	0	3	0	0	0	0	0	0	0	10	3	0	1	6
	4	28MAY96	29, -28	3	1	1	2	1	0	2	2	0	4	0	0	2	0	0	0	0	18	6	2	3	7
	5	04JUN96	36, -21	1	0	0	0	1	0	1	1	0	1	0	0	2	0	0	0	0	7	3	0	1	3
	6	11JUN96	43, -14	1	0	0	0	1	1	0	1	0	0	0	1	0	0	0	0	0	5	1	0	2	2
	7	18JUN96	50, -7	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	2	0	0	1	0
	8	25JUN96	57, 1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	12	23JUL96	85, 29	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	16	15AUG96	108, 52	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	20	24SEP96	148, 92	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	24	22OCT96	176, 120	3	1	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0	8	3	1	0	4
	28	19NOV96	204, 148	1	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	3	1	0	1	1
	32	17DEC96	232, 176	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	2	2	0	0	0
329.003.00075	SC	18JAN95	-7, -63	2	2	0	0	0	0	3	0	0	3	2	1	2	0	0	0	0	15	8	2	0	5
	BL	25JAN95	1, -56	2	1	0	0	0	0	3	0	0	3	2	1	2	0	0	0	0	14	8	1	0	5
	1	01FEB95	8, -49	1	1	1	0	0	0	1	0	1	2	2	1	1	0	0	0	0	11	6	3	0	2
	2	08FEB95	15, -42	1	1	1	0	0	0	1	0	0	1	0	1	1	0	0	0	0	7	3	2	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00075	3	15FEB95	22, -35	3	0	1	0	0	0	1	0	1	1	1	1	2	0	0	0	0	11	5	2	0	4
	4	21FEB95	28, -29	1	0	1	0	0	0	1	0	0	1	1	1	1	0	0	0	0	7	4	1	0	2
	5	01MAR95	36, -21	1	0	2	0	0	0	0	0	1	0	0	0	0	0	0	0	0	4	0	3	0	1
	6	08MAR95	43, -14	1	0	1	0	0	0	1	0	0	1	0	0	1	0	0	0	0	5	2	1	0	2
	7	15MAR95	50, -7	3	1	2	0	1	0	3	1	0	2	2	1	1	0	0	0	0	17	6	3	1	7
	8	22MAR95	57, 1	2	0	2	0	0	0	2	0	0	2	0	0	0	0	0	0	0	8	2	2	0	4
	12	19APR95	85, 29	1	0	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	4	2	1	0	1
	16	17MAY95	113, 57	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	1	0	0	0
	20	14JUN95	141, 85	1	1	2	0	0	0	1	0	1	1	2	0	1	0	0	0	0	10	4	4	0	2
	24	12JUL95	169, 113	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	28	09AUG95	197, 141	1	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	3	1	1	0	1
	32	13SEP95	232, 176	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
329.003.00077	SC	01MAR95	-5, -64	3	1	1	1	0	0	4	2	1	0	1	0	0	0	2	0	0	16	3	3	1	9
	BL	06MAR95	1, -59	3	1	1	1	0	0	4	2	1	0	0	1	2	0	1	0	0	17	4	3	1	9
	1	13MAR95	8, -52	1	0	0	2	0	0	1	1	2	2	0	1	1	0	0	0	0	11	4	2	2	3
	2	20MAR95	15, -45	1	0	0	0	0	0	4	1	1	0	0	0	2	0	0	0	0	9	2	1	0	6
	3	27MAR95	22, -38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	05APR95	31, -29	1	1	0	0	0	0	2	0	1	1	0	0	1	0	0	0	0	7	2	2	0	3
	5	12APR95	38, -22	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0
	6	19APR95	45, -15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	26APR95	52, -8	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	8	03MAY95	59, -1	1	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	3	1	0	1	1
	12	07JUN95	94, 35	0	1	0	2	0	0	0	0	1	0	0	0	0	0	0	0	0	4	0	2	2	0
329.003.00081	BL	11DEC95	1, .	3	0	1	2	2	0	3	3	0	3	2	1	1	2	0	1	0	24	7	1	4	11
	1	18DEC95	8, .	1	0	1	0	0	0	3	1	1	1	1	0	2	2	0	0	0	13	4	2	0	7
	2	28DEC95	18, .	1	0	0	0	0	0	3	2	0	0	0	0	1	0	0	0	0	7	1	0	0	6
	3	03JAN96	24, .	2	0	0	0	0	0	2	0	0	0	1	0	2	0	0	0	0	7	3	0	0	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00081	4	10JAN96	31, .	2	0	0	2	0	2	3	1	0	0	0	0	0	0	0	0	1	11	1	0	4	6
	5	17JAN96	38, .	2	0	0	1	0	2	2	0	0	0	0	0	0	0	0	0	0	7	0	0	3	4
	6	24JAN96	45, .	1	0	1	0	0	0	2	0	2	3	0	0	1	1	0	0	0	11	4	3	0	4
	7	31JAN96	52, .	1	0	0	0	0	0	3	1	3	3	0	0	1	0	0	0	0	12	4	3	0	5
	8	07FEB96	59, .	1	0	0	2	0	0	3	1	1	2	0	0	1	0	0	0	0	11	3	1	2	5
329.003.00087	SC	23JAN95	-8, .	2	0	0	1	0	0	3	1	2	4	2	0	2	0	3	0	0	20	11	2	1	6
	BL	30JAN95	-1, .	3	2	3	2	0	0	4	0	2	3	3	0	2	1	2	0	0	27	10	7	2	8
329.003.00089	SC	24FEB95	-11, .	2	1	2	0	1	0	3	1	2	2	2	0	1	0	0	0	0	17	5	5	1	6
	BL	07MAR95	1, .	2	2	2	2	2	1	2	0	2	2	1	0	0	0	0	0	0	18	3	6	5	4
	1	14MAR95	8, .	2	1	0	2	2	2	3	0	2	0	0	0	2	0	0	0	0	16	2	3	6	5
	2	21MAR95	15, .	2	0	1	0	0	2	2	0	2	0	0	0	2	0	0	0	0	11	2	3	2	4
	3	28MAR95	22, .	1	0	0	0	0	1	1	0	2	1	1	0	1	0	0	0	0	8	3	2	1	2
	4	04APR95	29, .	1	0	0	2	0	0	1	0	1	0	0	1	1	0	0	0	0	7	2	1	2	2
	5	11APR95	36, .	0	1	0	0	0	0	1	0	2	1	0	0	0	0	0	0	0	5	1	3	0	1
	6	18APR95	43, .	0	0	0	1	0	0	0	0	1	0	0	0	1	0	0	0	0	3	1	1	1	0
	7	25APR95	50, .	1	0	0	2	0	0	1	0	2	0	0	0	0	0	0	0	0	6	0	2	2	2
	8	02MAY95	57, .	0	0	0	2	2	2	0	0	2	0	0	0	0	0	0	0	0	8	0	2	6	0
329.003.00091	SC	14MAR95	-10, -64	2	0	2	0	0	0	2	1	2	2	2	0	2	0	0	0	0	15	6	4	0	5
	BL	24MAR95	1, -54	2	1	1	2	0	0	1	1	2	1	0	0	0	0	0	1	0	12	1	4	2	4
	1	28MAR95	5, -50	2	0	0	0	0	0	1	0	2	1	0	0	0	0	0	0	0	6	1	2	0	3
	2	04APR95	12, -43	1	0	0	0	0	0	2	0	2	0	0	0	1	0	0	0	0	6	1	2	0	3
	3	11APR95	19, -36	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	4	18APR95	26, -29	1	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	5	0	2	0	3
	5	25APR95	33, -22	2	0	2	1	0	0	3	0	2	0	0	0	0	0	0	0	0	10	0	4	1	5
	6	02MAY95	40, -15	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	3	1	0	0	2
	7	09MAY95	47, -8	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00091	8	16MAY95	54, -1	1	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	3	0	1	0	2
	12	16JUN95	85, 31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	14JUL95	113, 59	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20	10AUG95	140, 86	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	24	05SEP95	166, 112	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	28	03OCT95	194, 140	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	32	07NOV95	229, 175	0	0	0	0	0	0	0	0	0	1	0	0	2	0	0	0	0	3	3	0	0	0
329.003.00248	SC	14FEB96	-16, .	4	0	3	0	0	0	3	2	0	2	0	0	2	0	0	0	0	16	4	3	0	9
	BL	22FEB96	-8, .	3	0	1	2	0	0	3	2	2	2	0	0	2	0	0	0	0	17	4	3	2	8
	1	05MAR96	5, .	3	0	0	1	0	0	3	3	2	3	0	0	2	0	0	1	0	18	5	2	1	9
	2	12MAR96	12, .	1	0	1	0	0	0	3	2	2	3	0	1	2	0	0	1	0	16	6	3	0	6
	3	19MAR96	19, .	2	0	0	0	0	1	3	2	0	0	0	0	2	0	0	0	0	10	2	0	1	7
	4	26MAR96	26, .	3	0	0	0	0	0	3	2	1	3	0	0	2	0	0	0	0	14	5	1	0	8
	5	02APR96	33, .	1	0	0	0	0	0	3	1	1	0	0	0	2	0	0	0	0	8	2	1	0	5
	6	11APR96	42, .	3	0	0	0	0	0	3	2	2	0	0	0	2	0	0	0	0	12	2	2	0	8
	7	16APR96	47, .	3	0	0	0	0	0	3	2	1	1	0	1	2	0	0	0	0	13	4	1	0	8
	8	23APR96	54, .	3	0	0	0	0	0	3	1	2	1	0	1	2	0	0	0	0	13	4	2	0	7
329.003.00250	BL	14MAR96	1, -57	2	0	3	2	0	0	3	2	0	3	0	1	2	0	0	0	0	18	6	3	2	7
	1	19MAR96	6, -52	2	0	1	0	0	0	3	1	1	3	0	1	2	1	0	0	0	15	6	2	0	7
	2	26MAR96	13, -45	1	0	0	0	0	0	3	0	0	0	0	0	2	1	0	0	0	7	2	0	0	5
	3	02APR96	20, -38	2	1	1	0	0	0	3	0	1	2	0	0	2	1	0	0	0	13	4	3	0	6
	4	12APR96	30, -28	1	0	0	0	0	0	3	0	0	0	0	1	2	1	0	0	0	8	3	0	0	5
	5	16APR96	34, -24	3	1	3	0	0	0	3	1	3	3	0	1	2	1	0	0	0	21	6	7	0	8
	6	23APR96	41, -17	2	1	3	0	0	0	3	1	2	3	0	1	2	1	0	1	0	20	6	6	0	7
	7	30APR96	48, -10	0	0	1	0	0	0	3	0	0	1	0	0	2	0	0	0	0	7	3	1	0	3
	8	09MAY96	57, -1	1	0	1	0	0	0	1	0	0	0	0	1	2	0	0	0	0	6	3	1	0	2
	12	28MAY96	76, 19	3	3	4	0	0	0	3	0	1	0	0	0	2	1	0	0	0	17	2	8	0	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00292	BL	07AUG96	1, -58	4	2	0	2	0	0	3	2	0	0	0	0	2	0	2	0	1	18	5	2	2	9
	1	16AUG96	10, -49	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	2	2	0
	2	21AUG96	15, -44	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	2	2	0	0	0
	3	30AUG96	24, -35	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	3	3	0	0	0
	4	04SEP96	29, -30	1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	2	0	0	1
	6	18SEP96	43, -16	3	1	0	1	0	0	3	2	1	3	2	0	1	1	0	0	1	19	7	2	1	9
	7	25SEP96	50, -9	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	4	3	0	0	1
	8	04OCT96	59, 1	0	0	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	2	1	0	0
329.003.00313	SC	08MAY96	-9, .	4	2	3	2	1	0	3	2	0	4	0	0	2	1	0	0	0	24	6	5	3	10
	BL	17MAY96	1, .	4	3	3	2	2	0	3	2	0	3	0	0	2	1	0	0	0	25	5	6	4	10
	1	21MAY96	5, .	4	3	0	0	1	0	3	2	1	3	0	0	2	1	0	0	0	20	5	4	1	10
	2	28MAY96	12, .	3	4	4	0	0	0	3	2	1	3	0	1	2	1	0	2	0	26	6	9	0	9
329.004.00015	SC	30NOV94	-8, -65	3	0	0	2	1	0	3	1	2	2	0	1	2	2	0	0	0	19	5	2	3	9
	BL	07DEC94	-1, -58	3	0	0	2	1	0	3	1	2	2	0	1	2	2	0	0	0	19	5	2	3	9
	1	14DEC94	7, -51	3	0	0	2	2	0	3	2	2	1	1	1	2	1	0	0	0	20	5	2	4	9
	2	21DEC94	14, -44	3	2	1	2	0	0	2	0	2	3	1	1	1	1	0	0	0	19	6	5	2	6
	3	28DEC94	21, -37	2	2	1	1	1	0	1	0	1	1	0	1	2	1	0	0	0	14	4	4	2	4
	4	04JAN95	28, -30	2	0	1	2	0	0	2	0	1	1	0	1	2	0	0	0	0	12	4	2	2	4
	5	11JAN95	35, -23	3	0	1	2	1	0	1	0	1	1	0	1	2	0	0	0	0	13	4	2	3	4
	6	18JAN95	42, -16	0	0	0	0	0	0	2	1	2	1	0	1	2	0	0	0	0	9	4	2	0	3
	7	25JAN95	49, -9	0	0	0	2	1	0	2	0	2	1	0	0	2	0	0	0	0	10	3	2	3	2
	8	03FEB95	58, 1	0	0	0	0	0	0	2	0	0	1	0	0	1	0	0	0	0	4	2	0	0	2
	12	27FEB95	82, 25	0	1	0	0	1	0	1	0	1	1	1	1	1	0	0	2	0	10	4	2	1	1
	16	22MAR95	105, 48	1	2	0	1	0	0	0	0	2	1	0	0	0	0	0	0	0	7	1	4	1	1
	20	19APR95	133, 76	1	0	0	0	0	0	1	1	2	1	0	0	0	0	0	0	0	6	1	2	0	3
	24	17MAY95	161, 104	1	0	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	4	1	2	0	1
	28	14JUN95	189, 132	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.004.00017	SC	15MAR95	-7, -63	3	2	2	2	1	0	1	1	2	2	0	0	2	0	0	0	0	18	4	6	3	5
	BL	22MAR95	1, -56	3	2	2	2	0	0	2	1	2	1	0	0	1	1	0	0	0	17	2	6	2	7
	1	30MAR95	9, -48	2	0	1	2	2	1	2	1	2	3	1	2	0	0	1	0	0	20	7	3	5	5
	2	06APR95	16, -41	2	1	1	0	2	0	2	2	2	1	1	0	1	0	0	1	0	16	3	4	2	6
	3	13APR95	23, -34	2	1	1	1	2	0	2	1	1	1	0	0	0	0	0	0	0	12	1	3	3	5
	4	20APR95	30, -27	2	0	2	0	2	0	2	1	2	1	0	0	1	0	0	0	0	13	2	4	2	5
	5	26APR95	36, -21	2	0	2	0	2	0	2	1	1	1	0	0	2	0	0	0	0	13	3	3	2	5
	6	03MAY95	43, -14	2	0	1	0	2	1	1	1	1	1	0	0	2	0	0	0	0	12	3	2	3	4
	7	10MAY95	50, -7	2	0	1	0	1	1	0	0	1	1	0	0	1	0	0	0	0	8	2	2	2	2
	8	17MAY95	57, 1	1	0	1	0	2	1	0	1	1	1	0	0	0	0	0	0	0	8	1	2	3	2
	12	14JUN95	85, 29	1	0	1	0	2	1	1	1	1	1	0	0	0	0	0	1	0	10	1	2	3	3
	16	13JUL95	114, 58	1	0	1	1	1	1	2	0	0	0	0	0	1	0	0	0	0	8	1	1	3	3
	20	10AUG95	142, 86	2	0	1	0	2	0	2	1	2	0	0	0	0	0	0	0	0	10	0	3	2	5
	24	06SEP95	169, 113	0	0	0	0	2	0	1	0	1	0	0	0	0	0	0	0	0	4	0	1	2	1
	28	04OCT95	197, 141	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	4	0	2	1	1
	32	01NOV95	225, 169	1	0	1	0	1	0	1	0	0	1	0	0	0	0	0	0	0	5	1	1	1	2
329.004.00019	SC	24MAY95	-7, .	3	1	0	2	0	1	2	1	1	1	1	1	2	0	2	2	0	20	7	2	3	6
	BL	31MAY95	1, .	3	1	0	2	2	0	3	2	2	2	1	1	2	0	0	0	0	21	6	3	4	8
	1	07JUN95	8, .	3	1	0	0	0	2	3	1	2	3	1	1	2	0	1	0	0	20	8	3	2	7
	2	14JUN95	15, .	2	0	0	2	0	2	2	1	2	2	0	1	2	0	0	0	0	16	5	2	4	5
329.004.00212	SC	24MAY96	-10, .	3	2	1	2	0	2	4	1	0	1	0	1	2	1	1	0	0	21	5	3	4	9
	BL	03JUN96	1, .	3	1	2	2	0	1	3	1	0	1	0	2	2	1	0	1	0	20	5	3	3	8
	1	10JUN96	8, .	3	2	1	1	2	1	3	0	1	1	0	2	2	1	0	0	0	20	5	4	4	7
	3	21JUN96	19, .	4	2	2	0	0	0	4	1	0	1	0	2	2	2	0	0	0	20	5	4	0	11
	4	28JUN96	26, .	2	1	2	0	1	1	4	1	0	1	1	2	2	2	0	0	0	20	6	3	2	9
329.004.00214	SC	27SEP96	-7, -67	3	2	2	0	0	0	3	1	4	3	2	1	2	0	1	0	0	24	9	8	0	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.004.00214	BL	04OCT96	1, -60	2	2	0	0	1	0	3	1	2	3	3	0	2	0	1	2	0	22	9	4	1	6
	1	09OCT96	6, -55	3	2	2	0	2	0	3	1	2	3	3	0	2	0	1	0	0	24	9	6	2	7
	2	15OCT96	12, -49	1	2	0	0	1	0	3	1	2	2	1	0	2	0	2	0	0	17	7	4	1	5
	2	21OCT96	18, -43	1	0	0	0	0	1	2	1	2	2	2	0	2	0	2	0	0	15	8	2	1	4
	4	01NOV96	29, -32	1	2	1	0	1	0	2	1	2	2	3	0	2	0	1	0	0	18	8	5	1	4
	5	11NOV96	39, -22	0	2	0	0	1	1	2	0	2	2	2	1	2	0	0	0	0	15	7	4	2	2
	6	18NOV96	46, -15	1	1	1	0	1	1	2	1	2	2	2	0	2	0	0	0	0	16	6	4	2	4
	7	25NOV96	53, -8	1	1	0	0	1	0	2	0	2	2	1	0	2	0	1	1	0	14	6	3	1	3
	8	03DEC96	61, 1	1	0	0	0	1	0	2	0	2	2	1	0	2	0	2	0	0	13	7	2	1	3
	12	30DEC96	88, 28	1	2	3	0	1	0	2	0	2	2	1	0	2	0	0	0	0	16	5	7	1	3
329.005.00002	SC	20MAY94	-5, -61	3	0	0	2	2	2	4	1	1	0	1	0	1	0	0	1	0	18	2	1	6	8
	BL	25MAY94	1, -56	2	0	0	2	2	2	3	0	3	0	0	0	2	0	0	1	0	17	2	3	6	5
	1	01JUN94	8, -49	2	0	0	2	2	2	2	2	2	0	0	0	0	0	0	0	0	14	0	2	6	6
	2	08JUN94	15, -42	2	0	0	2	2	2	2	1	2	0	0	0	0	0	0	0	0	13	0	2	6	5
	3	15JUN94	22, -35	3	0	0	2	2	2	2	0	2	0	0	0	0	0	0	1	0	14	0	2	6	5
	4	23JUN94	30, -27	2	0	0	2	2	2	2	1	2	0	0	0	0	0	0	0	0	13	0	2	6	5
	5	30JUN94	37, -20	2	0	0	2	2	2	2	0	0	0	0	1	1	0	0	1	0	13	2	0	6	4
	6	07JUL94	44, -13	2	0	0	2	1	1	2	0	1	0	0	1	0	0	0	0	0	10	1	1	4	4
	7	14JUL94	51, -6	2	0	0	2	1	2	1	0	0	0	0	0	1	0	0	0	0	9	1	0	5	3
	8	20JUL94	57, 1	1	0	0	2	2	1	0	0	0	0	0	1	1	0	0	1	0	9	2	0	5	1
	12	17AUG94	85, 29	3	0	0	2	1	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	3	3
	16	15SEP94	114, 58	2	0	0	2	2	0	1	1	0	1	0	1	0	0	0	1	0	11	2	0	4	4
	20	18OCT94	147, 91	3	0	0	0	2	0	2	0	0	0	0	1	0	0	0	1	0	9	1	0	2	5
329.005.00004	SC	22SEP94	-18, -77	3	2	0	2	1	2	0	2	0	0	0	0	0	0	0	2	0	14	0	2	5	5
	BL	10OCT94	1, -59	3	1	0	2	1	2	1	2	1	0	0	0	0	0	0	1	0	14	0	2	5	6
	1	20OCT94	11, -49	2	0	2	2	2	2	2	2	2	0	1	1	0	0	0	0	0	18	2	4	6	6
	2	27OCT94	18, -42	1	0	2	1	0	0	0	1	1	0	0	0	0	0	0	0	2	8	2	3	1	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00004	3	03NOV94	25, -35	1	0	0	1	0	0	0	1	1	1	0	0	0	0	0	0	2	7	3	1	1	2
	4	10NOV94	32, -28	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	0	4	0	1	0	2
	5	17NOV94	39, -21	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	6	23NOV94	45, -15	1	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	4	0	2	0	2
	7	01DEC94	53, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0
	8	08DEC94	60, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0
	12	05JAN95	88, 29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00008	SC	10NOV94	-6, -61	1	0	0	2	0	2	0	1	3	1	1	1	1	0	0	1	1	15	5	3	4	2
	BL	16NOV94	1, -55	3	0	0	1	0	0	1	1	4	1	0	1	1	0	0	0	2	15	5	4	1	5
	1	23NOV94	8, -48	2	0	0	0	0	2	1	1	3	1	0	0	1	0	0	1	2	14	4	3	2	4
	2	30NOV94	15, -41	0	0	0	0	0	0	1	0	3	1	0	0	1	0	0	0	0	6	2	3	0	1
	3	07DEC94	22, -34	1	0	0	2	0	0	1	0	0	0	0	0	0	0	0	1	0	5	0	0	2	2
	4	14DEC94	29, -27	0	0	0	0	0	0	1	0	3	0	0	0	0	0	0	0	2	6	2	3	0	1
	5	21DEC94	36, -20	0	0	0	0	2	2	2	1	1	1	0	0	2	0	0	0	0	11	3	1	4	3
	6	28DEC94	43, -13	0	0	0	0	0	2	1	0	1	0	0	0	0	0	0	0	0	4	0	1	2	1
	7	03JAN95	49, -7	1	2	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	4	0	3	0	1
	8	10JAN95	56, 1	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	3	0	0	0	3
	12	06FEB95	83, 28	1	1	0	0	2	2	1	0	1	1	0	0	0	0	0	0	0	9	1	2	4	2
	16	08MAR95	113, 58	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	2	0	0
	24	10MAY95	176, 121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00011	SC	06DEC94	-7, -63	3	0	1	2	1	1	2	1	3	1	0	1	1	0	1	1	0	19	4	4	4	6
	BL	13DEC94	1, -56	3	0	1	2	2	2	2	1	2	1	0	1	1	0	0	0	0	18	3	3	6	6
	1	20DEC94	8, -49	2	0	0	0	2	2	2	1	2	1	0	1	0	0	0	0	0	13	2	2	4	5
	2	27DEC94	15, -42	1	0	0	0	1	1	1	0	3	1	0	0	2	0	0	1	0	11	3	3	2	2
	3	03JAN95	22, -35	1	0	0	1	2	2	2	1	3	1	0	0	1	0	0	0	0	14	2	3	5	4
	4	09JAN95	28, -29	1	0	0	2	2	0	1	1	2	1	0	1	0	0	0	0	0	11	2	2	4	3
	5	17JAN95	36, -21	1	0	0	2	1	0	1	1	1	1	0	1	1	0	0	0	0	10	3	1	3	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00011	6	23JAN95	42, -15	0	0	0	1	1	2	1	0	1	1	0	0	0	0	0	0	0	7	1	1	4	1
	7	31JAN95	50, -7	1	0	0	0	1	2	1	1	1	1	0	0	2	0	0	1	0	11	3	1	3	3
	8	07FEB95	57, 1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	12	09MAR95	87, 31	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	1	0	4	1	1	0	1
	16	06APR95	115, 59	0	0	0	0	2	0	1	0	1	0	0	1	1	0	0	0	0	6	2	1	2	1
	20	03MAY95	142, 86	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
329.005.00109	SC	22DEC94	-8, -61	3	0	0	2	2	2	3	2	0	1	2	2	2	2	0	2	0	25	7	0	6	10
	BL	30DEC94	1, -53	3	0	0	2	2	2	3	2	0	1	0	2	2	2	0	2	0	23	5	0	6	10
	1	05JAN95	7, -47	0	0	0	2	2	2	0	0	3	0	0	0	0	2	0	0	0	11	0	3	6	2
	2	12JAN95	14, -40	1	0	0	0	0	1	0	0	2	1	0	0	0	2	0	1	0	8	1	2	1	3
	3	19JAN95	21, -33	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	1	0	4	0	1	0	2
	4	26JAN95	28, -26	2	0	0	0	0	0	0	1	0	1	0	0	0	2	0	0	0	6	1	0	0	5
	5	02FEB95	35, -19	0	0	0	0	0	0	1	0	1	1	0	1	2	0	0	2	0	8	4	1	0	1
	6	08FEB95	41, -13	1	0	0	0	0	0	0	0	0	1	0	1	0	1	0	0	0	4	2	0	0	2
	7	16FEB95	49, -5	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	21FEB95	54, 1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0	3	1	1	0	0
	12	23MAR95	84, 31	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	2	2	0	0	0
	16	24APR95	116, 63	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20	25MAY95	147, 94	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00112	SC	17JAN95	-9, -64	3	2	0	2	0	0	2	1	0	2	1	0	2	0	0	0	0	15	5	2	2	6
	BL	26JAN95	1, -55	2	0	0	0	0	0	3	2	1	1	0	1	2	0	0	1	0	13	4	1	0	7
	1	01FEB95	7, -49	2	0	0	1	1	2	0	1	1	0	0	0	0	0	0	0	0	8	0	1	4	3
	2	08FEB95	14, -42	1	1	0	2	0	0	0	0	3	1	0	0	0	0	0	0	0	8	1	4	2	1
	3	15FEB95	21, -35	1	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	4	1	1	0	2
	4	23FEB95	29, -27	0	0	0	0	1	0	0	1	3	0	0	0	0	0	0	0	0	5	0	3	1	1
	5	01MAR95	35, -21	3	1	0	2	1	1	2	0	3	3	0	0	0	0	0	0	0	16	3	4	4	5
	6	08MAR95	42, -14	2	0	0	2	2	2	4	0	0	0	0	1	0	0	0	0	0	13	1	0	6	6

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.005.00112	7	15MAR95	49, -7	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	1	1	0
	8	22MAR95	56, 1	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	1	0
	12	19APR95	84, 29	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	20	21JUN95	147, 92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00116	SC	30JAN95	-8, -66	2	2	2	0	2	0	2	1	3	1	0	1	1	2	0	0	0	19	3	7	2	7
	BL	07FEB95	1, -58	2	1	0	0	1	1	2	1	2	1	0	1	1	2	0	0	0	15	3	3	2	7
	1	13FEB95	7, -52	1	0	0	0	2	0	0	0	3	1	0	0	0	2	0	0	0	9	1	3	2	3
	2	20FEB95	14, -45	1	0	0	0	1	0	1	0	2	1	0	0	0	0	0	1	0	7	1	2	1	2
	3	27FEB95	21, -38	1	1	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	5	1	1	2	1
	4	09MAR95	31, -28	0	1	0	0	0	0	1	0	1	1	0	0	2	0	0	1	0	7	3	2	0	1
	5	16MAR95	38, -21	2	1	0	1	1	0	1	0	1	1	0	0	0	0	0	0	0	8	1	2	2	3
	6	23MAR95	45, -14	1	0	0	0	1	0	0	0	1	1	0	0	0	1	0	0	0	5	1	1	1	2
	7	30MAR95	52, -7	1	0	0	0	1	0	0	0	3	0	0	0	0	1	0	0	0	6	0	3	1	2
	8	06APR95	59, 1	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0	0	3	0	1	1	1
	12	04MAY95	87, 29	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	16	31MAY95	114, 56	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0	0	3	0	1	1	1
	20	28JUN95	142, 84	3	2	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	7	0	3	0	3
	24	26JUL95	170, 112	0	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	1	2	0	0
329.005.00119	SC	27JUN95	-14, -73	3	0	0	1	2	0	2	2	0	0	2	0	0	0	0	0	0	12	2	0	3	7
	BL	11JUL95	1, -59	3	0	0	0	2	2	2	1	0	0	0	0	2	0	0	0	0	12	2	0	4	6
	1	18JUL95	8, -52	2	0	0	2	2	1	0	1	0	0	2	0	1	0	0	0	0	11	3	0	5	3
	2	26JUL95	16, -44	2	0	0	0	2	2	2	1	0	0	1	0	0	0	0	0	0	10	1	0	4	5
	3	02AUG95	23, -37	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	4	0	0	3	1
	4	08AUG95	29, -31	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1
	5	15AUG95	36, -24	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	6	23AUG95	44, -16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	29AUG95	50, -10	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00119	8	08SEP95	60, 1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	12	03OCT95	85, 26	1	0	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	4	1	0	2	1
	16	30OCT95	112, 53	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	2	1	0	1	0
	20	28NOV95	141, 82	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	24	02JAN96	176, 117	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00151	SC	29AUG95	-8, -65	3	2	0	2	0	0	1	0	4	1	2	1	1	0	2	0	0	19	7	6	2	4
	BL	06SEP95	1, -57	3	2	0	0	0	0	3	0	0	1	1	1	1	0	2	0	1	15	7	2	0	6
	1	14SEP95	9, -49	2	0	2	1	2	2	1	1	3	1	0	1	1	1	0	1	0	19	3	5	5	5
	2	20SEP95	15, -43	2	0	0	2	1	0	1	1	1	1	0	1	0	0	0	1	0	11	2	1	3	4
	3	28SEP95	23, -35	3	0	2	1	0	0	0	0	0	1	0	1	0	0	0	0	0	8	2	2	1	3
	4	03OCT95	28, -30	2	0	1	0	0	0	0	0	1	1	0	1	0	0	1	1	0	8	3	2	0	2
	5	11OCT95	36, -22	2	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	4	0	0	0	4
	6	19OCT95	44, -14	2	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	4	0	0	0	4
	7	26OCT95	51, -7	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	1	0	0	1
	8	02NOV95	58, 1	2	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	4	1	0	0	3
	12	28NOV95	84, 27	2	0	0	1	0	0	0	0	0	2	0	0	0	0	0	0	0	5	2	0	1	2
	16	02JAN96	119, 62	2	0	1	0	0	0	2	0	0	1	0	0	0	0	0	0	0	6	1	1	0	4
	20	31JAN96	148, 91	1	0	2	0	0	0	0	0	1	1	0	0	0	0	0	0	0	5	1	3	0	1
	24	27FEB96	175, 118	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	2	0	2
	28	27MAR96	204, 147	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	3	2	0	0	1
	32	01MAY96	239, 182	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
329.005.00152	SC	12OCT95	-14, .	3	2	0	1	1	0	1	1	2	2	0	0	1	0	0	0	0	14	3	4	2	5
	BL	23OCT95	-3, .	3	0	0	1	0	0	3	2	0	2	1	0	0	0	0	0	0	12	3	0	1	8
	1	02NOV95	8, .	3	0	0	0	0	2	2	1	2	1	0	1	2	0	0	1	0	15	4	2	2	6
329.005.00257	SC	05MAR96	-6, -62	3	2	0	0	0	0	3	1	0	1	0	0	2	0	0	0	1	13	4	2	0	7
	BL	11MAR96	1, -56	3	2	0	0	0	0	3	1	0	1	2	0	2	0	0	0	1	15	6	2	0	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00257	1	18MAR96	8, -49	1	0	0	1	0	0	2	0	0	1	0	0	0	0	0	1	0	6	1	0	1	3
	2	25MAR96	15, -42	1	0	0	1	0	0	2	1	0	0	0	0	0	0	0	0	0	5	0	0	1	4
	3	01APR96	22, -35	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	4	08APR96	29, -28	1	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	3	1	0	0	2
	5	15APR96	36, -21	2	0	0	0	0	0	2	0	0	0	0	0	1	0	0	1	0	6	1	0	0	4
	6	22APR96	43, -14	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	3	1	0	0	2
	7	29APR96	50, -7	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	8	06MAY96	57, 1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	12	03JUN96	85, 29	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	16	08JUL96	120, 64	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	2	0	0	0
	20	07AUG96	150, 94	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24	27AUG96	170, 114	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0
	28	01OCT96	205, 149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	21OCT96	225, 169	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
329.005.00258	SC	06FEB96	-35, .	3	1	0	1	0	0	3	2	0	0	0	0	0	0	0	0	2	12	2	1	1	8
	BL	20FEB96	-21, .	3	0	0	0	0	0	3	2	0	1	0	0	2	0	0	0	2	13	5	0	0	8
	1	19MAR96	8, .	3	0	0	0	0	0	3	1	0	1	0	0	0	0	0	0	0	8	1	0	0	7
	2	26MAR96	15, .	1	0	0	0	0	0	2	2	0	1	1	0	0	0	0	0	0	7	2	0	0	5
	3	02APR96	22, .	3	0	0	0	0	0	2	1	0	0	0	0	1	0	0	0	0	7	1	0	0	6
	4	09APR96	29, .	1	0	0	0	0	0	2	0	0	1	1	0	1	0	0	0	0	6	3	0	0	3
	5	18APR96	38, .	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	3	0	2	0	1
	6	23APR96	43, .	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	7	30APR96	50, .	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	8	07MAY96	57, .	1	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	4	1	0	0	3
329.005.00299	SC	28MAY96	-11, -71	3	2	1	2	0	0	3	2	0	1	0	0	2	0	0	0	2	18	5	3	2	8
	BL	04JUN96	-4, -64	3	0	0	2	0	0	3	1	0	1	0	0	1	0	0	0	2	13	4	0	2	7
	1	18JUN96	11, -50	1	0	0	0	0	0	1	0	.	1	0	0	0	0	0	0	0	3	1	0	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00299	2	25JUN96	18, -43	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0	3	2	0	0	1
	3	02JUL96	25, -36	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	5	10JUL96	33, -28	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	5	16JUL96	39, -22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6	22JUL96	45, -16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	31JUL96	54, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	07AUG96	61, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	03SEP96	88, 28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	01OCT96	116, 56	0	0	0	1	0	0	1	0	0	1	0	0	1	0	0	0	0	4	2	0	1	1
	20	29OCT96	144, 84	2	0	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	5	2	1	0	2
	20	05NOV96	151, 91	2	0	1	0	0	0	2	1	0	1	0	0	0	0	0	0	2	9	3	1	0	5
329.005.00300	SC	12SEP96	-7, .	3	0	2	1	0	0	0	3	1	1	0	0	0	0	0	0	2	13	3	3	1	6
	BL	19SEP96	1, .	2	0	2	1	0	0	1	2	1	1	0	1	0	0	0	0	2	13	4	3	1	5
	1	26SEP96	8, .	2	0	2	0	0	0	1	1	2	1	0	0	1	0	0	1	2	13	4	4	0	4
	2	03OCT96	15, .	1	0	0	1	0	0	0	1	3	1	0	1	0	0	0	1	2	11	4	3	1	2
	3	10OCT96	22, .	1	0	1	0	0	0	2	1	0	1	0	0	0	0	0	0	2	8	3	1	0	4
	4	17OCT96	29, .	1	1	1	0	0	0	0	1	2	1	0	1	0	0	0	0	2	10	4	4	0	2
	5	24OCT96	36, .	0	0	1	0	0	0	0	1	1	1	0	1	0	0	0	1	2	8	4	2	0	1
	6	31OCT96	43, .	1	0	2	0	0	0	0	2	3	1	0	1	0	0	0	0	2	12	4	5	0	3
	7	07NOV96	50, .	2	0	2	0	0	0	0	1	2	1	0	0	0	0	0	0	2	10	3	4	0	3
	8	14NOV96	57, .	3	0	2	0	0	0	1	3	3	1	0	1	2	0	0	0	2	18	6	5	0	7
329.005.00333	SC	15JAN97	-8, .	3	1	2	2	0	0	2	2	0	1	2	1	2	0	0	1	0	19	6	3	2	7
	BL	23JAN97	1, .	4	0	0	0	0	0	3	2	0	1	0	1	2	0	0	1	0	14	4	0	0	9
	1	31JAN97	9, .	2	0	0	0	0	0	1	1	2	1	0	0	1	0	0	0	0	8	2	2	0	4
	2	06FEB97	15, .	4	0	1	0	0	0	3	2	2	1	0	0	2	0	0	0	0	15	3	3	0	9
	3	13FEB97	22, .	2	0	0	0	0	0	2	1	2	1	0	0	2	0	0	1	0	11	3	2	0	5
	4	20FEB97	29, .	2	0	1	0	2	0	1	1	2	1	0	1	1	0	0	0	0	12	3	3	2	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.005.00333	5	26FEB97	35, .	3	0	2	0	0	0	3	2	3	2	1	1	2	0	1	0	0	20	7	5	0	8
329.005.00336	SC	26FEB97	-6, .	3	1	1	0	1	0	2	2	3	2	1	1	2	0	3	2	0	24	9	5	1	7
	BL	04MAR97	1, .	2	1	0	1	2	1	2	1	2	1	0	0	2	0	1	0	0	16	4	3	4	5
	1	12MAR97	9, .	1	0	0	0	2	2	1	1	3	1	0	1	0	0	1	1	0	14	3	3	4	3
	2	19MAR97	16, .	1	0	0	0	2	1	0	0	1	1	0	1	0	0	0	1	0	8	2	1	3	1
	3	25MAR97	22, .	1	1	1	0	2	1	0	1	2	0	0	0	0	0	0	0	0	9	0	4	3	2
	4	02APR97	30, .	1	0	0	0	2	1	0	0	1	0	0	1	1	0	1	0	0	8	3	1	3	1
	5	09APR97	37, .	0	0	0	0	2	0	1	1	1	1	0	0	1	0	0	0	0	7	2	1	2	2
	6	16APR97	44, .	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	1	0	3	1	0	1	0
	7	23APR97	51, .	1	1	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	6	2	2	0	2
	8	30APR97	58, .	1	0	1	0	0	0	1	0	2	0	0	1	0	0	0	0	0	6	1	3	0	2
329.006.00038	SC	01FEB95	-14, .	1	2	0	2	2	1	3	2	2	3	1	0	2	0	0	0	0	21	6	4	5	6
	BL	08FEB95	-7, .	1	2	0	2	2	1	2	0	3	2	2	2	2	1	1	2	0	25	9	5	5	4
	1	22FEB95	8, .	2	2	0	2	2	0	3	0	0	2	0	1	1	2	0	0	0	17	4	2	4	7
	2	03MAR95	17, .	0	1	0	1	0	0	0	0	0	0	0	1	1	0	1	2	0	7	3	1	1	0
	3	08MAR95	22, .	0	0	0	2	1	0	1	0	1	0	0	1	1	0	0	0	0	7	2	1	3	1
	4	15MAR95	29, .	0	1	0	2	1	0	0	0	1	2	1	1	2	0	3	2	0	16	9	2	3	0
	5	22MAR95	36, .	0	0	0	2	1	1	0	0	1	1	1	1	1	0	0	0	0	9	4	1	4	0
	6	29MAR95	43, .	0	0	0	2	1	2	0	0	1	0	0	1	1	0	0	0	0	8	2	1	5	0
	7	05APR95	50, .	0	0	0	2	1	0	1	0	0	0	0	1	1	0	0	0	0	6	2	0	3	1
329.006.00039	SC	03FEB95	-5, -66	3	1	1	2	0	0	3	2	2	3	2	0	1	1	1	0	0	22	7	4	2	9
	BL	10FEB95	3, -59	3	1	2	2	0	0	3	2	0	3	2	0	2	0	0	0	0	20	7	3	2	8
	1	13FEB95	6, -56	3	1	2	0	0	0	3	2	2	2	3	0	2	0	2	0	0	22	9	5	0	8
	2	22FEB95	15, -47	3	2	2	0	0	0	3	2	0	2	3	0	2	0	2	0	0	21	9	4	0	8
	3	01MAR95	22, -40	3	2	1	1	0	0	2	2	2	3	0	0	2	0	3	0	0	21	8	5	1	7
	4	08MAR95	29, -33	1	2	2	1	1	0	2	2	1	2	1	1	1	0	1	0	0	18	6	5	2	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.006.00039	5	17MAR95	38, -24	3	2	3	0	0	0	1	1	2	2	0	0	1	0	1	0	0	16	4	7	0	5
	6	22MAR95	43, -19	1	1	3	0	0	0	2	1	2	1	0	0	2	0	0	0	0	13	3	6	0	4
	7	29MAR95	50, -12	3	1	2	0	0	0	2	2	1	2	0	0	2	0	0	0	0	15	4	4	0	7
	8	05APR95	57, -5	1	1	1	1	0	0	1	0	1	1	1	0	1	0	0	0	0	9	3	3	1	2
	12	01MAY95	83, 22	3	2	2	2	0	1	2	1	0	3	3	0	2	0	3	0	0	24	11	4	3	6
329.006.00260	SC	12JUL96	-6, -64	3	2	0	0	0	0	1	0	1	1	2	0	1	0	0	0	2	13	6	3	0	4
	BL	18JUL96	1, -58	3	2	0	0	0	0	3	0	2	1	2	0	1	0	0	0	2	16	6	4	0	6
	1	26JUL96	9, -50	1	1	0	0	0	0	0	0	2	1	2	0	0	0	0	0	2	9	5	3	0	1
	2	01AUG96	15, -44	1	2	0	0	0	0	1	0	2	1	1	0	1	0	0	1	2	12	5	4	0	2
	3	07AUG96	21, -38	1	2	0	0	0	0	1	0	2	3	1	0	0	0	0	0	0	10	4	4	0	2
	4	14AUG96	28, -31	1	2	0	0	0	0	1	0	2	2	1	0	1	0	1	2	0	13	5	4	0	2
	5	21AUG96	35, -24	1	1	0	0	0	0	0	0	2	1	1	0	0	0	0	0	0	6	2	3	0	1
	6	28AUG96	42, -17	3	1	0	0	0	0	1	0	2	2	1	0	0	0	0	0	0	10	3	3	0	4
	7	04SEP96	49, -10	2	2	1	0	0	0	0	0	2	2	1	0	1	0	0	0	0	11	4	5	0	2
	8	18SEP96	63, 5	1	2	0	0	0	0	0	0	2	1	1	0	0	0	0	0	0	7	2	4	0	1
	12	09OCT96	84, 26	1	1	0	0	0	0	0	0	2	2	1	0	1	0	0	2	0	10	4	3	0	1
	16	06NOV96	112, 54	3	2	0	0	0	0	0	0	2	3	1	0	0	0	0	0	0	11	4	4	0	3
329.006.00261	SC	07NOV96	-19, -77	3	4	4	2	1	0	2	2	1	2	2	0	2	0	3	0	0	28	9	9	3	7
	BL	22NOV96	-4, -62	3	3	0	1	0	0	2	2	1	2	2	0	1	1	3	1	0	22	8	4	1	8
	1	03DEC96	8, -51	3	2	2	0	2	0	3	2	4	3	3	0	0	2	1	0	0	27	7	8	2	10
	2	10DEC96	15, -44	2	2	0	0	0	0	2	2	4	3	2	1	1	2	0	0	0	21	7	6	0	8
	3	17DEC96	22, -37	3	2	2	1	1	0	3	1	4	3	2	1	1	0	1	2	0	27	8	8	2	7
	4	24DEC96	29, -30	3	2	2	0	0	0	3	2	4	2	2	1	0	0	0	0	0	21	5	8	0	8
	5	02JAN97	38, -21	1	1	0	0	1	0	1	1	4	0	2	0	1	1	2	0	0	15	5	5	1	4
	6	09JAN97	45, -14	0	2	0	0	0	0	0	1	4	0	2	0	0	0	0	0	0	9	2	6	0	1
	7	15JAN97	51, -8	1	1	0	0	0	0	0	1	4	0	1	0	0	0	0	0	0	8	1	5	0	2
	8	23JAN97	59, 1	2	2	0	2	0	0	2	1	4	3	2	0	2	0	1	0	0	21	8	6	2	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.006.00261	12	20FEB97	87, 29	0	1	0	0	0	0	1	1	1	0	2	0	1	0	3	0	0	10	6	2	0	2
	20	02APR97	128, 70	3	2	0	0	0	0	1	1	1	2	1	0	1	0	2	0	0	14	6	3	0	5
329.007.00140	SC	07SEP95	-8, -63	3	1	2	2	0	0	1	2	1	1	1	0	1	0	0	0	0	15	3	4	2	6
	BL	14SEP95	-1, -56	2	0	1	2	1	0	2	0	2	0	2	0	2	0	0	0	1	15	5	3	3	4
	1	21SEP95	7, -49	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0	1	0	4	0	1	1	1
	2	28SEP95	14, -42	0	0	0	0	0	0	0	0	2	1	0	0	0	0	0	1	0	4	1	2	0	0
	3	05OCT95	21, -35	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	4	12OCT95	28, -28	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	1	0	0	0
	5	18OCT95	34, -22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6	26OCT95	42, -14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	02NOV95	49, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	09NOV95	56, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	22NOV95	69, 14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.007.00142	SC	12OCT95	-6, .	2	1	0	2	0	0	3	1	1	1	0	0	2	0	1	0	0	14	4	2	2	6
	BL	18OCT95	1, .	4	2	0	0	0	0	3	2	2	3	1	0	1	0	1	0	0	19	6	4	0	9
	1	26OCT95	9, .	3	1	0	0	0	0	3	2	0	1	0	0	0	0	0	0	1	11	2	1	0	8
	2	02NOV95	16, .	3	1	0	0	0	0	3	2	1	0	0	0	1	0	1	1	0	13	2	2	0	8
	3	09NOV95	23, .	2	1	0	0	0	0	1	1	1	1	0	0	1	0	0	0	0	8	2	2	0	4
	4	16NOV95	30, .	2	0	0	0	0	0	3	1	1	1	0	0	1	0	0	0	0	9	2	1	0	6
	5	22NOV95	36, .	2	1	0	0	0	0	1	1	1	1	1	0	0	0	0	0	1	9	3	2	0	4
	6	30NOV95	44, .	3	1	0	0	0	0	3	2	2	3	1	0	1	0	0	0	0	16	5	3	0	8
	8	21DEC95	65, .	3	0	0	2	1	0	3	2	1	2	1	0	1	0	0	0	0	16	4	1	3	8
329.007.00145	SC	04JAN96	-7, -63	3	1	0	1	1	0	2	2	0	3	0	1	0	0	0	1	1	16	5	1	2	7
	BL	11JAN96	1, -56	1	0	0	1	0	0	2	2	0	3	0	1	0	0	0	1	2	13	6	0	1	5
	1	18JAN96	8, -49	2	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0	1	8	2	1	1	4
	2	25JAN96	15, -42	3	1	0	0	0	0	3	3	1	1	0	0	0	0	0	0	2	14	3	2	0	9

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.007.00145	3	01FEB96	22, -35	2	0	0	0	0	0	3	2	1	1	1	0	1	0	0	0	2	13	5	1	0	7
	4	08FEB96	29, -28	0	1	0	0	0	1	1	1	1	0	0	0	0	0	0	0	1	6	1	2	1	2
	5	12FEB96	33, -24	0	1	0	0	0	0	1	1	1	0	1	0	0	0	0	0	1	6	2	2	0	2
	6	21FEB96	42, -15	3	0	0	0	0	0	1	2	1	0	0	0	0	0	0	0	2	9	2	1	0	6
	7	26FEB96	47, -10	0	0	0	0	0	0	1	1	0	2	0	0	0	0	0	0	0	4	2	0	0	2
	8	07MAR96	57, 1	1	1	0	0	0	0	1	0	2	1	0	0	0	0	0	0	0	6	1	3	0	2
	12	04APR96	85, 29	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	16	02MAY96	113, 57	0	0	0	0	0	1	0	0	1	0	0	0	1	0	0	0	0	3	1	1	1	0
	20	30MAY96	141, 85	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24	27JUN96	169, 113	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	25JUL96	197, 141	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	23AUG96	226, 170	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.007.00265	SC	25JAN96	-7, .	4	2	2	2	0	0	3	3	1	3	0	0	0	0	0	0	1	21	4	5	2	10
	BL	01FEB96	1, .	3	1	0	1	0	0	3	2	2	3	1	0	1	0	0	0	1	18	6	3	1	8
	2	15FEB96	15, .	3	1	0	0	1	0	3	2	2	3	1	1	0	0	0	2	1	20	6	3	1	8
329.007.00268	SC	21MAR96	-11, -70	3	1	1	0	0	0	3	1	0	3	2	0	1	0	0	0	0	15	6	2	0	7
	BL	01APR96	1, -59	3	2	1	0	0	2	1	0	4	4	0	1	0	0	0	1	0	19	5	7	2	4
	1	11APR96	11, -49	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	2	0	0
	2	18APR96	18, -42	0	1	0	0	0	0	0	0	1	1	1	1	0	0	0	1	0	6	3	2	0	0
	3	25APR96	25, -35	1	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	4	2	1	0	1
	4	02MAY96	32, -28	1	0	0	0	1	0	0	0	0	2	0	0	0	0	0	0	0	4	2	0	1	1
	5	09MAY96	39, -21	2	0	0	2	0	0	1	0	2	1	0	0	0	0	0	0	0	8	1	2	2	3
	6	16MAY96	46, -14	2	0	0	0	0	0	2	0	2	2	0	0	0	0	0	1	1	10	3	2	0	4
	8	30MAY96	60, 1	0	1	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	3	1	1	0	1
	12	27JUN96	88, 29	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	16	01AUG96	123, 64	2	0	0	1	0	0	1	0	2	1	0	0	0	0	0	0	0	7	1	2	1	3
	20	30AUG96	152, 93	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.007.00268	24	30SEP96	183, 124	0	0	0	0	0	2	1	0	2	0	1	0	2	0	0	0	0	8	3	2	2	1
	32	07NOV96	221, 162	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	32	05DEC96	249, 190	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.007.00294	SC	20FEB97	-8, .	4	2	1	2	1	1	3	2	0	3	1	1	1	0	0	0	0	22	6	3	4	9
	BL	27FEB97	-1, .	3	2	0	2	2	2	3	0	2	3	2	0	1	0	0	0	0	22	6	4	6	6
	1	10MAR97	11, .	2	1	2	2	2	2	2	0	2	3	2	1	1	0	0	1	0	23	7	5	6	4
	2	17MAR97	18, .	3	1	0	2	2	1	2	2	0	0	2	1	2	0	0	1	0	19	5	1	5	7
	4	28MAR97	29, .	4	0	0	1	1	1	2	1	2	3	0	0	0	0	0	0	1	16	4	2	3	7
	5	03APR97	35, .	3	0	0	1	2	2	3	1	2	3	2	1	1	0	0	0	0	21	7	2	5	7
	6	10APR97	42, .	3	1	0	2	1	1	3	2	1	3	1	1	0	0	0	0	0	19	5	2	4	8
329.007.00309	SC	02JUL96	-13, -65	2	1	1	1	1	1	3	0	1	3	2	2	1	0	3	1	0	23	11	3	3	5
	BL	15JUL96	1, -52	4	2	2	0	2	0	3	0	3	4	3	2	2	0	1	0	0	28	12	7	2	7
	1	18JUL96	4, -49	1	1	0	1	0	0	0	0	2	0	0	0	0	0	0	0	0	5	0	3	1	1
	1	25JUL96	11, -42	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	2	01AUG96	18, -35	2	0	0	1	1	1	0	0	1	1	1	1	0	0	0	0	0	9	3	1	3	2
	3	08AUG96	25, -28	1	1	0	0	0	0	1	0	2	1	0	0	1	0	0	1	0	8	2	3	0	2
	4	15AUG96	32, -21	1	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	3	0	1	1	1
	6	23AUG96	40, -13	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	2	0	1	1	0
	7	30AUG96	47, -6	1	0	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0	4	2	0	0	2
	7	05SEP96	53, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	03OCT96	81, 29	0	0	0	0	0	0	0	0	1	2	1	0	0	0	0	0	0	4	3	1	0	0
	16	31OCT96	109, 57	0	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	3	2	1	0	0
	20	13DEC96	152, 100	1	0	0	0	1	1	0	0	1	1	1	0	0	0	0	1	0	7	2	1	2	1
	24	09JAN97	179, 127	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	28	10FEB97	211, 159	2	2	0	1	1	1	0	0	2	2	2	1	1	1	0	1	0	17	6	4	3	3
	32	13MAR97	242, 190	2	0	1	2	1	0	1	0	0	2	1	0	0	0	0	0	0	10	3	1	3	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.007.00310	SC	19SEP96	-7, -67	3	2	0	0	1	0	3	1	2	3	0	0	1	0	0	0	1	17	5	4	1	7
	BL	26SEP96	1, -60	3	1	0	1	1	0	2	0	2	3	1	0	0	0	0	0	0	14	4	3	2	5
	1	03OCT96	8, -53	3	1	0	0	0	1	1	0	1	2	0	0	0	0	0	0	0	9	2	2	1	4
	2	10OCT96	15, -46	0	0	0	0	1	1	0	0	0	0	0	1	1	0	0	0	0	4	2	0	2	0
	3	17OCT96	22, -39	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	5	28OCT96	33, -28	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	1	0	0	1
	5	31OCT96	36, -25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6	08NOV96	44, -17	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	8	18NOV96	54, -7	1	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	7	0	0	6	1
	8	25NOV96	61, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	02JAN97	99, 39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	20	14FEB97	142, 82	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24	13MAR97	169, 109	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	17APR97	204, 144	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	15MAY97	232, 172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	12JUN97	260, 200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.007.00318	SC	22NOV96	-10, .	3	1	0	1	0	0	3	0	2	2	1	1	1	0	0	0	1	16	6	3	1	6
	BL	02DEC96	1, .	3	2	0	1	0	0	3	0	2	2	0	0	0	0	0	0	1	14	3	4	1	6
329.008.00157	SC	16AUG95	-14, -69	3	2	0	1	0	0	3	1	3	3	0	0	1	0	0	0	0	17	4	5	1	7
	BL	29AUG95	-1, -56	3	0	0	0	0	0	3	2	2	2	0	0	1	0	0	0	0	13	3	2	0	8
	1	05SEP95	7, -49	1	1	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	6	2	2	0	2
	2	12SEP95	14, -42	1	0	0	1	0	0	1	0	1	2	0	0	0	0	0	1	0	7	2	1	1	2
	3	20SEP95	22, -34	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	4	26SEP95	28, -28	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	5	04OCT95	36, -20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6	10OCT95	42, -14	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	7	16OCT95	48, -8	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	2	1	0	0	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.008.00157	8	24OCT95	56, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	23NOV95	86, 31	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	2	0	0	0	1
	16	15DEC95	108, 53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20	23JAN96	147, 92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24	20FEB96	175, 120	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.008.00160	SC	25OCT95	-7, -73	2	2	2	2	1	0	2	1	3	2	0	0	1	0	1	0	0	19	4	7	3	5
	BL	01NOV95	1, -66	1	2	2	2	1	0	2	1	3	2	0	0	2	0	0	0	0	18	4	7	3	4
	1	10NOV95	10, -57	2	1	0	1	1	0	1	0	0	2	0	1	2	0	0	0	0	11	5	1	2	3
	3	20NOV95	20, -47	2	2	0	0	0	2	2	0	1	2	0	1	2	0	1	0	0	15	6	3	2	4
	4	27NOV95	27, -40	2	0	0	0	0	2	0	1	1	0	0	0	0	0	0	0	0	6	0	1	2	3
	5	05DEC95	35, -32	2	0	0	0	1	2	1	0	0	0	0	0	1	0	0	0	0	7	1	0	3	3
	6	13DEC95	43, -24	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	4	2	2	0	0
	7	20DEC95	50, -17	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0
	8	27DEC95	57, -10	0	0	0	0	0	2	0	0	0	0	0	0	1	0	0	0	0	3	1	0	2	0
	8	05JAN96	66, -1	0	0	0	0	0	2	0	0	0	0	0	0	1	0	0	0	0	3	1	0	2	0
	12	31JAN96	92, 26	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	2	2	0	0	0
	16	05MAR96	126, 60	2	0	1	0	0	0	3	1	1	0	0	0	0	0	0	0	0	8	0	2	0	6
	24	09APR96	161, 95	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	16MAY96	198, 132	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	32	18JUN96	231, 165	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	23JUL96	266, 200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.008.00188	SC	14DEC95	-21, .	4	1	3	2	2	2	3	2	0	3	0	1	2	0	1	0	0	26	7	4	6	9
	BL	04JAN96	1, .	3	2	0	2	2	1	3	2	2	2	0	0	2	0	1	0	0	22	5	4	5	8
	1	10JAN96	7, .	2	1	0	1	2	1	3	1	0	0	0	0	1	0	0	0	0	12	1	1	4	6
	2	17JAN96	14, .	2	1	0	1	2	1	3	2	0	1	0	0	1	1	0	0	0	15	2	1	4	8
	3	24JAN96	21, .	1	1	0	2	1	0	1	1	0	1	0	0	1	0	0	0	0	9	2	1	3	3
	4	31JAN96	28, .	2	1	3	0	2	1	0	1	1	0	0	1	2	0	0	0	0	14	3	5	3	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.008.00188	5	07FEB96	35, .	2	1	2	0	2	0	2	1	0	0	0	0	1	0	0	0	0	11	1	3	2	5
	6	14FEB96	42, .	1	0	0	1	2	1	2	0	2	1	0	0	1	0	0	0	0	11	2	2	4	3
	7	21FEB96	49, .	0	1	0	1	2	2	3	1	0	0	0	0	2	0	1	0	0	13	3	1	5	4
	8	27FEB96	55, .	2	2	1	0	2	2	3	1	2	2	2	1	2	0	1	0	0	23	8	5	4	6
329.008.00271	SC	25JAN96	-46,-110	4	2	0	2	0	0	3	2	0	3	0	0	2	0	0	0	0	18	5	2	2	9
	BL	11MAR96	1, -64	4	2	1	2	0	0	3	2	0	2	0	0	2	0	0	0	0	18	4	3	2	9
	1	18MAR96	8, -57	1	2	0	2	1	1	1	0	1	2	1	1	1	0	0	1	0	15	5	3	4	2
	2	25MAR96	15, -50	1	2	0	1	1	0	3	1	0	2	0	1	1	0	0	1	0	14	4	2	2	5
	3	01APR96	22, -43	1	2	0	0	1	1	1	0	1	2	1	0	1	0	1	0	0	12	5	3	2	2
	4	08APR96	29, -36	1	2	0	0	0	0	1	1	1	2	1	1	1	0	1	0	0	12	6	3	0	3
	5	15APR96	36, -29	1	0	0	0	1	0	0	0	0	2	0	0	0	0	1	0	0	5	3	0	1	1
	6	22APR96	43, -22	1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	2	0	0	1
	7	02MAY96	53, -12	0	1	0	0	1	0	0	0	0	2	1	0	0	0	0	0	0	5	3	1	1	0
	8	14MAY96	65, 1	1	1	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0	6	2	1	0	3
	12	10JUN96	92, 28	1	2	0	0	0	0	1	0	0	2	0	0	1	0	0	0	0	7	3	2	0	2
	16	12JUL96	124, 60	2	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	5	1	0	0	4
	20	09AUG96	152, 88	2	0	0	0	0	1	3	1	0	1	0	0	0	0	0	0	0	8	1	0	1	6
	24	06SEP96	180, 116	2	0	0	2	0	0	0	1	0	1	1	0	0	0	0	0	0	7	2	0	2	3
	28	07OCT96	211, 147	2	0	0	2	1	0	2	1	1	0	0	0	0	0	0	0	0	9	0	1	3	5
	32	05NOV96	240, 176	3	0	0	1	1	1	4	2	0	0	0	0	0	0	0	0	0	12	0	0	3	9
329.008.00275	SC	30APR96	-8, -63	2	1	0	2	0	0	2	0	0	3	2	0	1	0	0	0	0	13	6	1	2	4
	BL	07MAY96	-1, -56	2	1	0	2	0	0	3	1	3	2	2	0	2	0	0	0	0	18	6	4	2	6
	1	15MAY96	8, -48	2	0	0	2	1	0	3	1	0	4	2	1	0	0	0	0	0	16	7	0	3	6
	2	21MAY96	14, -42	2	0	0	1	0	2	4	2	0	2	2	1	1	0	0	0	0	17	6	0	3	8
	3	28MAY96	21, -35	3	2	1	0	0	1	3	2	0	1	2	1	1	0	1	0	0	18	6	3	1	8
	4	04JUN96	28, -28	1	0	0	0	0	1	0	1	1	0	1	1	1	0	0	1	0	8	3	1	1	2
	5	11JUN96	35, -21	1	0	0	1	0	0	0	0	0	0	1	0	1	0	0	0	0	4	2	0	1	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.008.00275	7	25JUN96	49, -7	1	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	3	1	0	1	1
	8	02JUL96	56, 1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0
	12	23JUL96	77, 22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	20AUG96	105, 50	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	1	0	3	1	1	0	0
	20	16SEP96	132, 77	1	1	0	1	0	0	1	0	0	2	1	0	1	0	1	0	0	9	5	1	1	2
	24	21OCT96	167, 112	1	0	0	0	0	0	1	1	2	1	1	0	1	0	0	0	0	8	3	2	0	3
	28	25NOV96	202, 147	1	1	0	0	0	0	1	1	0	1	0	0	1	0	1	0	0	7	3	1	0	3
	32	16DEC96	223, 168	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	2	0	0	0	2
329.009.00130	SC	12APR95	-6, -62	3	1	2	2	2	1	2	1	3	2	3	1	2	0	2	0	1	28	11	6	5	6
	BL	18APR95	1, -56	2	1	1	2	2	1	2	1	3	2	2	0	1	0	1	0	1	22	7	5	5	5
	1	25APR95	8, -49	3	1	1	2	1	0	2	2	2	2	2	1	1	0	2	0	0	22	8	4	3	7
	2	02MAY95	15, -42	2	1	1	2	1	0	2	2	2	2	2	1	1	0	2	0	0	21	8	4	3	6
	3	09MAY95	22, -35	2	1	0	1	1	0	2	1	2	1	1	0	0	0	1	0	0	13	3	3	2	5
	4	16MAY95	29, -28	1	1	0	1	0	0	1	1	2	1	0	0	0	0	1	0	0	9	2	3	1	3
	5	23MAY95	36, -21	3	1	1	2	1	1	1	1	2	1	1	1	1	0	1	0	1	19	6	4	4	5
	6	30MAY95	43, -14	1	1	1	0	0	0	2	1	2	2	2	1	0	0	1	0	0	14	6	4	0	4
	7	06JUN95	50, -7	0	1	0	1	0	0	0	0	3	0	0	0	0	0	0	0	0	5	0	4	1	0
	8	13JUN95	57, 1	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	1	0	0
	16	07AUG95	112, 56	0	0	0	2	0	0	2	0	1	0	0	0	0	0	0	0	0	5	0	1	2	2
	20	19SEP95	155, 99	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	24	03OCT95	169, 113	2	1	1	2	1	1	1	1	2	2	2	0	0	0	1	0	0	17	5	4	4	4
329.009.00131	SC	26APR95	-6, -62	3	3	3	2	2	2	3	2	4	3	3	1	2	1	2	2	0	38	11	10	6	9
	BL	02MAY95	1, -56	4	2	1	2	2	2	2	2	2	3	2	1	2	0	1	0	1	29	10	5	6	8
	1	09MAY95	8, -49	3	2	1	2	1	0	2	2	2	1	1	1	1	0	1	1	0	21	5	5	3	7
	2	16MAY95	15, -42	3	2	1	2	1	0	2	2	1	2	1	1	1	0	2	0	0	21	7	4	3	7
	3	23MAY95	22, -35	3	2	1	2	1	0	1	1	1	1	1	1	1	0	0	0	0	16	4	4	3	5
	4	30MAY95	29, -28	1	1	0	1	1	0	1	1	2	1	2	1	1	0	0	1	0	14	5	3	2	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00131	5	06JUN95	36, -21	0	0	0	1	0	1	1	1	1	0	1	0	0	0	0	0	0	6	1	1	2	2
	6	13JUN95	43, -14	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	2	0	0
	7	20JUN95	50, -7	1	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	4	0	2	0	2
	8	27JUN95	57, 1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2	1	0	0	0
	12	25JUL95	85, 29	1	1	0	1	0	0	0	1	2	3	1	0	0	0	1	0	0	11	5	3	1	2
	16	24AUG95	115, 59	1	1	0	0	0	0	1	0	2	2	1	1	1	0	1	0	0	11	6	3	0	2
	20	26SEP95	148, 92	1	1	0	2	0	0	0	1	1	1	0	0	0	0	0	1	0	8	1	2	2	2
329.009.00133	SC	07JUN95	-6, .	2	1	2	2	2	0	3	2	1	2	1	0	1	0	1	0	1	21	6	4	4	7
	BL	13JUN95	1, .	3	1	2	2	1	1	3	1	2	2	2	1	1	0	1	0	0	23	7	5	4	7
	1	20JUN95	8, .	3	1	2	2	2	2	3	1	2	2	2	1	1	0	1	0	0	25	7	5	6	7
	2	27JUN95	15, .	3	1	2	2	2	2	3	2	2	2	2	1	1	0	2	0	0	27	8	5	6	8
	3	05JUL95	23, .	3	1	1	2	1	2	2	2	1	3	2	0	1	0	1	0	0	22	7	3	5	7
	4	11JUL95	29, .	4	2	1	2	1	1	3	2	2	3	2	0	1	0	1	0	0	25	7	5	4	9
	5	18JUL95	36, .	4	2	2	2	2	0	3	2	2	2	2	0	1	0	1	0	0	25	6	6	4	9
	6	27JUL95	45, .	2	1	1	2	1	1	2	2	1	3	2	0	1	0	1	0	0	20	7	3	4	6
329.009.00138	SC	02OCT95	-8, .	2	2	2	2	2	0	3	2	1	2	2	2	2	0	0	2	0	26	8	5	4	7
	BL	10OCT95	1, .	3	1	1	2	1	0	3	2	2	3	2	1	2	0	2	2	0	27	10	4	3	8
	1	17OCT95	8, .	3	2	1	2	1	1	2	1	2	2	2	1	1	0	1	1	0	23	7	5	4	6
329.009.00170	SC	26OCT95	-12, -69	3	0	1	1	0	1	3	0	3	2	2	0	1	1	1	0	2	21	8	4	2	7
	BL	07NOV95	1, -57	3	1	2	2	1	0	3	3	0	3	2	1	1	0	3	1	2	28	12	3	3	9
	1	14NOV95	8, -50	3	1	0	2	1	1	3	2	0	2	2	1	0	0	2	0	2	22	9	1	4	8
	2	21NOV95	15, -43	3	1	1	1	1	0	3	2	1	2	1	1	1	0	1	0	2	21	8	3	2	8
	3	28NOV95	22, -36	3	1	0	1	2	0	3	2	0	2	1	1	0	0	2	0	2	20	8	1	3	8
	4	05DEC95	29, -29	3	2	0	1	2	0	3	3	0	3	1	1	1	1	2	0	2	25	10	2	3	10
	5	12DEC95	36, -22	2	1	0	1	0	0	2	1	0	2	0	0	0	0	0	0	1	10	3	1	1	5
	6	21DEC95	45, -13	1	1	0	0	1	0	1	1	0	1	1	1	0	0	0	0	0	8	3	1	1	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.009.00170	7	29DEC95	53, -5	1	1	0	0	0	0	2	1	0	1	0	2	0	0	0	0	0	8	3	1	0	4
	8	03JAN96	58, 1	0	1	0	0	1	0	1	0	1	1	1	1	0	0	0	0	0	7	3	2	1	1
	12	29JAN96	84, 27	1	0	0	0	0	0	2	1	0	1	0	0	0	0	0	0	1	6	2	0	0	4
	16	26FEB96	112, 55	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	20	01APR96	147, 90	0	0	0	0	2	0	1	0	1	0	0	0	1	0	0	0	0	5	1	1	2	1
	24	22APR96	168, 111	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	3	1	1	0	1
	28	23MAY96	199, 142	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	32	24JUN96	231, 174	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
329.009.00173	SC	08NOV95	-12, -75	3	3	2	2	0	2	3	1	2	2	2	0	2	1	1	0	0	26	7	7	4	8
	BL	20NOV95	1, -63	3	2	2	2	0	2	4	3	1	2	2	0	2	0	0	0	1	26	7	5	4	10
	1	27NOV95	8, -56	3	3	2	2	0	2	3	2	2	2	2	0	2	1	1	0	0	27	7	7	4	9
	2	04DEC95	15, -49	3	2	2	0	0	0	4	3	1	2	2	2	2	0	0	0	1	24	9	5	0	10
	3	11DEC95	22, -42	4	3	2	0	0	0	4	2	1	3	1	2	1	0	1	0	0	24	8	6	0	10
	4	18DEC95	29, -35	3	2	1	0	0	1	4	1	0	2	1	2	2	0	0	1	0	20	7	3	1	8
	6	29DEC95	40, -24	2	2	0	1	0	0	4	0	3	1	1	1	2	0	0	1	0	18	5	5	1	6
	7	08JAN96	50, -14	2	2	0	0	0	0	4	0	3	1	1	1	1	0	0	1	0	16	4	5	0	6
	8	15JAN96	57, -7	2	1	0	0	1	1	4	1	2	2	1	1	1	0	1	0	0	18	6	3	2	7
	8	22JAN96	64, 1	1	1	0	0	1	0	2	1	0	1	0	0	1	0	0	0	0	8	2	1	1	4
	12	26FEB96	99, 36	1	1	1	2	0	0	2	1	0	1	0	0	1	0	0	0	1	11	3	2	2	4
329.009.00193	SC	21NOV95	-7, .	4	2	2	2	2	2	3	1	2	2	1	1	2	1	0	1	0	28	6	6	6	9
	BL	28NOV95	1, .	4	2	1	2	2	2	3	2	2	2	2	1	2	0	1	1	0	29	8	5	6	9
	1	05DEC95	8, .	4	2	1	2	1	1	3	2	3	2	2	1	1	0	2	0	0	27	8	6	4	9
	2	12DEC95	15, .	4	2	1	2	1	1	3	2	3	2	2	1	1	0	2	0	0	27	8	6	4	9
	3	19DEC95	22, .	3	1	2	2	1	1	3	2	1	2	1	2	1	0	0	0	1	23	7	4	4	8
	4	27DEC95	30, .	3	1	1	2	2	1	2	2	2	2	1	1	0	0	1	0	0	21	5	4	5	7
	5	05JAN96	39, .	3	1	1	2	2	1	2	2	2	2	1	1	1	0	1	1	1	24	7	4	5	7
	6	09JAN96	43, .	4	2	1	2	2	1	3	2	1	2	2	1	1	0	1	0	1	26	8	4	5	9

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00193	7	16JAN96	50, .	4	2	1	2	2	1	3	2	1	2	2	1	1	0	1	0	1	26	8	4	5	9
	8	24JAN96	58, .	4	2	1	2	2	2	3	2	1	2	2	0	1	0	1	0	1	26	7	4	6	9
329.009.00196	SC	11DEC95	-7, .	3	2	3	1	2	2	3	1	0	2	1	1	2	2	2	1	0	28	8	5	5	9
	BL	18DEC95	1, .	3	2	2	2	0	2	3	1	0	1	0	1	2	2	1	1	0	23	5	4	4	9
	1	27DEC95	10, .	2	2	1	1	2	2	3	1	0	2	1	2	2	2	1	1	0	25	8	3	5	8
	2	02JAN96	16, .	2	1	0	1	2	1	3	1	0	1	0	0	2	1	1	0	0	16	4	1	4	7
	3	08JAN96	22, .	3	2	0	0	2	2	3	1	1	2	1	0	1	2	0	0	0	20	4	3	4	9
	4	15JAN96	29, .	2	1	0	0	1	1	3	1	0	2	0	0	1	2	0	0	0	14	3	1	2	8
	5	22JAN96	36, .	1	1	0	0	0	0	3	0	0	2	1	0	1	2	0	0	0	11	4	1	0	6
	6	29JAN96	43, .	2	1	0	1	0	0	2	1	0	1	0	0	1	2	0	0	0	11	2	1	1	7
	7	05FEB96	50, .	2	1	0	0	0	0	2	1	0	0	0	0	1	1	0	0	0	8	1	1	0	6
	8	12FEB96	57, .	1	1	0	0	0	0	2	1	0	2	0	0	1	2	0	0	0	10	3	1	0	6
329.009.00201	SC	31JAN96	-6, .	3	2	1	2	2	2	4	2	0	3	0	0	1	1	0	0	0	23	4	3	6	10
	BL	06FEB96	1, .	3	2	1	2	2	1	3	2	3	2	2	0	1	0	1	0	2	27	8	6	5	8
	1	13FEB96	8, .	3	2	1	2	2	1	3	2	3	2	2	0	1	0	1	0	1	26	7	6	5	8
	2	20FEB96	15, .	1	1	0	0	1	0	2	2	3	2	1	0	0	0	0	0	1	14	4	4	1	5
	3	28FEB96	23, .	1	1	0	2	1	0	2	1	2	1	1	1	0	0	1	0	1	15	5	3	3	4
	4	05MAR96	29, .	0	0	0	2	0	0	0	1	2	0	0	0	0	0	0	0	0	5	0	2	2	1
	5	12MAR96	36, .	0	1	0	2	0	0	0	1	1	0	1	0	0	0	0	0	0	6	1	2	2	1
	6	19MAR96	43, .	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	3	0	0	2	1
	7	26MAR96	50, .	3	2	1	2	1	0	2	1	2	1	0	0	0	0	0	0	1	16	2	5	3	6
	8	02APR96	57, .	0	0	0	2	0	0	0	1	1	0	0	0	0	0	0	0	0	4	0	1	2	1
329.009.00204	SC	13MAR96	-6, -62	3	2	0	2	0	1	3	0	3	3	2	0	1	1	0	0	2	23	8	5	3	7
	BL	19MAR96	1, -56	3	1	1	2	1	0	2	2	3	2	1	0	2	0	0	0	2	22	7	5	3	7
	1	26MAR96	8, -49	3	1	1	2	1	0	2	2	2	1	1	0	2	0	0	0	2	20	6	4	3	7
	2	02APR96	15, -42	1	1	0	1	1	0	2	2	2	1	1	0	2	0	0	0	1	15	5	3	2	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00204	3	09APR96	22, -35	1	1	0	1	1	0	1	1	1	1	1	0	1	0	0	0	2	12	5	2	2	3
	4	16APR96	29, -28	1	0	0	1	0	0	1	1	1	1	1	0	0	0	0	0	2	9	4	1	1	3
	5	23APR96	36, -21	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	3	0	1	0	2
	6	30APR96	43, -14	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	7	07MAY96	50, -7	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	8	14MAY96	57, 1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	12	11JUN96	85, 29	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	16	09JUL96	113, 57	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20	13AUG96	148, 92	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	24	10SEP96	176, 120	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	28	14OCT96	210, 154	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	0	1	0	1
329.009.00235	SC	10DEC96	-8, -62	1	1	0	2	0	0	3	1	1	1	1	0	2	0	0	0	2	15	6	2	2	5
	BL	17DEC96	-1, -55	3	1	1	0	1	0	2	2	1	1	1	0	2	0	1	0	1	17	6	3	1	7
	1	23DEC96	6, -49	3	1	1	0	0	0	2	2	1	1	1	0	2	0	0	0	1	15	5	3	0	7
	2	30DEC96	13, -42	1	0	0	0	0	0	2	1	1	1	0	0	0	0	0	0	0	6	1	1	0	4
	3	06JAN97	20, -35	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0	1	0	5	0	1	0	3
	4	15JAN97	29, -26	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	1	0	4	1	1	0	1
	5	20JAN97	34, -21	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	6	27JAN97	41, -14	0	0	0	0	0	0	0	1	0	0	0	0	2	0	1	0	0	4	3	0	0	1
	7	03FEB97	48, -7	0	0	0	2	0	0	1	1	0	0	0	0	0	0	0	0	0	4	0	0	2	2
	8	10FEB97	55, 1	0	0	0	0	0	0	0	1	0	0	0	0	2	0	0	0	0	3	2	0	0	1
	12	17MAR97	90, 36	1	1	0	0	0	0	1	1	1	0	0	0	2	0	0	0	1	8	3	2	0	3
	16	14APR97	118, 64	3	1	1	1	0	1	3	1	2	1	0	1	0	0	1	1	2	19	5	4	2	7
329.009.00240	SC	03JAN97	-11, .	4	2	3	2	2	0	4	2	0	1	0	1	2	1	0	0	0	24	4	5	4	11
	BL	10JAN97	-4, .	4	1	3	2	1	0	4	2	0	0	0	2	1	1	0	0	1	22	4	4	3	11
	1	21JAN97	8, .	4	0	1	2	2	0	3	2	0	1	0	1	2	1	0	0	0	19	4	1	4	10
	2	28JAN97	15, .	3	1	1	2	0	0	4	2	0	1	0	1	0	0	0	0	1	16	3	2	2	9

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.009.00240	3	04FEB97	22, .	3	1	0	2	0	0	4	1	1	1	0	1	2	0	0	0	0	16	4	2	2	8
	4	11FEB97	29, .	1	0	0	1	0	0	2	1	0	2	0	0	1	0	0	0	0	8	3	0	1	4
	5	18FEB97	36, .	3	1	0	2	1	0	4	2	0	1	1	0	2	1	0	0	1	19	5	1	3	10
	6	25FEB97	43, .	1	1	0	2	0	0	3	1	0	1	0	0	2	0	0	0	1	12	4	1	2	5
	7	04MAR97	50, .	3	1	0	2	0	0	4	1	0	3	0	0	2	1	0	0	1	18	6	1	2	9
329.009.00303	SC	25MAR96	-8, -64	3	2	2	1	2	0	3	2	1	3	3	0	2	0	2	0	0	26	10	5	3	8
	BL	02APR96	1, -56	3	2	1	2	1	1	3	1	1	4	2	0	2	0	3	0	0	26	11	4	4	7
	1	09APR96	8, -49	3	2	1	1	1	0	3	1	1	3	1	0	2	0	2	0	0	21	8	4	2	7
	2	16APR96	15, -42	2	1	0	2	1	0	2	1	1	3	1	0	2	0	2	0	0	18	8	2	3	5
	3	23APR96	22, -35	1	1	0	1	0	0	1	1	1	2	0	0	1	0	0	0	0	9	3	2	1	3
	4	30APR96	29, -28	1	0	0	1	0	0	1	1	0	1	0	0	2	0	1	0	0	8	4	0	1	3
	5	07MAY96	36, -21	1	0	0	0	0	0	1	0	0	1	0	0	1	0	1	0	0	5	3	0	0	2
	6	14MAY96	43, -14	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	7	22MAY96	51, -6	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	8	28MAY96	57, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	25JUN96	85, 29	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	16	30JUL96	120, 64	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20	27AUG96	148, 92	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	24	25SEP96	177, 121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	30OCT96	212, 156	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	32	10DEC96	253, 197	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1	1	0
329.009.00304	SC	03APR96	-6, -62	4	3	1	2	0	0	2	2	1	1	0	1	2	1	0	0	1	21	5	5	2	9
	BL	09APR96	1, -56	4	1	1	2	0	0	2	2	2	2	1	1	1	0	0	1	2	22	7	4	2	8
	1	16APR96	8, -49	4	1	1	2	0	0	2	2	1	2	1	1	1	0	0	1	2	21	7	3	2	8
	2	23APR96	15, -42	4	1	1	0	1	1	3	2	1	2	1	2	2	0	0	1	0	22	7	3	2	9
	3	30APR96	22, -35	3	2	1	0	1	0	2	2	1	1	1	1	1	0	1	0	1	18	6	4	1	7
	4	07MAY96	29, -28	2	2	0	0	0	0	2	2	1	1	1	1	1	0	1	0	1	15	6	3	0	6

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00304	5	14MAY96	36, -21	1	1	0	0	0	0	1	2	1	1	0	0	0	0	0	1	1	9	2	2	0	4
	6	21MAY96	43, -14	1	1	0	0	0	0	2	2	1	1	1	0	2	0	0	0	1	12	5	2	0	5
	7	28MAY96	50, -7	1	1	0	0	0	0	2	2	0	1	0	0	0	0	0	0	1	8	2	1	0	5
	8	04JUN96	57, 1	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0	1	0	4	0	0	0	3
	12	02JUL96	85, 29	0	0	0	0	0	0	0	2	0	1	0	0	0	0	0	0	0	3	1	0	0	2
	16	30JUL96	113, 57	2	1	0	1	0	0	2	1	0	0	0	1	1	0	0	0	0	9	2	1	1	5
	20	27AUG96	141, 85	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	24	23SEP96	168, 112	3	1	1	0	1	0	2	2	1	1	0	0	0	0	0	0	0	12	1	3	1	7
	28	21OCT96	196, 140	3	1	0	0	0	0	1	2	0	0	1	0	0	0	0	0	2	10	3	1	0	6
329.009.00324	SC	21OCT96	-7, .	3	0	3	2	2	2	3	0	2	2	1	1	1	1	0	1	1	25	6	5	6	7
	BL	28OCT96	1, .	3	1	2	2	2	2	3	2	1	3	2	1	2	0	1	1	1	29	10	4	6	8
	1	04NOV96	8, .	3	1	2	1	2	2	3	2	1	3	2	1	2	0	1	1	1	28	10	4	5	8
	2	11NOV96	15, .	1	0	0	2	2	2	2	1	1	1	1	1	1	0	0	0	0	15	4	1	6	4
	3	18NOV96	22, .	1	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	4	1	1	0	2
	4	25NOV96	29, .	0	0	0	0	0	0	0	1	0	0	0	0	2	0	0	1	0	4	2	0	0	1
	5	02DEC96	36, .	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	3	0	1	0	2
	6	09DEC96	43, .	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	7	16DEC96	50, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	8	27DEC96	61, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.009.00328	SC	30SEP96	-7, .	3	2	0	2	2	1	3	0	4	3	1	2	2	1	0	1	1	28	9	6	5	7
	BL	07OCT96	1, .	3	1	1	0	1	1	2	2	2	2	2	1	2	0	1	0	1	22	9	4	2	7
329.009.00329	SC	01OCT96	-8, .	3	1	0	1	0	0	2	2	3	2	0	0	0	1	0	2	2	19	4	4	1	8
	BL	09OCT96	1, .	3	1	0	0	0	0	4	3	0	3	1	1	2	0	1	2	1	22	9	1	0	10
	1	16OCT96	8, .	3	1	0	0	0	0	3	2	1	0	0	1	2	0	0	2	1	16	4	2	0	8
	2	23OCT96	15, .	3	0	0	0	0	0	2	2	1	0	0	1	2	0	0	2	1	14	4	1	0	7
	3	29OCT96	21, .	3	0	0	0	0	0	2	2	0	0	0	0	1	0	0	0	1	9	2	0	0	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.009.00329	4	05NOV96	28, .	3	1	0	0	0	0	3	3	1	0	0	0	1	0	0	1	1	14	2	2	0	9
	5	12NOV96	35, .	3	0	0	0	0	0	2	1	2	0	0	0	1	0	0	0	2	11	3	2	0	6
	6	19NOV96	42, .	3	1	0	0	0	0	2	2	0	1	0	0	1	0	0	0	1	11	3	1	0	7
	7	26NOV96	49, .	4	1	0	0	0	0	3	3	1	1	0	0	2	0	0	0	1	16	4	2	0	10
	8	03DEC96	56, .	3	0	0	0	0	0	3	3	1	2	0	0	2	0	0	0	1	15	5	1	0	9
329.010.00182	SC	05DEC95	-14, .	3	2	2	2	0	0	4	1	3	1	3	2	2	2	3	2	0	32	11	7	2	10
	BL	19DEC95	1, .	4	0	2	2	0	0	4	1	4	1	3	2	2	2	3	0	0	30	11	6	2	11
	3	12JAN96	25, .	2	0	0	1	0	0	2	0	1	1	1	1	1	0	1	1	0	12	5	1	1	4
	4	19JAN96	32, .	1	0	0	0	0	0	1	0	1	1	2	0	1	0	0	0	0	7	4	1	0	2
329.010.00278	SC	02FEB96	-7, -63	4	3	1	2	2	0	3	2	0	3	2	2	2	1	3	2	0	32	12	4	4	10
	BL	09FEB96	1, -56	4	3	1	2	2	0	3	2	0	3	2	1	2	1	2	0	0	28	10	4	4	10
	1	16FEB96	8, -49	2	0	0	2	0	0	3	2	1	2	2	2	2	0	1	0	0	19	9	1	2	7
	2	23FEB96	15, -42	2	0	0	0	0	0	3	0	0	1	1	1	1	0	2	1	0	12	6	0	0	5
	3	01MAR96	22, -35	1	0	0	0	1	0	2	1	1	1	2	1	1	0	0	0	0	11	5	1	1	4
	4	08MAR96	29, -28	3	2	0	1	0	0	2	0	1	4	1	1	2	0	0	0	0	17	8	3	1	5
	5	15MAR96	36, -21	0	0	0	0	0	1	2	0	0	0	1	1	0	0	0	0	0	5	2	0	1	2
	6	22MAR96	43, -14	2	0	1	0	1	2	2	1	1	2	1	0	0	0	0	0	0	13	3	2	3	5
	7	29MAR96	50, -7	1	0	0	2	1	0	2	0	1	0	1	1	0	0	0	0	0	9	2	1	3	3
	8	05APR96	57, 1	1	0	0	2	1	0	0	0	2	0	0	1	0	0	0	0	0	7	1	2	3	1
	12	03MAY96	85, 29	1	0	0	0	0	0	2	2	1	0	2	0	2	0	0	0	0	10	4	1	0	5
	16	31MAY96	113, 57	0	0	0	1	1	0	0	0	2	0	0	0	0	0	0	0	0	4	0	2	2	0
	20	27JUN96	140, 84	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	24	25JUL96	168, 112	3	0	2	2	0	0	1	0	0	1	0	1	0	0	0	0	0	10	2	2	2	4
	28	22AUG96	196, 140	0	0	0	2	0	0	1	0	0	0	0	1	0	0	1	0	0	5	2	0	2	1
	32	19SEP96	224, 168	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
329.010.00280	SC	10MAY96	-7, -62	2	2	1	0	0	0	3	0	3	1	0	0	0	0	0	0	1	13	2	6	0	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.010.00280	BL	17MAY96	1, -55	3	2	0	0	0	0	3	1	0	0	1	0	1	0	2	0	1	14	5	2	0	7
	1	24MAY96	8, -48	3	0	0	1	0	0	2	1	0	0	1	0	0	0	2	0	1	11	4	0	1	6
	2	31MAY96	15, -41	0	0	0	1	0	0	1	2	2	0	0	0	0	0	0	0	2	8	2	2	1	3
	3	07JUN96	22, -34	0	0	0	1	1	0	1	1	2	1	0	0	0	0	0	0	2	9	3	2	2	2
	4	14JUN96	29, -27	0	0	0	2	0	0	3	0	4	0	2	0	0	0	1	0	1	13	4	4	2	3
	5	21JUN96	36, -20	0	0	0	0	0	0	3	0	1	0	0	0	1	0	1	0	1	7	3	1	0	3
	6	27JUN96	42, -14	1	0	0	0	0	0	1	0	1	0	0	0	1	0	1	0	1	6	3	1	0	2
	7	03JUL96	48, -8	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	1	3	1	1	0	1
	8	11JUL96	56, 1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	3	0	1	6	4	1	0	1
	12	21AUG96	97, 42	1	0	0	0	0	0	1	1	1	1	0	0	0	0	3	0	2	10	6	1	0	3
329.011.00283	SC	30JAN96	-9, -66	3	0	0	1	0	0	2	1	1	2	0	1	0	0	0	1	0	12	3	1	1	6
	BL	07FEB96	-1, -58	3	0	0	2	0	0	1	1	1	2	1	0	1	0	1	0	0	13	5	1	2	5
	1	14FEB96	7, -51	2	1	0	0	0	0	1	1	2	2	1	0	1	0	1	0	0	12	5	3	0	4
	2	21FEB96	14, -44	1	1	0	0	0	0	1	0	2	2	0	1	1	0	0	1	0	10	4	3	0	2
	3	29FEB96	22, -36	0	0	0	0	0	0	0	0	2	1	1	0	1	0	0	0	0	5	3	2	0	0
	4	07MAR96	29, -29	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	4	2	2	0	0
	5	15MAR96	37, -21	1	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0	4	1	2	0	1
	6	22MAR96	44, -14	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	1	0	3	0	2	0	0
	7	28MAR96	50, -8	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	04APR96	57, -1	1	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	3	0	1	0	2
329.011.00288	SC	01JUL96	-24, .	2	0	3	1	0	0	1	0	4	1	1	0	1	0	0	0	0	14	3	7	1	3
	BL	18JUL96	-7, .	3	0	0	0	0	0	2	1	4	1	1	1	1	0	0	0	0	14	4	4	0	6
	1	01AUG96	8, .	2	0	1	1	1	0	1	0	2	2	0	1	1	0	0	1	0	13	4	3	2	3
	2	09AUG96	16, .	2	0	0	0	0	0	2	0	2	1	0	1	1	0	0	1	0	10	3	2	0	4
	4	19AUG96	26, .	3	1	0	0	0	0	1	0	4	0	0	1	1	0	0	0	0	11	2	5	0	4
	5	29AUG96	36, .	2	0	0	0	0	0	1	0	2	1	0	1	1	0	0	1	0	9	3	2	0	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.012.00025	SC	17OCT95	-7, .	3	2	1	2	0	1	3	1	0	2	1	1	2	0	1	0	0	20	7	3	3	7
	BL	24OCT95	1, .	4	1	1	1	1	1	3	2	0	1	1	1	2	0	0	0	0	19	5	2	3	9
	1	31OCT95	8, .	3	1	0	2	1	1	3	1	0	0	1	1	1	0	0	0	0	15	3	1	4	7
	2	07NOV95	15, .	3	1	0	2	1	1	3	2	0	0	1	1	1	0	0	0	0	16	3	1	4	8
	3	14NOV95	22, .	4	1	1	1	0	1	3	1	0	0	0	2	1	0	0	0	0	15	3	2	2	8
	4	21NOV95	29, .	0	0	0	0	0	0	1	1	0	0	0	1	2	0	0	0	0	5	3	0	0	2
	5	28NOV95	36, .	3	1	1	0	2	0	2	1	1	0	0	2	1	0	0	0	0	14	3	3	2	6
	6	05DEC95	43, .	4	2	2	2	0	0	2	1	0	0	1	2	2	0	0	1	0	19	5	4	2	7
	7	12DEC95	50, .	4	0	0	2	1	0	3	0	0	1	0	1	1	0	0	0	0	13	3	0	3	7
	8	19DEC95	57, .	3	1	0	2	1	1	3	0	0	1	1	2	2	0	0	0	0	17	6	1	4	6
329.012.00220	SC	04JUN96	-13, -73	4	1	2	2	2	2	2	0	0	3	1	1	1	0	0	0	0	21	6	3	6	6
	BL	14JUN96	-3, -63	4	1	0	2	1	0	3	0	3	3	0	1	2	0	0	0	0	20	6	4	3	7
	1	22JUN96	6, -55	4	2	2	2	2	1	3	0	0	3	0	1	1	0	0	0	0	21	5	4	5	7
	2	28JUN96	12, -49	2	1	0	2	1	0	2	0	1	3	0	0	0	0	1	0	0	13	4	2	3	4
	3	05JUL96	19, -42	2	2	1	2	2	0	1	0	2	0	0	0	1	0	0	0	0	13	1	5	4	3
	4	12JUL96	26, -35	1	2	0	1	1	0	2	0	0	2	0	1	1	0	0	0	0	11	4	2	2	3
	5	19JUL96	33, -28	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	6	29JUL96	43, -18	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	1	0	1
	7	06AUG96	51, -10	1	2	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	6	1	3	0	2
	8	16AUG96	61, 1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	2	0	0
	12	13SEP96	89, 29	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	16	11OCT96	117, 57	0	2	0	2	0	0	1	0	2	4	0	0	0	0	0	0	0	11	4	4	2	1
	20	08NOV96	145, 85	0	1	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	3	0	1	1	1
	24	06DEC96	173, 113	1	2	0	2	1	0	3	0	2	2	0	0	1	0	0	0	1	15	4	4	3	4
329.012.00222	SC	18JUN96	-10, -73	4	2	3	2	2	1	3	0	0	4	0	2	2	0	0	0	0	25	8	5	5	7
	BL	28JUN96	1, -63	4	2	3	2	2	2	3	1	0	4	0	1	2	0	0	0	0	26	7	5	6	8
	1	05JUL96	8, -56	4	1	2	2	2	2	3	1	1	0	0	2	2	0	0	0	0	22	4	4	6	8

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.012.00222	2	12JUL96	15, -49	2	2	2	2	1	0	2	0	0	2	1	2	2	0	0	0	0	18	7	4	3	4
	3	19JUL96	22, -42	1	2	0	2	2	1	0	0	0	1	0	0	0	0	0	0	0	9	1	2	5	1
	4	29JUL96	32, -32	1	1	1	1	1	0	2	0	1	1	0	2	1	0	0	0	0	12	4	3	2	3
	6	06AUG96	40, -24	2	2	0	0	1	2	2	0	0	0	0	2	1	0	0	1	0	13	3	2	3	4
	7	13AUG96	47, -17	2	2	0	2	1	0	0	0	1	1	0	2	2	0	0	0	0	13	5	3	3	2
	8	20AUG96	54, -10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	0
	8	30AUG96	64, 1	0	0	0	0	0	0	0	0	0	1	0	2	0	0	0	0	0	3	3	0	0	0
	12	27SEP96	92, 29	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
329.012.00226	SC	26NOV96	-7, .	4	2	3	2	2	1	3	1	2	1	0	1	2	0	0	1	0	25	4	7	5	8
	BL	03DEC96	1, .	4	0	1	2	1	0	3	1	1	1	1	1	1	0	0	1	0	18	4	2	3	8
	1	10DEC96	8, .	4	0	2	2	1	0	3	1	1	1	1	0	1	0	0	0	0	17	3	3	3	8
	2	20DEC96	18, .	4	1	3	2	2	0	3	0	1	2	0	1	1	0	0	0	0	20	4	5	4	7
329.012.00228	SC	04MAR97	-15, .	3	2	1	1	0	2	2	0	1	2	1	1	1	0	1	1	0	19	6	4	3	5
	BL	19MAR97	1, .	4	2	1	1	2	2	3	0	2	3	0	0	2	0	0	0	0	22	5	5	5	7
	1	27MAR97	9, .	2	2	1	1	0	0	3	0	1	2	1	1	0	0	1	0	1	16	6	4	1	5
329.012.00231	SC	26FEB97	-9, -70	3	2	2	0	0	0	3	0	2	2	1	1	1	0	1	0	0	18	6	6	0	6
	BL	07MAR97	1, -61	3	2	0	0	0	0	3	0	2	2	2	1	2	0	0	1	0	18	7	4	0	6
	1	17MAR97	11, -51	3	1	2	1	0	0	3	0	2	4	0	0	1	0	0	0	0	17	5	5	1	6
	2	24MAR97	18, -44	3	1	0	0	0	1	3	0	2	3	0	2	2	0	0	0	0	17	7	3	1	6
	4	02APR97	27, -35	1	2	0	0	0	0	2	0	2	2	1	0	1	0	0	0	0	11	4	4	0	3
	5	09APR97	34, -28	2	0	0	0	0	0	3	0	2	2	1	1	2	0	0	1	0	14	6	2	0	5
	6	17APR97	42, -20	1	2	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	7	0	4	0	3
	7	25APR97	50, -12	3	2	0	0	0	0	1	0	2	3	2	0	1	1	1	0	0	16	7	4	0	5
	8	01MAY97	56, -6	1	0	0	0	0	0	1	0	1	2	1	0	1	0	1	0	0	8	5	1	0	2
	8	07MAY97	62, 1	2	0	0	0	0	0	1	0	1	1	0	0	1	2	0	0	0	8	2	1	0	5
	12	04JUN97	90, 29	3	0	0	1	0	0	2	1	2	2	2	1	2	0	0	0	0	16	7	2	1	6

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.012.00231	16	30JUN97	116, 55	3	1	0	1	0	0	2	0	1	2	1	0	2	0	1	0	0	14	6	2	1	5
	20	05AUG97	152, 91	1	2	0	1	0	0	2	0	1	1	0	0	0	0	0	0	0	8	1	3	1	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.001.00061	SC	19JUL94	-10,	.	4	3	1	2	0	2	4	3	2	0	3	1	2	0	2	2	1	32	9	6	4	11
	BL	29JUL94	1,	.	1	1	0	2	0	0	4	1	2	1	0	1	0	0	0	0	1	14	3	3	2	6
	1	04AUG94	7,	.	0	2	0	0	0	0	4	2	1	0	1	0	2	0	0	0	2	14	5	3	0	6
	2	11AUG94	14,	.	2	0	0	1	1	0	3	3	0	2	1	0	1	0	0	0	0	14	4	0	2	8
	3	18AUG94	21,	.	0	0	0	0	0	0	3	1	1	2	0	0	1	0	0	0	0	8	3	1	0	4
	4	25AUG94	28,	.	0	0	0	0	1	0	2	0	0	1	0	0	1	0	0	0	0	5	2	0	1	2
	5	01SEP94	35,	.	0	0	0	1	2	0	2	0	0	0	1	0	1	0	0	0	0	7	2	0	3	2
329.001.00066	SC	14NOV94	-8,	.	3	2	1	2	0	0	4	2	2	3	2	0	2	1	0	0	0	24	7	5	2	10
	BL	21NOV94	-1,	.	3	1	0	0	0	0	4	2	1	2	1	0	2	1	0	0	0	17	5	2	0	10
	1	28NOV94	7,	.	2	1	0	0	0	0	4	2	2	2	3	2	1	1	0	1	1	22	9	3	0	9
	2	05DEC94	14,	.	0	0	0	0	0	0	1	1	1	1	0	1	1	1	0	0	0	7	3	1	0	3
329.001.00067	SC	15NOV94	-7,	.	4	2	1	2	1	0	4	2	3	3	1	0	2	0	1	0	0	26	7	6	3	10
	BL	22NOV94	1,	.	3	0	1	2	0	0	4	2	2	0	1	0	1	0	0	0	0	16	2	3	2	9
	1	29NOV94	8,	.	2	0	0	2	0	0	4	2	1	3	0	0	0	0	0	0	1	15	4	1	2	8
	2	06DEC94	15,	.	3	0	0	2	0	0	3	0	3	0	0	0	0	0	0	0	2	13	2	3	2	6
329.001.00070	SC	14FEB95	-8,	.	4	3	2	2	1	1	4	3	1	2	2	0	1	0	0	0	0	26	5	6	4	11
	BL	22FEB95	1,	.	3	1	0	1	0	0	4	3	1	2	3	1	2	0	0	0	0	21	8	2	1	10
	1	28FEB95	7,	.	3	2	0	0	2	0	4	3	3	0	3	1	2	0	0	0	0	23	6	5	2	10
	2	08MAR95	15,	.	1	0	0	1	2	1	3	1	1	0	3	1	1	0	0	0	0	15	5	1	4	5
	3	15MAR95	22,	.	0	0	0	0	0	2	3	1	1	0	3	0	1	0	0	0	0	11	4	1	2	4
329.001.00122	SC	13JUN95	-7,	-64	3	1	2	1	0	0	4	3	2	2	2	0	2	0	0	0	0	22	6	5	1	10
	BL	20JUN95	1,	-57	2	0	0	1	0	0	3	2	0	2	1	0	2	0	0	0	0	13	5	0	1	7
	1	27JUN95	8,	-50	1	0	0	1	0	0	4	1	1	0	0	0	1	0	0	0	2	11	3	1	1	6
	2	05JUL95	16,	-42	0	0	0	0	0	0	3	1	2	1	0	0	1	0	0	0	0	8	2	2	0	4
	3	11JUL95	22,	-36	0	0	0	0	0	0	3	1	2	0	1	0	1	0	0	0	0	8	2	2	0	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.001.00122	4	18JUL95	29, -29	0	0	0	0	0	0	2	2	0	2	0	0	1	0	0	0	0	7	3	0	0	4
	5	25JUL95	36, -22	0	0	0	1	0	0	2	0	2	2	0	0	0	0	0	0	0	7	2	2	1	2
	6	01AUG95	43, -15	0	0	0	0	0	0	2	0	2	2	0	0	0	0	0	0	0	6	2	2	0	2
	7	08AUG95	50, -8	0	0	0	0	0	0	2	0	1	1	0	0	1	0	0	0	0	5	2	1	0	2
	8	16AUG95	58, 1	0	0	0	0	0	0	2	0	1	2	0	0	1	0	0	0	0	6	3	1	0	2
	12	12SEP95	85, 28	0	0	0	1	0	0	2	0	2	1	0	0	1	0	0	0	0	7	2	2	1	2
	16	10OCT95	113, 56	0	0	0	0	0	0	2	0	1	1	0	0	0	0	1	0	0	5	2	1	0	2
	20	07NOV95	141, 84	1	0	0	1	0	0	2	0	2	1	1	0	1	0	0	0	0	9	3	2	1	3
	24	05DEC95	169, 112	1	0	0	1	0	0	3	0	2	0	2	0	1	0	0	0	0	10	3	2	1	4
329.002.00050	SC	10MAR95	-13, .	4	1	0	2	0	0	3	2	0	0	0	1	1	0	0	0	1	15	3	1	2	9
	BL	22MAR95	-1, .	4	0	0	2	0	0	4	2	0	0	0	1	2	1	0	0	1	17	4	0	2	11
	1	29MAR95	7, .	3	0	1	0	0	0	3	2	0	0	0	1	1	0	0	0	0	11	2	1	0	8
	2	05APR95	14, .	4	0	0	0	0	0	3	2	0	1	0	1	1	0	0	0	0	12	3	0	0	9
	3	12APR95	21, .	3	0	0	0	0	0	2	1	0	0	0	1	1	0	0	0	0	8	2	0	0	6
	5	28APR95	37, .	3	0	0	1	0	0	3	2	0	1	0	1	1	0	0	0	1	13	4	0	1	8
329.002.00056	SC	24JUN94	-25, .	3	0	3	0	0	0	3	0	2	2	3	2	1	1	0	2	0	22	8	5	0	7
	BL	19JUL94	1, .	2	0	0	0	0	0	3	2	0	2	2	0	2	0	0	2	0	15	6	0	0	7
	1	26JUL94	8, .	2	1	1	0	0	0	3	0	0	2	1	0	1	0	0	1	0	12	4	2	0	5
	2	02AUG94	15, .	1	0	0	0	0	0	2	0	0	1	2	1	1	0	0	0	0	8	5	0	0	3
	3	09AUG94	22, .	1	0	0	0	0	0	2	0	0	0	0	1	1	0	0	0	0	5	2	0	0	3
	4	16AUG94	29, .	1	0	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	5	2	1	1	1
329.002.00057	SC	11AUG94	-28, -85	4	0	2	2	2	2	3	2	2	1	1	0	1	1	0	0	0	23	3	4	6	10
	BL	08SEP94	1, -57	4	1	2	2	2	2	3	2	2	3	2	0	1	0	0	0	0	26	6	5	6	9
	1	15SEP94	8, -50	4	0	2	0	2	2	2	0	2	3	0	0	2	0	0	0	0	19	5	4	4	6
	2	22SEP94	15, -43	3	0	1	0	0	0	2	1	1	2	0	0	1	0	1	0	1	13	5	2	0	6
	3	29SEP94	22, -36	3	1	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	8	3	2	0	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00057	4	06OCT94	29, -29	3	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	5	1	1	0	3
	5	13OCT94	36, -22	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	6	20OCT94	43, -15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	27OCT94	50, -8	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	03NOV94	57, -1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	01DEC94	85, 28	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	2	0	0	0
	16	29DEC94	113, 56	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	2	5	4	0	0	0
329.002.00098	SC	20DEC94	-14, .	3	1	1	2	2	1	3	2	0	4	0	0	2	0	1	0	0	22	7	2	5	8
	BL	03JAN95	1, .	3	1	1	2	2	1	3	2	0	4	0	0	2	0	1	0	0	22	7	2	5	8
	1	10JAN95	8, .	3	0	0	0	2	0	2	2	0	4	2	1	1	0	1	0	0	18	9	0	2	7
	2	18JAN95	16, .	3	1	0	0	1	0	2	1	0	3	1	1	1	0	1	0	0	15	7	1	1	6
	3	24JAN95	22, .	3	1	0	0	1	0	2	1	0	3	1	1	1	0	1	0	0	15	7	1	1	6
	4	31JAN95	29, .	3	0	1	0	1	0	2	2	0	3	2	0	1	0	0	0	0	15	6	1	1	7
	5	07FEB95	36, .	3	0	0	0	0	0	2	1	0	3	1	0	1	0	0	0	0	11	5	0	0	6
	6	14FEB95	43, .	2	1	0	0	1	1	3	1	3	3	1	1	1	0	1	0	0	19	7	4	2	6
	7	21FEB95	50, .	3	2	1	0	0	2	3	2	1	4	1	1	1	0	1	0	0	22	8	4	2	8
	8	02MAR95	59, .	3	0	1	0	2	0	3	1	1	3	1	0	1	0	0	0	0	16	5	2	2	7
329.002.00100	SC	16FEB95	-19, -77	3	1	2	2	0	1	2	1	1	1	1	1	1	0	0	0	0	17	4	4	3	6
	BL	07MAR95	1, -58	3	1	2	2	0	1	2	1	2	2	1	0	1	0	0	0	0	18	4	5	3	6
	1	14MAR95	8, -51	3	0	0	2	1	0	2	1	1	3	2	0	0	0	0	0	0	15	5	1	3	6
	2	21MAR95	15, -44	2	0	1	0	0	0	1	2	1	3	2	0	2	0	1	0	0	15	8	2	0	5
	3	28MAR95	22, -37	2	0	0	0	1	0	0	1	1	1	2	0	1	0	0	0	0	9	4	1	1	3
	4	04APR95	29, -30	3	0	0	0	0	0	0	1	2	3	1	0	1	0	0	0	0	11	5	2	0	4
	5	11APR95	36, -23	1	0	0	2	0	0	0	0	2	1	2	0	0	0	0	0	0	8	3	2	2	1
	6	18APR95	43, -16	1	0	0	0	0	0	1	0	1	0	2	1	1	0	0	0	0	7	4	1	0	2
	7	25APR95	50, -9	1	0	0	0	0	1	1	0	1	1	2	0	1	0	0	0	0	8	4	1	1	2
	8	04MAY95	59, 1	1	0	0	0	1	0	0	0	0	1	2	1	0	0	0	0	0	6	4	0	1	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.002.00100	12	30MAY95	85, 27	2	0	1	0	0	0	1	0	3	1	0	0	1	0	0	0	0	9	2	4	0	3
	16	27JUN95	113, 55	0	0	0	0	0	2	0	0	2	3	2	0	0	0	0	0	0	9	5	2	2	0
	16	06JUL95	122, 64	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	2	6	5	1	0	0
329.002.00103	SC	11APR95	-9, -65	3	3	0	2	1	2	3	2	3	3	2	0	2	1	0	0	0	27	7	6	5	9
	BL	20APR95	1, -56	3	3	0	2	1	2	3	2	3	3	2	0	2	1	0	0	0	27	7	6	5	9
	1	27APR95	8, -49	3	2	0	0	1	0	1	1	2	4	1	0	1	0	0	0	0	16	6	4	1	5
	2	02MAY95	13, -44	2	1	0	0	0	0	1	1	1	2	1	0	1	0	0	0	0	10	4	2	0	4
	3	09MAY95	20, -37	1	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0	0	4	1	1	1	1
	4	16MAY95	27, -30	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	3	2	0	0	1
	5	25MAY95	36, -21	1	0	0	0	0	0	0	0	1	0	2	0	0	0	0	0	0	4	2	1	0	1
	6	30MAY95	41, -16	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	2	0	0	0
	7	06JUN95	48, -9	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	8	15JUN95	57, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	13JUL95	85, 29	0	0	0	0	0	0	1	0	1	0	1	0	0	0	0	0	0	3	1	1	0	1
	16	10AUG95	113, 57	2	1	0	2	2	1	0	0	1	2	1	0	1	0	0	0	0	13	4	2	5	2
329.002.00104	SC	28APR95	-6, -62	3	0	1	0	1	2	3	2	0	2	2	1	1	0	0	1	0	19	6	1	3	8
	BL	04MAY95	1, -56	1	1	1	0	2	2	3	1	0	3	2	0	2	0	0	0	0	18	7	2	4	5
	1	11MAY95	8, -49	1	0	1	0	1	2	2	2	0	1	2	1	1	0	0	1	0	15	5	1	3	5
	2	18MAY95	15, -42	2	0	1	0	1	2	2	2	0	1	1	1	1	0	0	0	0	14	4	1	3	6
	3	25MAY95	22, -35	3	0	1	1	1	2	3	2	0	3	1	1	1	0	0	0	0	19	6	1	4	8
	4	01JUN95	29, -28	0	0	0	2	0	2	3	1	0	1	1	0	1	0	0	0	0	11	3	0	4	4
	5	09JUN95	37, -20	2	0	1	2	0	0	2	1	0	1	1	0	1	0	0	0	0	11	3	1	2	5
	6	16JUN95	44, -13	1	0	0	2	0	2	2	1	0	1	1	0	1	0	0	0	0	11	3	0	4	4
	7	22JUN95	50, -7	0	0	0	0	1	0	1	1	0	3	1	0	1	0	0	0	0	8	5	0	1	2
	8	29JUN95	57, 1	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	3	1	0	0	2
	12	25JUL95	83, 27	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	1	0	0	0
	16	29AUG95	118, 62	1	0	0	0	0	0	1	1	0	0	0	0	1	0	0	1	0	5	1	0	0	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00104	20	03OCT95	153, 97	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	28	06NOV95	187, 131	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0
	32	06DEC95	217, 161	0	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	3	0	0	2	1
	32	02JAN96	244, 188	0	0	0	0	0	1	1	0	0	0	0	0	1	0	0	1	0	4	1	0	1	1
329.002.00243	SC	27FEB96	-16, .	1	1	1	2	2	1	2	0	1	1	1	0	2	0	0	0	0	15	4	3	5	3
	BL	14MAR96	1, .	2	0	0	2	2	0	3	2	0	1	1	1	2	0	0	2	0	18	5	0	4	7
	1	21MAR96	8, .	1	0	0	0	1	0	1	2	0	2	0	1	2	0	1	1	0	12	6	0	1	4
	2	28MAR96	15, .	4	2	2	2	2	2	3	1	1	3	2	0	2	0	0	1	0	27	7	5	6	8
	3	04APR96	22, .	3	2	1	2	2	1	3	1	0	4	2	0	2	0	1	0	0	24	9	3	5	7
329.002.00244	SC	14MAR96	-7, -64	4	0	2	0	1	1	1	2	0	1	0	0	2	0	0	0	0	14	3	2	2	7
	BL	21MAR96	1, -57	3	1	2	2	2	1	1	2	0	3	0	1	2	0	0	0	0	20	6	3	5	6
	1	28MAR96	8, -50	4	1	2	0	0	0	1	2	0	3	0	1	2	0	0	0	0	16	6	3	0	7
	2	04APR96	15, -43	4	1	2	0	0	0	3	2	0	1	0	1	2	0	0	0	0	16	4	3	0	9
	3	11APR96	22, -36	2	1	1	0	0	0	1	1	0	1	1	0	1	0	0	0	0	9	3	2	0	4
	4	18APR96	29, -29	3	1	0	0	0	0	2	1	0	1	1	0	1	0	0	0	0	10	3	1	0	6
	5	25APR96	36, -22	1	1	1	0	0	1	1	0	1	1	1	0	1	0	0	0	0	9	3	3	1	2
	6	02MAY96	43, -15	3	1	0	0	0	0	2	2	0	2	1	0	1	0	0	0	0	12	4	1	0	7
	7	09MAY96	50, -8	2	1	0	0	0	0	0	0	0	2	1	0	1	0	0	0	0	7	4	1	0	2
	8	16MAY96	57, -1	2	1	0	0	0	1	1	1	0	1	1	0	1	0	0	0	0	9	3	1	1	4
329.002.00321	SC	15MAY96	-8, .	3	0	0	2	2	0	3	2	1	1	1	0	2	0	0	0	0	17	4	1	4	8
	BL	23MAY96	1, .	3	0	0	2	2	0	2	3	0	1	2	0	2	0	1	0	0	18	6	0	4	8
	1	30MAY96	8, .	0	0	0	2	2	0	2	3	1	0	2	0	2	0	0	0	0	14	4	1	4	5
329.002.00322	SC	06JAN97	-3, .	1	0	1	2	1	0	2	0	3	2	1	1	2	0	0	0	0	16	6	4	3	3
	BL	09JAN97	1, .	2	0	1	2	1	0	2	2	0	2	1	1	2	0	0	1	0	17	6	1	3	6
	1	16JAN97	8, .	3	0	0	2	0	0	3	2	0	3	2	1	2	0	0	0	0	18	8	0	2	8

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00322	2	23JAN97	15, .	1	0	0	2	0	0	2	1	0	3	0	1	2	0	0	0	0	12	6	0	2	4
	3	30JAN97	22, .	1	1	0	2	0	0	2	1	0	0	1	0	2	0	0	0	0	10	3	1	2	4
	4	04FEB97	27, .	1	1	0	2	0	0	1	1	0	1	1	1	2	0	0	0	0	11	5	1	2	3
	5	13FEB97	36, .	1	1	0	2	0	0	2	1	0	2	1	0	2	0	0	0	0	12	5	1	2	4
329.003.00073	SC	11JAN95	-8, .	4	2	0	2	2	0	4	2	2	1	1	0	1	1	0	0	0	22	3	4	4	11
	BL	18JAN95	-1, .	3	2	0	2	2	1	3	2	1	3	0	0	2	1	0	0	0	22	5	3	5	9
	1	25JAN95	7, .	3	1	0	2	0	0	3	1	1	3	0	0	2	0	0	0	0	16	5	2	2	7
	2	03FEB95	16, .	2	1	0	2	2	0	3	0	2	1	1	0	1	0	0	0	0	15	3	3	4	5
	3	07FEB95	20, .	1	1	0	2	2	0	3	1	1	3	2	0	1	0	0	0	0	17	6	2	4	5
	4	14FEB95	27, .	1	0	0	2	1	0	3	0	1	2	1	0	1	0	0	0	0	12	4	1	3	4
	5	22FEB95	35, .	3	1	0	2	1	1	2	1	1	1	2	0	2	1	0	0	0	18	5	2	4	7
	6	01MAR95	42, .	3	0	0	2	1	1	2	2	1	0	0	2	2	0	1	0	0	17	5	1	4	7
	7	08MAR95	49, .	3	0	0	2	2	2	4	1	1	1	2	2	2	0	2	1	0	25	9	1	6	8
329.003.00076	SC	24JAN95	-7, -62	4	0	3	1	0	0	3	1	1	2	2	0	2	0	0	0	0	19	6	4	1	8
	BL	31JAN95	1, -55	3	1	3	2	0	0	3	1	1	2	2	0	2	0	1	0	0	21	7	5	2	7
	1	07FEB95	8, -48	3	1	0	0	0	0	3	0	0	2	2	0	1	1	0	0	0	13	5	1	0	7
	2	14FEB95	15, -41	1	1	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	5	1	2	0	2
	3	21FEB95	22, -34	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	4	27FEB95	28, -28	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	5	06MAR95	35, -21	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	6	13MAR95	42, -14	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	7	20MAR95	49, -7	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	8	27MAR95	56, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	03MAY95	93, 38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	31MAY95	121, 66	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20	28JUN95	149, 94	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	02AUG95	184, 129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.003.00076	32	06SEP95	219, 164	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	32	11OCT95	254, 199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00079	SC	14APR95	-19, .	4	0	0	0	0	0	4	2	0	3	1	0	2	1	0	0	0	17	6	0	0	11
	BL	03MAY95	1, .	3	1	1	0	0	0	3	1	1	3	2	1	2	1	0	0	0	19	8	3	0	8
	1	10MAY95	8, .	2	1	0	0	0	0	3	1	1	3	1	0	2	0	0	0	0	14	6	2	0	6
	2	19MAY95	17, .	3	0	0	1	1	2	3	1	1	1	0	0	1	0	0	0	0	14	2	1	4	7
329.003.00082	SC	11DEC95	1, .	2	0	1	0	2	2	3	0	1	2	1	0	2	0	0	0	0	16	5	2	4	5
	2	28DEC95	18, .	2	2	1	0	2	0	2	0	0	2	0	1	2	1	0	0	0	15	5	3	2	5
	3	03JAN96	24, .	3	0	1	0	1	2	3	1	0	0	0	0	2	2	0	0	0	15	2	1	3	9
	4	11JAN96	32, .	2	1	1	0	1	1	2	0	2	1	2	0	2	2	0	0	0	17	5	4	2	6
	5	17JAN96	38, .	2	0	1	0	1	2	2	1	0	1	1	0	1	2	0	0	0	14	3	1	3	7
329.003.00088	SC	06FEB95	-22, .	3	2	2	0	0	0	2	1	2	0	0	0	0	0	0	0	0	12	0	6	0	6
	BL	28FEB95	1, .	3	2	2	0	0	0	2	1	2	0	0	0	0	0	0	0	0	12	0	6	0	6
	1	09MAR95	10, .	3	1	0	0	0	0	3	2	2	3	0	0	1	0	0	1	0	16	4	3	0	8
	2	14MAR95	15, .	3	2	0	0	0	0	2	2	2	0	1	0	0	0	0	0	0	12	1	4	0	7
	3	21MAR95	22, .	2	1	0	0	1	0	3	0	2	2	1	0	0	0	0	0	0	12	3	3	1	5
	4	30MAR95	31, .	2	0	0	0	2	2	3	1	2	1	1	0	2	0	0	0	0	16	4	2	4	6
	5	04APR95	36, .	3	2	2	0	0	0	3	0	3	3	0	0	2	0	0	0	0	18	5	7	0	6
	6	11APR95	43, .	3	0	3	0	0	0	3	2	2	3	0	0	2	0	0	0	0	18	5	5	0	8
329.003.00090	SC	08MAR95	-6, .	3	2	0	0	0	0	3	2	2	2	0	0	0	0	0	0	0	14	2	4	0	8
	BL	14MAR95	1, .	3	3	0	2	1	0	3	1	2	0	0	0	1	0	0	0	0	16	1	5	3	7
	2	28MAR95	15, .	2	1	0	0	0	2	3	1	2	2	0	0	0	1	0	0	0	14	2	3	2	7
	3	04APR95	22, .	2	1	2	0	2	2	3	1	1	2	0	0	2	0	0	0	0	18	4	4	4	6
	4	11APR95	29, .	1	0	0	0	2	2	1	0	0	2	0	0	0	0	0	0	0	8	2	0	4	2
	5	18APR95	36, .	3	1	1	0	2	2	2	2	2	2	0	0	2	0	0	0	0	19	4	4	4	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00090	6	25APR95	43, .	1	2	0	2	2	2	2	0	1	2	1	0	0	0	0	0	0	15	3	3	6	3
	7	02MAY95	50, .	3	2	1	2	2	2	3	1	2	3	0	0	1	0	0	1	0	23	4	5	6	7
	8	09MAY95	57, .	1	0	0	2	2	2	1	1	1	1	0	2	1	0	0	0	0	14	4	1	6	3
	8	16MAY95	64, .	3	1	1	2	2	2	3	1	1	3	2	0	2	0	0	0	0	23	7	3	6	7
329.003.00092	SC	13APR95	-20, -78	3	1	0	1	0	0	2	0	0	2	2	0	1	0	1	0	0	13	6	1	1	5
	BL	02MAY95	-1, -59	3	0	0	2	1	1	2	0	3	0	0	0	2	0	0	0	0	14	2	3	4	5
	1	11MAY95	9, -50	0	0	0	0	0	0	1	0	2	0	0	0	2	0	0	0	0	5	2	2	0	1
	2	16MAY95	14, -45	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	3	26MAY95	24, -35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	02JUN95	31, -28	0	0	0	1	0	0	0	0	1	0	0	1	1	0	0	0	0	4	2	1	1	0
	5	06JUN95	35, -24	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	6	13JUN95	42, -17	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	1	1	0	0
	7	20JUN95	49, -10	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	30JUN95	59, 1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	12	08AUG95	98, 40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	16	05SEP95	126, 68	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	20	26SEP95	147, 89	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	4	0	1	0	3
	28	07NOV95	189, 131	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	1	0	4	2	0	0	1
	32	05DEC95	217, 159	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0
	32	02JAN96	245, 187	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0
329.003.00093	SC	08JUN95	-13, -76	2	2	2	1	1	0	2	1	1	1	0	1	2	0	1	0	0	17	5	5	2	5
	BL	20JUN95	-1, -64	3	0	2	2	0	0	3	1	1	2	2	0	2	0	0	0	0	18	6	3	2	7
	1	27JUN95	7, -57	3	0	2	2	0	0	3	1	1	1	0	1	1	0	0	1	0	16	3	3	2	7
	2	06JUL95	16, -48	3	0	0	2	0	0	2	2	1	2	0	1	2	0	0	0	0	15	5	1	2	7
	4	21JUL95	31, -33	2	0	2	2	0	0	2	1	2	2	0	0	2	0	0	0	0	15	4	4	2	5
	5	25JUL95	35, -29	2	0	1	2	0	0	2	0	1	2	1	0	2	0	0	0	0	13	5	2	2	4
	6	01AUG95	42, -22	1	0	1	2	1	0	1	0	0	0	0	0	2	0	0	0	0	8	2	1	3	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.003.00093	7	10AUG95	51, -13	1	0	1	1	0	0	1	0	0	0	0	0	2	0	0	0	0	6	2	1	1	2
	8	22AUG95	63, -1	1	0	0	1	0	0	1	0	0	0	0	0	1	0	0	0	0	4	1	0	1	2
	16	03OCT95	105, 42	0	0	0	0	0	0	1	0	0	0	0	0	2	0	0	0	2	5	4	0	0	1
329.003.00247	BL	30JAN96	-2, -56	1	2	1	2	0	0	3	1	2	2	0	1	2	1	0	0	0	18	5	5	2	6
	1	06FEB96	6, -49	2	1	0	2	2	0	2	1	2	2	0	1	2	1	0	0	0	18	5	3	4	6
	2	13FEB96	13, -42	1	0	0	0	0	0	1	0	2	0	0	0	2	0	0	0	0	6	2	2	0	2
	3	20FEB96	20, -35	1	0	0	0	0	0	1	0	2	0	1	0	1	0	0	0	0	6	2	2	0	2
	4	27FEB96	27, -28	0	0	0	0	0	1	1	0	1	0	0	0	1	0	0	1	0	5	1	1	1	1
	5	07MAR96	36, -19	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	3	1	1	0	1
	6	12MAR96	41, -14	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	1	1	0	0
	7	21MAR96	50, -5	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	26MAR96	55, 1	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	2	1	1	0	0
	12	30APR96	90, 36	0	0	0	0	0	0	0	1	0	0	0	.	0	0	0	0	0	1	0	0	0	1
	16	21MAY96	111, 57	0	0	0	0	0	0	1	0	1	0	0	0	2	0	0	0	0	4	2	1	0	1
329.003.00249	SC	01MAR96	-6, .	3	2	3	0	0	0	4	1	0	3	3	0	1	0	2	0	0	22	9	5	0	8
	BL	07MAR96	1, .	3	2	2	0	0	0	4	2	0	2	0	0	1	0	0	0	0	16	3	4	0	9
	1	12MAR96	6, .	2	1	2	1	0	0	3	1	1	3	0	0	2	0	0	0	0	16	5	4	1	6
	2	19MAR96	13, .	2	2	0	1	0	0	3	2	0	2	0	0	1	0	0	0	0	13	3	2	1	7
	3	26MAR96	20, .	2	1	0	1	1	2	3	1	1	3	0	0	2	0	0	0	0	17	5	2	4	6
	4	02APR96	27, .	1	1	0	1	0	0	2	1	0	2	0	0	2	0	0	0	0	10	4	1	1	4
	5	09APR96	34, .	3	2	2	0	2	0	1	0	1	2	0	0	0	0	0	0	0	13	2	5	2	4
	6	16APR96	41, .	3	2	0	0	0	0	3	1	2	3	0	0	2	0	0	0	0	16	5	4	0	7
	7	23APR96	48, .	3	2	3	2	0	0	3	1	1	3	0	1	2	0	0	1	0	22	6	6	2	7
	8	30APR96	55, .	3	1	2	0	0	0	3	1	1	3	1	0	2	0	0	0	0	17	6	4	0	7
329.003.00289	SC	12FEB96	-16, -72	3	2	0	1	0	0	4	0	0	3	2	0	2	0	0	0	0	17	7	2	1	7
	BL	28FEB96	1, -56	3	2	0	2	2	0	2	0	0	2	0	0	1	0	0	1	1	16	4	2	4	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00289	1	06MAR96	8, -49	2	0	0	0	1	2	2	2	0	2	0	0	0	0	0	0	0	11	2	0	3	6
	2	13MAR96	15, -42	1	1	0	0	0	1	2	1	0	1	0	0	0	1	0	0	0	8	1	1	1	5
	3	20MAR96	22, -35	1	0	0	0	0	0	1	0	0	2	0	0	0	1	0	0	0	5	2	0	0	3
	4	27MAR96	29, -28	1	1	0	0	0	0	4	0	0	3	0	0	0	0	0	0	0	9	3	1	0	5
	5	03APR96	36, -21	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	6	10APR96	43, -14	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	7	17APR96	50, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	24APR96	57, 1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	12	22MAY96	85, 29	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	20	19JUL96	143, 87	0	0	0	0	1	0	0	0	1	1	0	0	0	0	0	1	0	4	1	1	1	0
	24	16AUG96	171, 115	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	13SEP96	199, 143	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	32	11OCT96	227, 171	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00290	BL	11MAR96	1, .	4	0	1	2	0	0	3	3	0	0	0	0	0	1	0	1	0	15	0	1	2	11
	1	20MAR96	10, .	3	0	2	2	0	0	3	2	0	1	4	1	0	1	0	0	0	19	6	2	2	9
329.003.00314	SC	15OCT96	-7, .	3	2	2	0	0	0	2	0	2	2	0	0	1	0	0	0	0	14	3	6	0	5
	BL	22OCT96	1, .	3	2	2	0	2	0	2	0	2	2	0	0	2	0	0	0	0	17	4	6	2	5
	1	29OCT96	8, .	1	1	0	1	0	0	2	0	2	2	0	0	2	0	0	0	0	11	4	3	1	3
	2	05NOV96	15, .	2	2	2	0	0	0	3	0	2	2	0	1	2	0	0	0	0	16	5	6	0	5
	5	26NOV96	36, .	2	1	0	0	0	0	1	0	3	1	0	0	0	0	0	0	0	8	1	4	0	3
	6	03DEC96	43, .	1	1	0	0	1	0	0	0	1	0	0	0	1	0	0	0	0	5	1	2	1	1
	7	10DEC96	50, .	1	0	0	1	0	0	1	0	1	2	0	0	1	0	0	0	0	7	3	1	1	2
	8	17DEC96	57, .	2	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	5	0	2	0	3
	8	23DEC96	63, .	2	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	4	1	0	0	3
329.003.00317	BL	17DEC96	-2, .	3	2	2	2	2	0	0	1	0	3	2	1	2	0	0	0	0	20	8	4	4	4
	1	23DEC96	5, .	2	2	0	2	2	1	1	2	3	2	2	1	1	0	0	1	0	22	6	5	5	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.003.00317	3	07JAN97	20, .	1	0	0	1	0	1	2	0	0	1	0	0	1	0	0	0	0	7	2	0	2	3
	4	14JAN97	27, .	2	0	0	0	1	1	1	0	0	2	1	0	2	0	0	0	0	10	5	0	2	3
	5	21JAN97	34, .	2	0	0	2	1	0	2	0	1	2	1	0	2	0	0	0	0	13	5	1	3	4
	6	28JAN97	41, .	3	1	0	2	2	0	1	1	1	2	1	0	2	0	0	0	0	16	5	2	4	5
	7	04FEB97	48, .	2	1	0	1	0	1	2	2	1	3	2	0	2	0	0	0	0	17	7	2	2	6
	8	11FEB97	55, .	2	1	1	2	1	2	1	1	1	3	2	2	2	0	0	0	0	21	9	3	5	4
329.004.00013	SC	05JUL94	-14, -73	2	2	1	1	0	0	2	1	1	2	2	0	1	0	2	2	0	19	7	4	1	5
	BL	19JUL94	1, -59	1	0	0	1	0	0	2	1	1	2	1	1	1	0	0	2	0	13	5	1	1	4
	1	26JUL94	8, -52	1	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0	0	6	2	1	0	3
	2	02AUG94	15, -45	1	1	0	0	0	0	1	1	0	0	0	0	0	0	1	0	0	5	1	1	0	3
	3	09AUG94	22, -38	1	0	0	0	1	0	1	0	0	0	0	0	1	0	0	0	0	4	1	0	1	2
	4	15AUG94	28, -32	0	1	0	0	0	1	0	0	1	0	0	0	1	0	0	0	0	4	1	2	1	0
	5	23AUG94	36, -24	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	2	1	1	0	0
	6	31AUG94	44, -16	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	7	08SEP94	52, -8	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	2	1	0	0	0
	8	16SEP94	60, 1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0
	12	11OCT94	85, 26	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	16	08NOV94	113, 54	1	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	4	2	1	0	1
	20	06DEC94	141, 82	1	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	3	2	0	0	1
	24	10JAN95	176, 117	0	0	0	0	0	0	0	0	1	0	1	0	1	0	0	0	0	3	2	1	0	0
	28	07FEB95	204, 145	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	32	10MAR95	235, 176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.004.00014	SC	22NOV94	-7, .	3	1	0	2	1	0	4	0	1	2	1	0	2	0	2	0	0	19	7	2	3	7
	BL	29NOV94	1, .	3	1	0	2	1	0	4	0	2	2	2	0	2	0	1	0	0	20	7	3	3	7
	1	05DEC94	7, .	3	1	0	2	1	0	4	0	1	1	1	0	2	0	2	0	0	18	6	2	3	7
	2	13DEC94	15, .	3	0	0	2	0	0	2	1	2	2	2	0	2	0	2	0	0	18	8	2	2	6

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.004.00211	SC	24JAN96	-9,	.	3	1	0	1	0	1	2	0	1	2	1	1	2	0	0	0	0	15	6	2	2	5
	BL	01FEB96	-1,	.	3	2	1	0	0	1	2	0	2	3	2	1	2	0	0	0	0	19	8	5	1	5
	1	08FEB96	7,	.	3	1	0	0	0	0	1	0	2	2	1	1	1	0	0	1	0	13	5	3	0	4
	2	16FEB96	15,	.	3	0	0	0	0	1	1	0	2	1	1	1	0	0	0	0	0	10	3	2	1	4
	3	23FEB96	22,	.	3	0	0	1	0	1	1	0	2	2	1	1	2	0	0	1	0	15	6	2	2	4
	4	29FEB96	28,	.	0	0	0	0	0	0	0	0	2	2	1	0	1	0	0	0	0	6	4	2	0	0
	5	07MAR96	35,	.	0	0	0	0	0	0	0	0	2	1	0	0	1	0	0	0	0	4	2	2	0	0
	6	14MAR96	42,	.	0	0	0	0	1	0	0	0	2	1	1	0	1	0	0	0	0	6	3	2	1	0
	7	25MAR96	53,	.	0	0	0	0	0	0	0	0	2	0	0	2	0	0	0	1	0	5	2	2	0	0
329.004.00215	SC	12MAR97	-8,	.	3	1	2	0	0	0	3	2	1	2	0	0	2	2	1	0	1	20	6	4	0	10
	BL	20MAR97	1,	.	3	0	0	0	1	1	3	2	1	2	0	0	2	2	1	0	1	19	6	1	2	10
	1	27MAR97	8,	.	2	1	1	0	1	1	2	2	0	1	0	0	2	2	1	0	1	17	5	2	2	8
	2	03APR97	15,	.	1	0	0	0	0	0	1	0	0	1	0	0	2	2	1	0	1	9	5	0	0	4
	3	10APR97	22,	.	0	0	0	0	0	0	1	0	0	0	0	0	2	1	0	0	1	5	3	0	0	2
	4	15APR97	27,	.	0	0	0	0	0	1	1	0	1	0	0	0	2	1	0	0	1	7	3	1	1	2
	5	24APR97	36,	.	0	0	0	0	0	0	1	0	0	1	0	0	2	0	0	0	1	5	4	0	0	1
	6	29APR97	41,	.	1	1	0	0	2	2	1	0	1	1	0	1	0	2	0	1	1	14	3	2	4	4
329.005.00003	SC	12SEP94	-8,	.	2	1	0	1	0	0	3	1	0	2	1	1	2	0	0	0	0	14	6	1	1	6
	BL	20SEP94	1,	.	2	2	0	0	0	0	3	2	0	2	2	1	2	0	0	0	0	16	7	2	0	7
	1	27SEP94	8,	.	0	1	0	1	0	0	1	1	0	0	1	0	1	0	0	0	0	6	2	1	1	2
	2	04OCT94	15,	.	2	1	0	0	0	0	2	0	0	1	2	0	0	0	1	1	0	10	4	1	0	4
329.005.00006	SC	27OCT94	-8,	-68	3	2	1	0	0	0	0	2	0	2	0	0	0	0	0	1	1	12	3	3	0	5
	BL	03NOV94	-1,	-61	3	1	1	0	0	0	1	2	2	1	0	1	0	0	0	1	0	13	2	4	0	6
	1	14NOV94	11,	-50	3	1	2	0	0	0	2	2	2	1	0	1	0	0	0	1	0	15	2	5	0	7
	2	21NOV94	18,	-43	3	1	2	0	0	0	1	1	1	1	0	1	0	0	0	0	0	11	2	4	0	5
	3	28NOV94	25,	-36	2	1	2	0	1	0	0	1	1	1	0	0	0	0	0	1	0	10	1	4	1	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00006	4	05DEC94	32, -29	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	5	12DEC94	39, -22	1	2	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	5	0	4	0	1
	6	19DEC94	46, -15	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	27DEC94	54, -7	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	03JAN95	61, 1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	12	02FEB95	91, 31	0	1	2	0	1	1	0	0	2	0	1	0	0	0	0	0	0	8	1	5	2	0
	16	27FEB95	116, 56	0	0	1	0	2	2	0	0	3	1	0	0	0	0	0	0	0	9	1	4	4	0
	20	05APR95	153, 93	0	2	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	6	2	4	0	0
329.005.00007	SC	02NOV94	-7, -70	3	0	3	0	0	0	3	2	2	1	0	0	1	0	0	0	0	15	2	5	0	8
	BL	09NOV94	1, -63	3	0	1	2	0	2	3	1	1	1	0	0	1	0	0	0	0	15	2	2	4	7
	2	23NOV94	15, -49	2	0	2	2	1	2	3	1	2	1	1	1	0	0	0	2	0	20	3	4	5	6
	3	30NOV94	22, -42	2	0	2	2	1	1	2	0	2	1	0	1	0	0	0	0	0	14	2	4	4	4
	4	07DEC94	29, -35	2	0	2	2	2	2	2	1	2	1	0	1	0	0	0	1	0	18	2	4	6	5
	5	14DEC94	36, -28	2	0	1	2	1	2	1	0	2	1	0	0	0	0	0	0	0	12	1	3	5	3
	6	21DEC94	43, -21	2	0	0	2	0	2	1	1	1	1	0	0	0	0	0	0	0	10	1	1	4	4
	7	28DEC94	50, -14	0	0	0	0	2	2	1	0	3	1	0	0	0	0	0	0	0	9	1	3	4	1
	8	04JAN95	57, -7	1	0	0	0	1	2	1	1	2	0	0	0	0	0	0	0	0	8	0	2	3	3
	8	11JAN95	64, 1	1	0	0	0	1	1	1	1	1	0	0	0	0	0	0	0	0	6	0	1	2	3
	12	15FEB95	99, 36	1	0	0	0	0	2	1	1	1	1	0	0	2	0	0	0	0	9	3	1	2	3
	20	22MAR95	134, 71	0	0	0	0	2	1	0	0	1	1	0	0	2	0	0	0	0	7	3	1	3	0
	24	19APR95	162, 99	1	0	2	0	0	0	0	0	1	0	0	0	2	0	0	0	0	6	2	3	0	1
	28	17MAY95	190, 127	1	0	0	0	1	1	1	0	0	0	0	0	2	0	0	0	0	6	2	0	2	2
	32	09AUG95	274, 211	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00009	SC	07DEC94	-5, .	3	2	3	2	2	0	2	2	2	3	2	1	1	0	0	0	0	25	7	7	4	7
	BL	12DEC94	1, .	3	0	2	2	2	1	3	2	3	1	0	1	1	0	0	1	0	22	3	5	5	8
	1	19DEC94	8, .	2	0	0	2	0	2	2	1	2	1	0	1	2	0	0	0	0	15	4	2	4	5
	2	27DEC94	16, .	2	0	1	2	1	0	2	1	1	1	0	1	0	0	0	0	0	12	2	2	3	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00009	3	03JAN95	23,	.	3	0	2	2	2	2	2	1	1	3	0	0	2	0	0	0	0	20	5	3	6	6
	4	11JAN95	31,	.	3	0	2	2	2	1	2	2	2	1	0	1	0	0	0	0	0	18	2	4	5	7
	5	18JAN95	38,	.	2	0	1	2	1	2	1	1	1	2	1	0	1	0	0	0	0	15	4	2	5	4
	6	25JAN95	45,	.	3	0	2	2	1	1	1	1	2	1	0	1	1	1	0	1	0	18	3	4	4	6
	7	31JAN95	51,	.	3	0	3	2	2	2	2	1	1	2	0	0	1	0	0	0	0	19	3	4	6	6
	8	07FEB95	58,	.	1	0	2	2	2	2	1	1	2	1	0	0	2	0	0	0	0	16	3	4	6	3
329.005.00110	SC	04JAN95	-7,	.	3	2	2	2	1	2	2	0	2	1	0	1	1	0	0	0	0	19	3	6	5	5
	BL	11JAN95	1,	.	3	1	2	0	1	1	2	1	2	1	0	1	1	1	0	0	0	17	3	5	2	7
	1	18JAN95	8,	.	1	0	0	0	0	2	2	1	1	2	0	0	1	1	0	0	0	11	3	1	2	5
	2	25JAN95	15,	.	2	1	0	1	1	0	1	1	1	1	0	0	0	0	0	0	0	9	1	2	2	4
329.005.00113	SC	20JAN95	-10,	.	3	0	2	2	2	2	2	1	3	1	0	1	1	0	0	1	0	21	3	5	6	6
	BL	30JAN95	1,	.	2	0	2	2	2	2	2	2	1	1	0	1	2	2	3	2	0	26	7	3	6	8
	1	08FEB95	10,	.	1	0	1	1	1	1	3	1	1	4	1	1	2	1	3	1	0	23	11	2	3	6
	2	16FEB95	18,	.	1	0	0	0	2	2	2	1	3	3	1	1	1	0	2	2	0	21	8	3	4	4
	3	23FEB95	25,	.	1	0	1	2	0	2	2	0	2	2	1	0	0	0	2	1	0	16	5	3	4	3
	4	02MAR95	32,	.	3	2	3	1	1	1	3	1	3	1	0	2	2	0	2	0	0	25	7	8	3	7
329.005.00117	SC	06MAR95	-12,	.	3	2	0	2	0	0	2	1	0	1	1	0	1	1	1	0	0	15	4	2	2	7
	BL	16MAR95	-2,	.	3	1	1	2	2	2	2	1	2	2	2	0	2	1	1	0	0	24	7	4	6	7
	1	27MAR95	10,	.	2	0	0	1	1	0	0	1	0	0	2	0	0	1	1	0	0	9	3	0	2	4
	2	03APR95	17,	.	1	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	5	3	1	0	1
	3	10APR95	24,	.	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	2	0	0	0
	4	17APR95	31,	.	1	0	1	0	0	0	2	0	0	0	0	0	0	0	1	0	1	6	2	1	0	3
	5	24APR95	38,	.	0	0	0	0	0	0	0	0	0	1	3	1	0	0	1	0	0	6	6	0	0	0
	6	01MAY95	45,	.	2	0	0	0	0	0	0	0	0	0	3	2	2	0	3	0	0	12	10	0	0	2
	7	08MAY95	52,	.	0	0	0	0	1	0	0	0	0	1	3	0	2	0	2	0	0	9	8	0	1	0
	8	15MAY95	59,	.	1	0	0	0	0	0	0	1	0	0	2	2	1	0	1	1	0	9	6	0	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.005.00118	SC	09MAY95	-8, .	2	2	2	2	0	0	2	2	0	1	0	0	0	0	0	0	0	13	1	4	2	6
	BL	17MAY95	1, .	3	1	2	2	0	0	3	2	0	1	0	0	1	0	0	0	1	16	3	3	2	8
	1	24MAY95	8, .	3	0	3	2	1	1	2	1	2	3	1	1	2	0	0	0	0	22	7	5	4	6
	2	30MAY95	14, .	3	0	2	2	0	0	2	1	0	0	2	0	0	0	0	0	0	12	2	2	2	6
	3	06JUN95	21, .	3	0	2	1	0	0	1	1	0	0	0	0	1	0	0	0	0	9	1	2	1	5
	4	14JUN95	29, .	2	0	0	1	0	0	1	1	0	1	1	0	1	0	0	0	0	8	3	0	1	4
	5	20JUN95	35, .	1	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0	5	2	0	0	3
	6	27JUN95	42, .	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	3	0	0	0	3
329.005.00153	SC	11JAN96	-14, -70	3	0	0	0	0	2	3	0	1	1	0	1	1	1	0	1	0	14	3	1	2	7
	BL	25JAN96	1, -56	3	1	0	0	0	2	3	0	1	1	2	0	0	1	0	0	0	14	3	2	2	7
	1	01FEB96	8, -49	3	1	0	1	0	1	3	0	1	0	0	1	1	1	0	1	0	14	2	2	2	7
	2	08FEB96	15, -42	2	0	0	2	2	1	3	0	1	1	1	1	1	0	0	0	0	15	4	1	5	5
	3	15FEB96	22, -35	3	0	0	0	0	0	2	0	1	2	1	1	1	1	0	0	0	12	5	1	0	6
	4	22FEB96	29, -28	3	0	0	0	2	0	2	0	1	2	1	0	1	1	0	0	0	13	4	1	2	6
	5	29FEB96	36, -21	2	0	0	1	1	0	2	0	1	1	0	0	0	0	0	0	0	8	1	1	2	4
	6	06MAR96	42, -15	1	0	0	0	1	0	1	0	1	1	0	0	1	0	0	0	0	6	2	1	1	2
	7	14MAR96	50, -7	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	3	0	2	0	1
	8	21MAR96	57, 1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	12	17APR96	84, 28	3	1	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	7	3	1	0	3
	16	15MAY96	112, 56	1	0	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0	4	2	0	0	2
	20	12JUN96	140, 84	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	24	10JUL96	168, 112	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	28	05AUG96	194, 138	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	3	0	1	0	1
	32	04SEP96	224, 168	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
329.005.00255	SC	26FEB96	-7, .	3	1	1	2	0	0	2	1	0	1	0	0	0	0	0	1	0	12	1	2	2	6
	BL	04MAR96	1, .	3	2	0	1	0	0	0	0	2	1	2	0	2	0	0	1	0	14	5	4	1	3
	1	11MAR96	8, .	1	1	1	0	0	0	2	1	0	1	2	0	2	0	0	0	0	11	5	2	0	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.005.00255	2	18MAR96	15, .	2	1	0	0	1	0	3	0	0	1	2	0	2	0	0	1	0	13	5	1	1	5
	3	25MAR96	22, .	1	2	0	0	1	0	2	1	0	1	0	0	1	0	0	0	0	9	2	2	1	4
	4	01APR96	29, .	2	2	0	0	0	0	2	0	0	1	0	0	2	0	0	0	0	9	3	2	0	4
	5	08APR96	36, .	1	2	0	0	0	0	2	0	0	0	0	0	1	0	0	0	0	6	1	2	0	3
	6	15APR96	43, .	2	1	0	0	0	2	1	0	0	0	0	1	0	0	0	1	0	8	1	1	2	3
	7	23APR96	51, .	0	1	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	3	0	1	0	2
	8	29APR96	57, .	3	1	0	0	1	0	2	0	0	1	2	0	0	0	0	1	0	11	3	1	1	5
329.005.00256	SC	20FEB96	-14, -70	1	0	0	2	0	0	0	0	3	1	2	1	0	0	0	2	1	13	5	3	2	1
	BL	05MAR96	1, -56	1	0	0	2	0	0	0	0	3	1	2	1	0	0	0	2	1	13	5	3	2	1
	1	12MAR96	8, -49	1	0	0	2	1	0	2	0	0	1	2	1	1	0	0	0	0	11	5	0	3	3
	2	21MAR96	17, -40	1	0	0	2	1	1	1	1	2	1	0	0	1	0	0	0	0	11	2	2	4	3
	3	26MAR96	22, -35	1	0	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0	5	3	0	0	2
	4	02APR96	29, -28	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1
	5	11APR96	38, -19	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	6	16APR96	43, -14	1	0	0	1	0	0	2	0	0	0	0	0	0	0	0	0	0	4	0	0	1	3
	7	23APR96	50, -7	2	0	0	2	0	0	2	0	0	1	0	0	0	0	0	0	0	7	1	0	2	4
	8	30APR96	57, 1	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	3	1	0	0	2
	12	28MAY96	85, 29	1	0	0	2	0	0	1	0	0	0	0	0	0	0	0	0	0	4	0	0	2	2
	16	02JUL96	120, 64	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	2	0	0	0	1
329.005.00295	SC	21MAR96	-7, .	3	1	3	0	0	0	3	2	2	1	0	0	1	1	0	0	0	17	2	6	0	9
	BL	28MAR96	1, .	2	2	0	0	0	0	2	1	2	1	0	1	1	0	0	0	0	12	3	4	0	5
	1	04APR96	8, .	2	0	0	1	0	1	0	0	0	1	0	1	2	0	0	1	0	9	4	0	2	2
	2	11APR96	15, .	2	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	5	1	1	0	3
	3	18APR96	22, .	1	0	0	0	1	0	0	0	1	1	0	0	2	0	0	1	0	7	3	1	1	1
	4	24APR96	28, .	1	0	2	0	0	0	1	0	1	1	0	0	0	0	0	0	0	6	1	3	0	2
	6	06MAY96	40, .	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0
	6	09MAY96	43, .	2	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	4	1	1	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00295	7	16MAY96	50,	.	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	22MAY96	56,	.	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	3	1	0	0	1
329.005.00297	SC	28MAR96	-22,	.	2	0	0	2	0	0	1	1	3	1	0	2	1	0	0	0	0	13	4	3	2	4
	BL	19APR96	1,	.	3	0	0	2	0	0	2	1	3	1	0	2	2	1	0	2	0	19	5	3	2	7
	1	26APR96	8,	.	2	0	0	0	0	0	2	0	3	1	0	2	1	0	0	0	0	11	4	3	0	4
	2	02MAY96	14,	.	0	0	0	0	0	0	2	0	3	0	0	1	0	0	0	0	0	6	1	3	0	2
	4	14MAY96	26,	.	1	0	0	0	0	0	2	0	1	1	0	0	1	0	0	0	0	6	2	1	0	3
329.005.00332	SC	05DEC96	-7,	.	3	1	1	0	0	0	2	2	1	1	0	1	1	0	0	0	0	13	3	3	0	7
	BL	12DEC96	1,	.	3	1	1	0	0	0	2	2	1	1	0	1	1	0	0	0	0	13	3	3	0	7
	1	19DEC96	8,	.	2	0	0	0	0	0	1	2	2	1	0	1	1	0	0	0	0	10	3	2	0	5
	2	26DEC96	15,	.	3	0	0	0	0	0	0	2	2	1	0	1	0	0	0	0	0	9	2	2	0	5
	3	02JAN97	22,	.	1	0	0	0	0	0	1	2	2	2	0	1	0	0	0	1	0	10	3	2	0	4
	4	09JAN97	29,	.	3	0	0	0	0	0	2	2	2	1	0	1	0	0	0	0	0	11	2	2	0	7
	5	16JAN97	36,	.	3	0	0	0	0	0	2	2	2	1	0	1	0	0	0	0	0	11	2	2	0	7
	6	23JAN97	43,	.	1	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	4	2	1	0	1
	7	30JAN97	50,	.	2	0	0	0	0	0	0	0	2	1	0	1	0	0	0	0	0	6	2	2	0	2
	8	06FEB97	57,	.	3	0	0	0	0	0	2	2	2	1	0	1	1	0	0	0	0	12	3	2	0	7
329.005.00335	SC	20FEB97	-8,	.	3	0	1	0	2	2	2	2	1	1	0	1	1	0	0	0	0	16	3	2	4	7
	BL	28FEB97	1,	.	3	0	0	2	2	1	3	1	2	1	0	1	1	0	0	0	0	17	3	2	5	7
	1	07MAR97	8,	.	4	0	0	0	1	2	2	1	3	1	0	0	1	0	0	1	0	16	2	3	3	7
	2	14MAR97	15,	.	1	0	0	0	1	1	1	2	1	1	0	1	1	0	0	0	0	10	3	1	2	4
	3	21MAR97	22,	.	2	0	0	0	0	0	0	0	1	1	0	1	0	0	0	2	0	7	2	1	0	2
	4	27MAR97	28,	.	3	0	0	2	1	0	2	2	1	1	0	1	0	0	0	0	0	13	2	1	3	7
	5	03APR97	35,	.	1	0	0	1	1	0	2	1	2	1	0	1	1	0	0	0	0	11	3	2	2	4
	6	10APR97	42,	.	1	1	0	2	2	0	0	2	1	0	0	1	0	0	0	0	0	10	1	2	4	3
	7	17APR97	49,	.	2	0	0	2	2	0	2	1	2	1	0	1	1	0	0	0	0	14	3	2	4	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00335	8	24APR97	56, .	2	0	0	2	2	0	1	2	2	1	0	1	1	0	0	0	0	14	3	2	4	5
329.006.00040	SC	10FEB95	-6, .	3	2	1	2	2	1	3	0	2	3	1	2	0	0	1	0	1	24	8	5	5	6
	BL	15FEB95	-1, .	3	2	0	2	2	1	1	0	1	2	1	0	1	0	0	0	1	17	5	3	5	4
	1	22FEB95	7, .	3	1	1	0	0	0	2	0	0	3	0	1	2	2	0	0	0	15	6	2	0	7
	2	01MAR95	14, .	1	0	0	0	0	0	3	1	1	2	2	2	2	0	1	0	0	15	9	1	0	5
329.006.00041	SC	22MAR95	-14, -78	3	0	1	2	1	1	1	1	2	3	2	0	2	0	2	0	0	21	9	3	4	5
	BL	05APR95	1, -64	1	0	0	2	0	0	2	1	0	1	2	0	2	0	1	0	0	12	6	0	2	4
	1	10APR95	6, -59	1	0	0	0	0	0	2	1	0	0	2	0	2	0	2	0	0	10	6	0	0	4
	2	19APR95	15, -50	3	0	0	2	1	0	3	2	0	3	2	1	1	0	2	0	0	20	9	0	3	8
	3	24APR95	20, -45	2	0	0	2	1	0	3	1	2	2	1	2	2	0	2	1	0	21	9	2	3	6
	4	01MAY95	27, -38	3	0	0	2	2	1	2	1	0	2	1	0	2	2	2	0	0	20	7	0	5	8
	5	08MAY95	34, -31	1	0	0	0	0	0	1	1	0	0	2	1	0	1	1	0	0	8	4	0	0	4
	6	15MAY95	41, -24	3	0	0	2	0	0	2	2	1	3	1	2	2	1	3	0	0	22	11	1	2	8
	7	24MAY95	50, -15	1	0	0	2	0	0	3	0	0	1	1	1	1	1	1	0	0	12	5	0	2	5
	8	31MAY95	57, -8	1	0	0	2	2	0	1	1	0	2	2	0	1	1	2	0	0	15	7	0	4	4
	12	05JUL95	92, 28	2	0	0	0	0	0	0	0	0	0	2	0	1	1	1	0	0	7	4	0	0	3
	16	31JUL95	118, 54	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	20	24AUG95	142, 78	0	0	0	2	2	2	0	1	0	0	2	0	0	0	0	0	0	9	2	0	6	1
	24	21SEP95	170, 106	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	24OCT95	203, 139	2	0	0	2	2	0	1	1	0	1	0	2	1	0	0	0	0	12	4	0	4	4
	32	21NOV95	231, 167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.007.00139	SC	04MAY95	-4, .	3	1	0	0	0	0	1	0	2	2	0	0	2	1	1	0	1	14	6	3	0	5
	BL	05MAY95	-3, .	3	1	0	0	0	0	1	0	2	2	0	0	2	1	1	0	1	14	6	3	0	5
	1	18MAY95	11, .	1	0	0	0	0	0	1	1	2	1	2	0	0	1	1	1	1	12	5	2	0	4
	2	25MAY95	18, .	2	0	0	0	0	0	1	1	1	1	2	0	1	0	0	0	0	9	4	1	0	4
	6	19JUN95	43, .	0	0	0	0	0	0	0	0	2	0	2	0	1	1	0	0	2	8	5	2	0	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.007.00143	SC	26OCT95	-14, .	4	1	0	2	1	0	3	3	0	3	2	0	1	0	2	0	0	22	8	1	3	10
	BL	09NOV95	1, .	4	2	0	2	1	0	3	3	1	1	0	0	1	0	0	0	1	19	3	3	3	10
	1	16NOV95	8, .	3	0	0	2	0	0	1	3	0	1	0	0	1	0	0	0	0	11	2	0	2	7
	2	22NOV95	14, .	3	2	0	1	1	0	2	3	1	1	1	0	0	0	0	0	2	17	4	3	2	8
329.007.00146	SC	18JAN96	-7, -60	3	1	1	0	0	0	3	2	2	1	1	0	1	0	1	0	1	17	5	4	0	8
	BL	25JAN96	1, -53	3	2	0	0	0	0	2	2	2	2	1	0	0	0	1	1	1	17	5	4	0	7
	1	01FEB96	8, -46	3	0	0	0	0	0	2	1	1	1	0	0	1	0	0	0	1	10	3	1	0	6
	2	05FEB96	12, -42	2	1	0	1	0	0	1	1	1	0	1	0	1	0	1	0	0	10	3	2	1	4
	3	12FEB96	19, -35	2	0	0	0	0	0	1	1	1	0	0	0	0	0	1	0	0	6	1	1	0	4
	4	19FEB96	26, -28	1	1	0	1	0	0	0	1	1	0	0	0	0	0	0	0	0	5	0	2	1	2
	5	26FEB96	33, -21	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	6	04MAR96	40, -14	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	7	11MAR96	47, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	18MAR96	54, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	15APR96	82, 29	2	1	0	1	0	0	2	2	2	2	0	0	0	0	0	0	0	12	2	3	1	6
	16	13MAY96	110, 57	1	0	0	0	0	0	1	0	2	0	0	0	0	0	0	0	0	4	0	2	0	2
	20	06JUN96	134, 81	0	1	0	0	0	0	1	0	1	1	0	0	0	0	0	0	1	5	2	2	0	1
	24	08JUL96	166, 113	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	05AUG96	194, 141	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	09SEP96	229, 176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.007.00269	SC	04APR96	-7, .	3	2	2	1	1	2	4	0	2	3	0	0	0	0	0	0	2	22	5	6	4	7
	BL	11APR96	1, .	3	0	1	2	0	0	4	1	3	3	0	0	0	0	0	1	0	18	3	4	2	8
	1	18APR96	8, .	3	1	0	1	1	0	3	1	2	2	0	0	1	0	0	1	2	18	5	3	2	7
	2	25APR96	15, .	2	1	0	0	0	0	2	0	1	0	0	0	0	0	0	0	2	8	2	2	0	4
329.007.00270	SC	02MAY96	-7, .	3	2	0	0	1	0	3	2	0	2	0	0	1	0	0	0	0	14	3	2	1	8
	BL	09MAY96	1, .	3	1	0	2	1	1	3	2	0	1	2	0	1	0	0	0	0	17	4	1	4	8

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
					HAMD Scores																					
329.007.00270	1	16MAY96	8,	.	3	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1	8	1	2	0	5
	2	23MAY96	15,	.	1	0	0	0	0	0	1	1	0	0	1	0	0	0	0	0	0	4	1	0	0	3
	3	30MAY96	22,	.	1	0	0	1	0	0	1	1	0	0	0	0	2	0	0	1	0	7	2	0	1	3
	4	06JUN96	29,	.	0	0	0	0	0	1	0	0	0	1	1	1	0	0	0	0	0	4	3	0	1	0
	5	13JUN96	36,	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6	20JUN96	43,	.	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	1	0	0	0
329.007.00307	SC	09MAY96	-7,	.	3	2	0	2	2	1	3	1	1	3	1	1	1	0	2	0	0	23	8	3	5	7
	BL	16MAY96	1,	.	4	0	0	2	1	0	3	0	2	3	1	0	1	0	1	0	0	18	6	2	3	7
	1	23MAY96	8,	.	2	2	0	2	2	2	2	0	1	3	1	0	1	0	0	0	0	18	5	3	6	4
	2	30MAY96	15,	.	2	0	0	2	2	1	0	0	2	1	2	0	1	0	0	0	0	13	4	2	5	2
	3	06JUN96	22,	.	1	1	0	2	2	2	1	0	2	2	1	0	1	0	0	0	0	15	4	3	6	2
	4	13JUN96	29,	.	0	0	0	1	1	0	1	0	1	0	0	0	0	0	0	0	0	4	0	1	2	1
	5	20JUN96	36,	.	0	0	0	0	1	0	0	0	2	0	0	0	0	0	0	0	0	3	0	2	1	0
329.007.00308	SC	27JUN96	-5,	.	3	1	0	1	0	0	2	3	0	1	0	0	0	0	0	0	2	13	3	1	1	8
	BL	02JUL96	1,	.	3	1	0	0	0	0	2	2	1	3	0	0	0	0	0	0	1	13	4	2	0	7
329.008.00159	SC	06SEP95	-7,	-69	2	1	2	2	1	0	2	1	1	1	1	1	1	0	0	1	0	17	4	4	3	5
	BL	13SEP95	1,	-62	2	0	1	2	1	1	3	2	0	1	0	0	1	0	0	0	0	14	2	1	4	7
	1	19SEP95	7,	-56	1	0	1	1	2	2	2	1	1	1	0	0	1	0	0	0	0	13	2	2	5	4
	2	27SEP95	15,	-48	1	0	0	0	0	1	1	1	0	0	0	0	1	0	1	0	0	6	2	0	1	3
	3	03OCT95	21,	-42	1	0	0	1	1	1	1	1	0	2	1	0	1	0	1	0	0	11	5	0	3	3
	4	10OCT95	28,	-35	2	1	0	0	2	2	1	1	1	2	1	0	1	0	1	0	0	15	5	2	4	4
	5	16OCT95	34,	-29	1	0	2	0	1	1	0	0	1	0	1	0	1	0	1	0	0	9	3	3	2	1
	6	24OCT95	42,	-21	1	0	1	0	0	1	0	1	1	0	1	1	1	0	1	0	0	9	4	2	1	2
	7	31OCT95	49,	-14	1	1	1	1	1	1	0	1	0	0	1	0	1	0	1	0	0	10	3	2	3	2
	8	14NOV95	63,	1	2	0	2	0	2	1	0	0	0	1	1	0	1	0	1	0	0	11	4	2	3	2
	16	26DEC95	105,	43	1	1	0	1	0	0	1	1	1	0	0	0	0	0	1	0	0	7	1	2	1	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.008.00159	20	23JAN96	133, 71	1	1	1	1	0	1	1	1	0	0	0	0	1	0	1	0	0	9	2	2	2	3
329.008.00161	SC	31OCT95	-16, -71	1	2	2	2	1	0	3	2	1	2	0	0	1	0	0	0	0	17	3	5	3	6
	BL	16NOV95	1, -55	1	2	0	0	0	0	3	0	3	2	0	0	1	0	1	0	0	13	4	5	0	4
	1	22NOV95	7, -49	1	0	0	1	1	1	1	0	1	1	1	1	0	0	0	0	0	9	3	1	3	2
	2	29NOV95	14, -42	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	3	3	0	0	0
	3	07DEC95	22, -34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	15DEC95	30, -26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6	27DEC95	42, -14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	0
	7	03JAN96	49, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	10JAN96	56, 1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
329.008.00187	SC	15NOV95	-14, .	4	0	2	2	2	0	3	3	0	3	1	0	2	0	2	0	0	24	8	2	4	10
	BL	29NOV95	1, .	3	0	2	2	2	0	3	3	0	1	0	1	1	0	1	0	0	19	4	2	4	9
	1	07DEC95	9, .	1	2	2	0	1	1	3	1	1	2	2	0	1	0	2	0	0	19	7	5	2	5
	2	14DEC95	16, .	2	0	1	1	0	0	1	1	1	0	1	0	1	0	2	0	0	11	4	2	1	4
	3	21DEC95	23, .	1	0	2	2	2	0	2	1	1	1	1	1	1	0	1	0	0	16	5	3	4	4
	4	28DEC95	30, .	3	1	2	0	2	0	0	1	0	2	0	1	2	0	3	0	0	17	8	3	2	4
	5	04JAN96	37, .	2	1	2	2	1	0	3	1	1	2	2	0	1	0	2	0	0	20	7	4	3	6
	6	11JAN96	44, .	1	0	2	2	1	0	2	1	0	2	2	0	2	0	2	0	0	17	8	2	3	4
	7	18JAN96	51, .	1	0	2	2	2	1	1	1	0	1	2	1	2	0	2	0	0	18	8	2	5	3
	8	26JAN96	59, .	1	1	1	2	1	0	1	1	0	2	1	0	1	0	2	0	0	14	6	2	3	3
329.008.00192	SC	14FEB96	-20, .	2	1	0	1	0	0	3	1	1	1	2	1	1	0	0	0	0	14	5	2	1	6
	BL	05MAR96	1, .	2	2	0	1	1	0	3	0	4	2	0	0	0	0	0	0	0	15	2	6	2	5
	1	11MAR96	7, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	18MAR96	14, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	25MAR96	21, .	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0	0	0	3	1	0	1	1
	4	03APR96	30, .	0	0	0	1	1	1	1	0	0	0	1	0	1	0	0	0	0	6	2	0	3	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.008.00192	5	12APR96	39, .	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
329.008.00272	SC	19MAR96	-15, -71	2	1	0	0	0	0	3	2	1	1	1	0	1	0	0	0	0	12	3	2	0	7
	BL	03APR96	1, -56	2	1	0	0	0	0	3	2	2	2	1	0	2	0	0	0	0	15	5	3	0	7
	1	10APR96	8, -49	1	0	0	1	0	0	1	0	0	0	1	0	0	0	1	0	0	5	2	0	1	2
	2	17APR96	15, -42	0	0	0	0	0	0	1	1	0	0	0	0	1	0	1	1	0	5	2	0	0	2
	3	26APR96	24, -33	0	0	0	0	0	0	1	0	0	0	0	0	1	0	1	0	0	3	2	0	0	1
	4	01MAY96	29, -28	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	2	2	0	0	0
	5	07MAY96	35, -22	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	0	0	3	1	0	1	1
	7	22MAY96	50, -7	0	2	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	5	1	2	0	2
	8	29MAY96	57, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	0
	12	26JUN96	85, 29	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0
	16	24JUL96	113, 57	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20	21AUG96	141, 85	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	2	0	0	0
	24	18SEP96	169, 113	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	2	2	0	0	0
329.008.00273	SC	19APR96	-28, -91	2	0	0	2	1	0	1	1	0	3	3	0	2	0	0	0	0	15	8	0	3	4
	BL	17MAY96	1, -63	2	2	1	2	0	0	3	2	0	3	1	0	2	0	0	0	0	18	6	3	2	7
	1	24MAY96	8, -56	1	0	0	0	0	1	0	1	1	0	0	1	2	0	0	0	1	8	4	1	1	2
	2	31MAY96	15, -49	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	1	5	5	0	0	0
	3	10JUN96	25, -39	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	1	3	3	0	0	0
	4	17JUN96	32, -32	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1	4	3	0	0	0
	5	24JUN96	39, -25	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	1	3	3	0	0	0
	6	01JUL96	46, -18	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	1	3	3	0	0	0
	8	11JUL96	56, -8	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	1	3	3	0	0	0
	8	19JUL96	64, 1	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	2	2	0	0	0
	16	04SEP96	111, 48	0	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0	1	4	3	0	1	0
329.009.00127	SC	03APR95	-7, .	3	2	3	2	2	1	4	3	1	4	3	1	1	1	3	1	0	35	12	6	5	11

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00127	BL	10APR95	1, .	4	2	2	2	2	0	4	2	1	2	3	1	1	0	2	0	1	29	10	5	4	10
	1	17APR95	8, .	3	2	2	0	0	0	4	2	1	3	2	1	1	1	3	1	0	26	10	5	0	10
	2	24APR95	15, .	2	0	0	2	0	0	2	1	0	1	1	0	1	1	2	0	0	13	5	0	2	6
	3	01MAY95	22, .	2	0	0	2	0	0	3	1	0	2	2	1	2	1	2	0	0	18	9	0	2	7
	4	08MAY95	29, .	1	0	0	0	2	1	2	1	0	2	1	1	1	0	1	0	0	13	6	0	3	4
	5	15MAY95	36, .	1	0	0	0	1	1	2	2	0	2	1	1	1	0	1	0	0	13	6	0	2	5
329.009.00132	SC	17MAY95	-6, -63	3	0	0	2	0	0	4	0	1	2	1	0	1	0	0	0	1	15	5	1	2	7
	BL	23MAY95	1, -57	3	1	2	2	1	1	3	2	1	1	1	1	1	0	1	0	1	22	6	4	4	8
	1	30MAY95	8, -50	1	1	1	1	1	1	3	1	1	1	1	1	1	0	1	0	1	17	6	3	3	5
	2	06JUN95	15, -43	1	1	0	2	1	1	1	2	1	1	1	0	0	0	0	0	0	12	2	2	4	4
	3	13JUN95	22, -36	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	4	20JUN95	29, -29	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	5	27JUN95	36, -22	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	6	05JUL95	44, -14	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	7	11JUL95	50, -8	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	8	19JUL95	58, 1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	12	24AUG95	94, 37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	15SEP95	116, 59	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	3	0	0	2	1
	20	24OCT95	155, 98	3	1	1	2	1	1	2	2	1	1	1	1	1	0	1	1	0	20	5	3	4	7
329.009.00134	SC	28JUN95	-8, .	3	2	3	0	0	2	3	1	1	3	2	0	2	1	2	0	0	25	9	6	2	8
	BL	06JUL95	1, .	4	2	1	2	2	1	3	2	1	3	2	0	1	0	2	0	0	26	8	4	5	9
	1	14JUL95	9, .	3	2	2	1	1	0	3	2	2	2	2	1	1	0	1	0	0	23	7	6	2	8
	2	19JUL95	14, .	3	2	2	1	1	0	3	2	2	2	2	1	1	0	1	0	0	23	7	6	2	8
	3	26JUL95	21, .	2	1	1	0	0	0	2	2	1	1	1	0	1	0	1	0	0	13	4	3	0	6
	4	03AUG95	29, .	2	1	0	0	0	0	3	1	1	1	2	1	1	0	1	0	0	14	6	2	0	6
	5	08AUG95	34, .	2	0	0	0	0	0	2	1	1	1	1	0	1	0	0	0	0	9	3	1	0	5
	6	15AUG95	41, .	1	0	0	1	1	0	0	1	1	0	1	0	1	0	0	0	0	7	2	1	2	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.009.00134	7	24AUG95	50, .	1	0	0	0	0	0	1	1	0	1	2	0	0	0	0	0	0	6	3	0	0	3
	8	29AUG95	55, .	3	1	2	0	1	0	0	1	1	2	1	0	1	0	1	0	0	14	5	4	1	4
329.009.00137	SC	03OCT95	-7, .	1	1	3	2	0	0	4	0	3	1	0	0	0	1	0	0	2	18	3	7	2	6
	BL	10OCT95	1, .	3	0	1	2	1	1	1	1	2	2	2	1	1	0	0	0	0	18	6	3	4	5
	1	17OCT95	8, .	2	1	1	1	1	2	2	1	2	2	2	1	1	0	1	0	0	20	7	4	4	5
	2	24OCT95	15, .	1	1	1	1	1	1	2	2	2	1	1	1	1	0	1	0	0	17	5	4	3	5
	3	31OCT95	22, .	3	1	1	0	1	1	1	2	2	2	1	0	1	0	1	0	0	17	5	4	2	6
	4	07NOV95	29, .	1	1	0	0	1	0	2	1	2	1	1	1	0	0	1	0	0	12	4	3	1	4
	5	14NOV95	36, .	1	1	0	0	0	0	1	2	2	1	1	0	1	0	0	0	0	10	3	3	0	4
	6	21NOV95	43, .	1	1	0	0	0	0	1	1	1	1	1	0	0	0	1	0	0	8	3	2	0	3
	7	28NOV95	50, .	1	0	0	0	1	0	0	1	2	1	0	0	0	0	0	1	0	7	1	2	1	2
	8	05DEC95	57, .	1	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	5	1	1	0	3
329.009.00171	SC	31OCT95	-7, .	4	2	3	1	0	0	4	0	3	2	1	1	1	0	1	2	0	25	6	8	1	8
	BL	07NOV95	1, .	3	1	1	1	1	0	3	2	2	3	2	1	1	0	2	2	0	25	9	4	2	8
	1	14NOV95	8, .	3	1	2	1	1	1	2	1	2	2	2	1	1	0	1	0	0	21	7	5	3	6
329.009.00172	SC	06NOV95	-7, -64	3	2	1	2	1	0	3	2	1	2	1	1	0	0	1	1	1	22	6	4	3	8
	BL	13NOV95	1, -57	3	2	1	2	1	1	3	1	2	2	1	0	0	0	1	1	1	22	5	5	4	7
	1	20NOV95	8, -50	3	1	0	1	1	1	3	1	0	2	1	0	0	0	1	1	1	17	5	1	3	7
	2	27NOV95	15, -43	3	2	1	2	1	2	2	1	1	2	1	1	0	0	1	0	1	21	6	4	5	6
	3	04DEC95	22, -36	3	2	0	1	1	0	2	1	1	2	1	0	2	0	0	0	0	16	5	3	2	6
	4	11DEC95	29, -29	2	2	0	1	1	0	2	1	1	2	1	0	1	0	1	0	0	15	5	3	2	5
	5	21DEC95	39, -19	1	1	0	0	0	0	1	1	1	2	2	0	1	0	0	0	0	10	5	2	0	3
	6	27DEC95	45, -13	0	1	0	2	0	2	0	0	2	0	2	0	1	0	2	0	0	12	5	3	4	0
	7	03JAN96	52, -6	1	1	0	0	0	0	1	0	1	2	1	0	0	0	1	0	0	8	4	2	0	2
	8	09JAN96	58, 1	1	2	0	0	0	0	1	1	1	2	1	0	1	0	1	0	0	11	5	3	0	3
	12	07FEB96	87, 30	0	1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	2	1	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.009.00172	16	04MAR96	113, 56	1	2	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	5	1	2	0	2
	20	01APR96	141, 84	0	1	0	0	2	0	1	0	1	0	0	0	0	0	0	0	0	5	0	2	2	1
	24	29APR96	169, 112	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	2	0	0	0
	28	10JUN96	211, 154	0	1	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	3	1	1	1	0
	32	08JUL96	239, 182	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
329.009.00194	SC	28NOV95	-7, -63	3	2	2	2	0	0	3	0	3	1	1	0	1	0	1	0	1	20	5	7	2	6
	BL	05DEC95	1, -56	4	1	1	2	1	0	3	2	2	2	2	0	2	0	2	0	1	25	9	4	3	9
	1	12DEC95	8, -49	4	1	1	2	1	0	3	2	1	2	2	0	1	0	2	0	1	23	8	3	3	9
	2	19DEC95	15, -42	3	1	1	1	1	0	3	2	1	2	2	0	1	0	1	0	1	20	7	3	2	8
	3	27DEC95	23, -34	3	1	1	0	1	0	2	2	1	2	2	1	1	0	1	0	1	19	8	3	1	7
	4	02JAN96	29, -28	2	2	2	0	1	1	2	2	2	1	2	0	1	0	1	1	0	20	5	6	2	6
	5	09JAN96	36, -21	3	1	1	1	2	1	2	1	1	1	1	0	2	0	2	0	2	21	8	3	4	6
	6	16JAN96	43, -14	2	2	1	1	1	1	2	2	1	1	1	0	1	0	0	0	0	16	3	4	3	6
	7	23JAN96	50, -7	1	1	1	1	1	0	1	2	1	1	1	0	0	0	0	0	0	11	2	3	2	4
	8	30JAN96	57, 1	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	0	0	3	1	0	1	1
	12	27FEB96	85, 29	0	0	0	2	0	0	0	1	0	1	0	0	0	0	0	0	0	4	1	0	2	1
	16	02APR96	120, 64	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	20	30APR96	148, 92	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	24	04JUN96	183, 127	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
329.009.00195	SC	06DEC95	-9, .	4	2	3	2	1	0	2	0	3	2	2	2	0	0	2	2	0	27	8	8	3	6
	BL	15DEC95	1, .	4	2	1	2	2	1	3	2	1	2	2	2	1	0	2	2	1	30	10	4	5	9
	1	19DEC95	5, .	3	1	1	2	1	0	2	2	2	2	1	2	1	0	1	1	1	23	8	4	3	7
	2	27DEC95	13, .	1	1	0	0	0	0	1	1	1	1	0	1	1	0	1	1	0	10	4	2	0	3
	3	02JAN96	19, .	1	1	0	0	0	0	1	1	1	1	1	1	1	0	1	0	1	11	6	2	0	3
	3	08JAN96	25, .	1	1	0	0	0	0	1	1	1	1	2	1	2	0	1	0	0	12	7	2	0	3
329.009.00199	SC	10JAN96	-6, .	4	3	3	2	0	1	3	2	1	2	0	1	1	0	2	1	0	26	6	7	3	9

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00199	BL	16JAN96	1,	.	3	2	3	1	2	0	3	0	2	2	1	1	1	0	0	1	0	22	5	7	3	6
	1	23JAN96	8,	.	2	2	1	1	0	2	2	0	2	2	2	1	1	0	1	0	0	19	7	5	3	4
	2	29JAN96	14,	.	3	2	2	2	1	0	2	0	2	2	1	1	0	0	0	0	0	18	4	6	3	5
	3	07FEB96	23,	.	2	2	1	1	0	2	2	1	2	1	1	1	1	1	1	0	0	19	5	5	3	6
	4	14FEB96	30,	.	3	2	0	2	2	0	2	2	2	2	2	1	1	0	1	1	0	23	7	4	4	7
	5	21FEB96	37,	.	2	2	0	1	1	0	1	1	2	2	1	0	0	0	1	1	0	15	4	4	2	4
	6	28FEB96	44,	.	3	1	0	2	1	0	2	1	2	2	2	0	1	0	0	0	0	17	5	3	3	6
	7	06MAR96	51,	.	3	1	0	0	0	0	3	2	2	1	1	1	0	0	0	0	0	14	3	3	0	8
	8	13MAR96	58,	.	3	2	0	1	0	2	2	1	2	1	2	0	0	0	0	1	0	17	3	4	3	6
329.009.00203	SC	28FEB96	-5,	.	3	1	0	2	2	0	4	2	0	2	1	2	1	0	0	1	1	22	7	1	4	9
	BL	04MAR96	1,	.	3	1	0	2	2	0	4	2	1	1	1	2	1	0	0	1	1	22	6	2	4	9
	1	11MAR96	8,	.	3	1	0	1	2	1	3	2	1	1	2	2	2	0	1	2	1	25	9	2	4	8
	2	19MAR96	16,	.	3	1	0	1	1	1	3	2	1	1	1	2	1	0	1	1	0	20	6	2	3	8
	3	26MAR96	23,	.	2	1	0	0	0	0	2	1	0	1	0	1	1	0	0	0	0	9	3	1	0	5
329.009.00236	SC	17DEC96	-13,	.	2	1	2	0	0	0	3	1	3	1	2	0	2	0	0	0	0	17	5	6	0	6
	BL	30DEC96	1,	.	4	1	1	0	1	1	3	2	1	1	0	2	2	0	1	0	1	21	7	3	2	9
	1	06JAN97	8,	.	3	1	1	1	1	1	2	2	1	1	0	2	2	0	0	1	1	20	6	3	3	7
	2	15JAN97	17,	.	3	1	1	1	1	0	2	2	1	1	0	2	2	0	1	1	1	20	7	3	2	7
	3	20JAN97	22,	.	3	1	1	0	1	0	2	2	1	1	0	2	2	0	1	0	1	18	7	3	1	7
	4	27JAN97	29,	.	3	1	1	1	1	1	3	2	1	1	0	2	2	0	1	1	0	21	6	3	3	8
329.009.00239	SC	11NOV96	-8,	-65	1	1	1	0	2	0	3	1	2	2	1	0	2	0	0	0	0	16	5	4	2	5
	BL	18NOV96	-1,	-58	3	1	1	0	1	1	2	2	1	1	1	0	2	0	1	0	0	17	5	3	2	7
	1	25NOV96	7,	-51	3	1	1	0	1	1	2	2	1	1	0	0	1	0	1	0	0	15	3	3	2	7
	2	02DEC96	14,	-44	0	0	0	1	1	0	1	1	1	1	1	1	2	0	0	1	2	13	7	1	2	2
	3	09DEC96	21,	-37	1	0	0	0	1	0	1	1	2	1	1	0	0	0	0	0	0	8	2	2	1	3
	4	16DEC96	28,	-30	0	0	0	0	0	0	0	1	0	1	0	0	1	0	0	0	0	3	2	0	0	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.009.00239	5	23DEC96	35, -23	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	6	30DEC96	42, -16	1	0	0	0	2	0	0	0	0	0	0	0	2	0	1	0	0	6	3	0	2	1
	7	06JAN97	49, -9	2	0	0	0	0	0	1	1	0	1	0	0	1	0	1	0	0	7	3	0	0	4
	8	15JAN97	58, 1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0	3	1	0	0	1
	12	18FEB97	92, 35	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	16	17MAR97	119, 62	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	20	14APR97	147, 90	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	24	12MAY97	175, 118	3	2	1	1	1	0	2	2	2	1	1	2	2	0	0	0	1	21	7	5	2	7
329.009.00262	SC	07FEB97	-10, .	3	2	2	0	0	0	2	2	0	2	2	2	2	1	0	0	0	20	8	4	0	8
	BL	17FEB97	1, .	3	1	2	1	0	0	2	2	1	2	1	0	1	0	0	0	1	17	5	4	1	7
	1	24FEB97	8, .	3	1	0	0	0	0	2	2	0	1	0	2	2	0	0	0	1	14	6	1	0	7
	2	03MAR97	15, .	2	1	0	0	1	1	1	1	1	1	0	1	0	0	1	0	1	12	4	2	2	4
	3	07MAR97	19, .	1	0	0	0	0	0	1	1	1	1	1	1	2	0	0	1	0	10	5	1	0	3
	4	17MAR97	29, .	2	1	0	0	0	0	1	2	0	1	0	1	2	0	1	1	1	13	6	1	0	5
	5	24MAR97	36, .	3	1	1	0	0	0	2	2	1	3	0	1	1	0	0	1	0	16	5	3	0	7
	6	31MAR97	43, .	3	1	0	0	0	0	2	2	1	1	0	1	1	0	0	1	1	14	4	2	0	7
	7	07APR97	50, .	3	2	1	0	0	0	3	2	2	2	0	1	0	0	1	1	0	18	4	5	0	8
	8	14APR97	57, .	4	2	1	0	0	0	3	2	1	2	1	2	1	0	1	1	1	22	8	4	0	9
329.009.00264	SC	25OCT96	-7, .	1	1	0	0	1	1	4	1	0	2	2	1	2	0	0	0	1	17	8	1	2	6
	BL	01NOV96	1, .	3	1	0	2	2	0	3	2	0	1	1	0	2	0	0	0	2	19	6	1	4	8
	1	08NOV96	8, .	3	1	0	1	0	0	3	2	1	1	1	0	2	0	0	1	2	18	6	2	1	8
	1	11NOV96	11, .	3	1	0	1	0	0	2	2	4	2	1	1	2	0	0	0	2	21	8	5	1	7
	2	18NOV96	18, .	2	1	0	0	1	0	2	1	1	2	1	0	2	0	1	0	2	16	8	2	1	5
	3	25NOV96	25, .	3	0	0	0	0	0	2	2	2	1	2	0	1	0	1	0	2	16	7	2	0	7
	4	02DEC96	32, .	1	1	0	0	0	0	2	2	1	2	1	0	1	0	1	0	2	14	7	2	0	5
	6	11DEC96	41, .	3	0	0	2	1	0	2	2	1	1	0	0	1	0	1	1	0	15	3	1	3	7
	6	16DEC96	46, .	3	0	0	0	0	0	3	2	2	1	0	0	1	0	1	0	2	15	5	2	0	8

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.009.00264	7	23DEC96	53, .	3	1	0	0	0	0	3	2	1	1	0	1	1	0	1	0	2	16	6	2	0	8
329.009.00301	SC	06MAR96	-13, -69	3	1	2	2	1	1	3	2	2	2	2	1	2	1	0	0	2	27	9	5	4	9
	BL	19MAR96	1, -56	3	1	1	1	2	1	2	2	1	1	0	2	1	0	0	1	2	21	6	3	4	7
	1	26MAR96	8, -49	3	1	1	1	2	0	2	2	1	1	0	1	1	0	0	0	2	18	5	3	3	7
	2	05APR96	18, -39	4	2	1	1	1	1	3	2	1	1	2	1	1	0	0	1	1	23	6	4	3	9
	3	12APR96	25, -32	3	1	1	1	1	0	4	2	1	2	2	2	2	0	2	0	1	25	11	3	2	9
	4	16APR96	29, -28	2	1	0	1	0	0	2	2	1	1	1	1	1	0	2	0	1	16	7	2	1	6
	5	23APR96	36, -21	2	1	0	0	0	0	2	2	1	1	1	0	1	0	2	1	0	14	5	2	0	6
	6	30APR96	43, -14	1	1	0	0	0	0	1	2	1	1	1	0	1	0	1	0	0	10	4	2	0	4
	7	07MAY96	50, -7	1	1	0	0	0	0	1	1	0	0	0	0	0	0	1	0	1	6	2	1	0	3
	8	14MAY96	57, 1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	0	3	0	0	0	2
	12	11JUN96	85, 29	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
329.009.00305	SC	01MAY96	-6, -63	3	2	1	1	0	0	3	2	2	3	2	1	1	1	1	1	1	25	9	5	1	9
	BL	07MAY96	1, -57	3	1	0	2	1	0	3	3	1	3	2	1	2	0	0	2	1	25	9	2	3	9
	1	14MAY96	8, -50	3	1	0	2	0	0	3	2	1	3	1	1	1	0	1	1	1	21	8	2	2	8
	2	21MAY96	15, -43	3	1	0	2	0	0	3	3	1	3	1	1	2	0	1	2	1	24	9	2	2	9
	3	28MAY96	22, -36	3	1	0	2	0	0	3	3	0	3	1	0	2	0	1	0	1	20	8	1	2	9
	4	04JUN96	29, -29	3	1	0	2	0	0	3	2	0	3	0	0	1	0	1	0	1	17	6	1	2	8
	5	11JUN96	36, -22	3	1	0	1	0	0	3	2	1	1	0	0	2	0	1	0	1	16	5	2	1	8
	6	19JUN96	44, -14	3	1	0	1	1	0	1	1	0	3	0	0	1	0	0	0	0	12	4	1	2	5
	7	25JUN96	50, -8	1	1	0	1	0	0	1	1	0	1	0	0	1	0	0	0	0	7	2	1	1	3
	8	03JUL96	58, 1	1	0	0	0	0	0	1	1	1	1	1	0	2	0	0	0	1	9	5	1	0	3
	12	06AUG96	92, 35	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	16	27AUG96	113, 56	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0	3	1	1	0	0
	20	24SEP96	141, 84	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	24	29OCT96	176, 119	1	1	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0	7	3	1	0	3
	28	03DEC96	211, 154	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00305	32	10JAN97	249, 192	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
329.009.00325	SC	21AUG96	-6, -61	2	1	2	2	2	0	3	1	2	2	1	2	2	0	0	2	0	24	7	5	4	6
	BL	27AUG96	1, -55	2	2	2	2	2	1	3	1	2	2	1	2	2	1	0	1	1	27	8	6	5	7
	1	03SEP96	8, -48	3	1	1	2	1	2	2	1	1	1	2	2	2	1	2	1	1	26	10	3	5	7
	2	09SEP96	14, -42	3	2	1	1	1	1	3	1	1	2	2	2	2	1	1	0	0	24	9	4	3	8
	3	16SEP96	21, -35	2	1	1	2	1	1	3	1	1	2	1	0	0	1	1	0	1	19	5	3	4	7
	4	23SEP96	28, -28	1	1	0	0	1	1	2	1	1	0	1	1	2	0	1	0	0	13	5	2	2	4
	5	30SEP96	35, -21	1	0	0	0	1	1	1	0	1	1	0	0	0	0	0	1	0	7	1	1	2	2
	6	10OCT96	45, -11	1	0	0	0	2	2	1	2	1	0	0	2	2	0	1	1	0	15	5	1	4	4
	7	14OCT96	49, -7	1	0	0	0	2	2	1	1	1	1	0	1	1	0	1	0	1	13	5	1	4	3
	8	21OCT96	56, 1	0	0	0	1	1	0	1	1	1	1	0	0	2	0	0	0	0	8	3	1	2	2
	12	18NOV96	84, 29	1	0	1	0	2	1	2	1	1	1	0	0	0	0	0	0	0	10	1	2	3	4
	16	16DEC96	112, 57	4	2	1	0	2	1	3	2	2	2	1	2	1	0	0	1	0	24	6	5	3	9
329.009.00326	SC	26AUG96	-10, -63	3	2	2	2	2	2	3	2	1	2	1	0	2	1	0	0	0	25	5	5	6	9
	BL	05SEP96	1, -53	3	2	2	2	1	1	3	1	1	2	2	0	2	0	1	0	1	24	8	5	4	7
	1	09SEP96	5, -49	3	2	1	0	1	2	2	2	1	1	2	1	2	0	1	0	1	22	8	4	3	7
	2	16SEP96	12, -42	1	1	0	0	1	0	2	1	1	0	1	1	0	0	1	1	1	12	4	2	1	4
	3	23SEP96	19, -35	1	1	0	0	1	0	1	1	1	0	1	0	0	0	0	0	0	7	1	2	1	3
	4	30SEP96	26, -28	1	0	0	0	0	1	1	1	1	0	1	0	1	0	0	1	0	8	2	1	1	3
	5	07OCT96	33, -21	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	3	0	1	0	2
	6	17OCT96	43, -11	1	0	0	1	0	0	0	1	1	1	1	0	2	0	0	0	0	8	4	1	1	2
	7	24OCT96	50, -4	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	4	1	1	0	2
	8	28OCT96	54, 1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	12	25NOV96	82, 29	3	1	0	2	0	1	2	2	0	1	0	1	0	0	0	1	0	14	2	1	3	7
	16	16DEC96	103, 50	4	1	1	2	0	1	3	2	0	1	0	2	1	0	0	1	0	19	4	2	3	9
329.010.00279	SC	08MAR96	-14, -70	3	0	0	0	1	0	3	2	0	1	0	2	2	0	0	1	0	15	5	0	1	8

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.010.00279	BL	22MAR96	1, -56	3	0	0	1	0	0	3	2	0	1	0	2	2	0	0	1	0	15	5	0	1	8
	1	29MAR96	8, -49	3	1	1	0	0	0	3	1	3	1	1	2	1	0	0	0	1	18	6	5	0	7
	2	05APR96	15, -42	3	0	0	0	0	0	3	0	2	0	0	2	0	0	1	0	1	12	4	2	0	6
	3	12APR96	22, -35	3	1	2	1	0	0	3	1	2	1	1	2	0	0	0	0	1	18	5	5	1	7
	4	19APR96	29, -28	3	2	1	0	0	0	3	0	0	0	1	1	2	0	0	0	1	14	5	3	0	6
	5	25APR96	35, -22	2	1	0	1	0	0	1	0	1	0	0	2	1	0	0	0	1	10	4	2	1	3
	6	03MAY96	43, -14	3	0	0	2	0	0	2	0	1	2	1	2	1	0	0	0	1	15	7	1	2	5
	7	10MAY96	50, -7	1	0	0	1	0	0	2	0	1	0	0	1	0	0	0	0	0	6	1	1	1	3
	8	17MAY96	57, 1	2	0	0	2	0	0	3	0	0	0	0	0	0	0	0	0	1	8	1	0	2	5
	12	14JUN96	85, 29	3	0	0	0	0	0	3	0	1	0	0	0	0	0	0	0	1	8	1	1	0	6
	16	11JUL96	112, 56	1	0	0	1	0	0	1	0	1	0	0	0	0	0	0	0	1	5	1	1	1	2
	20	08AUG96	140, 84	3	0	0	2	0	0	3	1	1	1	0	0	0	0	0	0	1	12	2	1	2	7
	24	05SEP96	168, 112	2	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1	7	2	1	0	4
	28	02OCT96	195, 139	3	0	0	0	0	0	2	0	1	1	0	0	2	0	0	0	1	10	4	1	0	5
	32	06NOV96	230, 174	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	3	2	0	0	1
329.010.00281	SC	19JUL96	-7, -68	4	0	2	2	2	0	2	1	4	1	0	0	0	0	0	0	2	20	3	6	4	7
	BL	26JUL96	1, -61	3	1	0	2	1	0	2	2	3	1	0	0	0	0	0	0	2	17	3	4	3	7
	1	02AUG96	8, -54	3	0	0	2	1	0	2	2	2	0	0	0	0	0	0	0	2	14	2	2	3	7
	2	09AUG96	15, -47	1	0	0	1	1	0	2	1	1	1	0	0	0	0	0	0	2	10	3	1	2	4
	3	19AUG96	25, -37	1	0	0	1	1	0	1	1	1	0	0	0	0	0	0	1	2	9	2	1	2	3
	4	26AUG96	32, -30	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	1	2	7	2	1	0	3
	6	04SEP96	41, -21	0	0	0	0	0	0	1	1	4	1	0	0	1	0	0	0	2	10	4	4	0	2
	6	09SEP96	46, -16	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	2	6	2	2	0	2
	8	18SEP96	55, -7	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1	4	1	1	0	2
	8	25SEP96	62, 1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	2	1	0	0	1
	12	25OCT96	92, 31	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	1	4	1	0	0	3
	16	20NOV96	118, 57	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	1	3	1	2	0	0
	20	20DEC96	148, 87	0	0	0	0	0	0	2	2	0	0	0	0	1	0	0	0	2	7	3	0	0	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.010.00281	24	03JAN97	162, 101	0	0	0	0	0	0	3	2	2	0	0	0	2	0	0	0	2	11	4	2	0	5
329.011.00163	SC	18NOV95	-7, .	2	0	3	1	0	0	2	0	0	2	2	0	1	0	3	1	0	17	8	3	1	4
	BL	24NOV95	-1, .	2	0	1	1	0	0	3	0	1	2	2	0	1	0	3	1	0	17	8	2	1	5
	1	01DEC95	7, .	2	0	2	0	0	0	2	0	2	2	2	0	2	0	3	1	0	18	9	4	0	4
	2	11DEC95	17, .	2	0	2	1	0	0	2	0	2	3	2	0	1	0	2	0	0	17	8	4	1	4
	3	18DEC95	24, .	2	0	0	1	0	0	2	0	2	2	1	1	1	0	2	2	0	16	7	2	1	4
	5	27DEC95	33, .	2	0	0	1	0	0	2	0	3	3	2	1	2	0	3	0	0	19	11	3	1	4
329.011.00208	SC	22AUG96	-15, -74	3	2	3	2	2	0	1	0	0	4	2	1	2	0	2	0	0	24	11	5	4	4
	BL	05SEP96	-1, -60	3	1	2	2	2	0	1	0	0	2	2	1	2	0	0	0	0	18	7	3	4	4
	1	11SEP96	6, -54	3	2	2	1	1	0	2	0	1	2	1	1	2	0	0	0	0	18	6	5	2	5
	2	17SEP96	12, -48	3	0	0	2	2	1	1	0	0	2	1	1	1	0	0	0	0	14	5	0	5	4
	3	26SEP96	21, -39	3	0	0	2	2	2	2	0	0	0	1	1	2	0	0	0	0	15	4	0	6	5
	4	03OCT96	28, -32	3	0	1	0	0	0	2	0	0	2	0	1	1	0	0	1	0	11	4	1	0	5
	5	10OCT96	35, -25	3	0	0	0	0	0	2	0	2	1	0	1	1	0	0	0	0	10	3	2	0	5
	6	17OCT96	42, -18	0	0	0	0	0	0	2	0	0	1	1	0	1	0	0	0	0	5	3	0	0	2
	7	24OCT96	49, -11	1	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	0	4	1	1	1	1
	8	03NOV96	59, -1	0	0	0	0	0	0	1	1	0	1	0	1	1	0	0	0	0	5	3	0	0	2
329.011.00209	SC	23AUG96	-19, -81	3	0	2	0	1	0	3	1	2	1	0	0	1	0	0	0	0	14	2	4	1	7
	BL	10SEP96	-1, -63	3	0	1	0	0	0	2	2	2	1	1	0	1	0	0	0	0	13	3	3	0	7
	1	19SEP96	9, -54	3	0	0	1	0	0	2	1	2	1	0	0	1	0	0	1	0	12	2	2	1	6
	2	26SEP96	16, -47	3	0	0	0	0	0	1	1	2	0	0	0	1	0	1	1	0	10	2	2	0	5
	3	03OCT96	23, -40	3	0	0	0	0	0	2	1	2	2	0	1	1	0	0	0	0	12	4	2	0	6
	4	11OCT96	31, -32	0	0	0	0	0	0	1	1	1	0	0	1	1	0	0	0	0	5	2	1	0	2
	5	17OCT96	37, -26	0	0	0	0	0	0	1	1	2	1	0	1	0	0	0	0	0	6	2	2	0	2
	6	24OCT96	44, -19	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	3	0	2	0	1
	7	01NOV96	52, -11	1	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0	0	6	2	1	0	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.011.00209	8	11NOV96	62, -1	0	0	0	0	0	0	1	1	1	1	0	1	1	0	0	0	0	6	3	1	0	2
	12	18DEC96	99, 37	1	0	0	1	1	0	1	1	1	1	0	1	1	0	0	1	0	10	3	1	2	3
329.011.00284	SC	13MAR96	-9, -65	4	0	1	2	2	1	4	1	0	1	1	0	1	0	0	0	0	18	3	1	5	9
	BL	21MAR96	-1, -57	3	0	0	2	0	0	4	2	0	2	1	1	1	0	0	1	0	17	5	0	2	9
	1	28MAR96	7, -50	3	0	0	0	0	2	3	1	1	0	0	1	1	0	0	1	0	13	2	1	2	7
	2	05APR96	15, -42	2	0	0	0	0	0	1	2	1	1	1	1	1	0	0	0	0	10	4	1	0	5
	3	11APR96	21, -36	1	0	0	1	0	0	0	1	1	1	0	1	0	0	0	0	0	6	2	1	1	2
	4	19APR96	29, -28	0	0	0	1	1	0	0	1	1	1	0	0	0	0	0	0	0	5	1	1	2	1
	5	25APR96	35, -22	2	1	0	1	2	2	2	0	1	2	0	2	1	0	0	0	0	16	5	2	5	4
	6	02MAY96	42, -15	1	1	0	0	0	2	1	1	0	1	0	0	1	0	0	1	0	9	2	1	2	3
	7	09MAY96	49, -8	1	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	4	1	1	0	2
	8	16MAY96	56, -1	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	1	0	3	1	1	0	0
	12	10JUN96	81, 25	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	16	08JUL96	109, 53	1	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	4	1	0	0	3
	20	05AUG96	137, 81	1	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0	0	6	2	1	0	3
329.011.00286	SC	15MAY96	-22, -90	3	1	1	2	2	1	2	1	0	1	0	0	1	0	0	0	2	17	4	2	5	6
	BL	05JUN96	-1, -69	3	0	0	2	1	0	3	1	2	1	1	0	1	0	0	0	1	16	4	2	3	7
	1	14JUN96	9, -60	3	1	0	2	2	0	2	1	0	1	0	0	0	0	0	1	2	15	3	1	4	6
	2	21JUN96	16, -53	3	1	0	0	0	0	2	1	1	2	0	0	1	0	0	0	2	13	5	2	0	6
	3	28JUN96	23, -46	3	0	0	0	1	1	1	1	0	0	0	0	0	0	0	1	2	10	2	0	2	5
	5	08JUL96	33, -36	3	0	0	0	0	0	1	1	2	2	0	0	1	0	0	0	2	12	5	2	0	5
	6	17JUL96	42, -27	3	0	0	0	1	1	1	1	1	1	0	0	1	0	0	1	2	13	4	1	2	5
	7	24JUL96	49, -20	3	0	0	0	0	0	1	1	1	1	0	0	1	0	0	1	2	11	4	1	0	5
	8	02AUG96	58, -11	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	2	5	2	1	0	1
	8	09AUG96	65, -4	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	1	5	1	1	0	3
	16	17SEP96	104, 36	0	0	0	1	1	1	1	0	1	0	0	0	0	0	0	0	0	5	0	1	3	1
	20	24OCT96	141, 73	2	0	0	0	0	0	1	0	2	0	0	0	1	0	0	1	0	7	1	2	0	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.011.00286	24	25NOV96	173, 105	0	0	0	0	0	0	1	1	2	1	0	0	1	0	0	0	1	7	3	2	0	2
	28	30DEC96	208, 140	1	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	4	0	2	0	2
329.012.00026	SC	09NOV95	-19, .	3	3	0	2	1	1	3	0	0	3	0	1	2	0	0	0	2	21	8	3	4	6
	BL	28NOV95	1, .	4	3	0	2	1	0	3	0	0	4	0	2	0	0	0	0	2	21	8	3	3	7
	1	05DEC95	8, .	2	2	1	2	1	0	2	0	1	1	0	0	1	0	0	0	2	15	4	4	3	4
329.012.00219	SC	24MAY96	-7, -67	3	0	3	2	0	0	3	0	0	1	0	1	2	0	2	2	0	19	6	3	2	6
	BL	31MAY96	1, -60	2	1	3	2	0	1	3	1	0	1	0	1	2	0	2	0	0	19	6	4	3	6
	1	07JUN96	8, -53	2	0	0	1	0	1	1	0	2	1	0	0	1	0	0	0	0	9	2	2	2	3
	2	14JUN96	15, -46	3	1	0	2	1	0	3	1	0	3	0	0	1	0	0	0	0	15	4	1	3	7
	3	24JUN96	25, -36	1	1	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	4	0	1	1	2
	5	02JUL96	33, -28	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	0	0	5	2	0	1	2
	6	09JUL96	40, -21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	0
	7	16JUL96	47, -14	0	2	0	2	2	0	0	0	0	3	0	0	0	0	0	0	0	9	3	2	4	0
	8	23JUL96	54, -7	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	2	0	0
	8	30JUL96	61, 1	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	1	1	0	0
	12	30AUG96	92, 32	0	1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	3	2	1	0	0
	16	26SEP96	119, 59	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	20	25OCT96	148, 88	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24	22NOV96	176, 116	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1	1	0
	28	20DEC96	204, 144	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1	1	0
	32	24JAN97	239, 179	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.012.00221	SC	18JUN96	-7, -70	4	3	2	2	2	1	4	0	4	4	0	2	1	0	0	0	0	29	7	9	5	8
	BL	25JUN96	1, -63	4	3	3	2	2	1	4	0	4	4	0	2	2	0	0	0	0	31	8	10	5	8
	1	02JUL96	8, -56	3	2	1	0	0	0	3	0	3	4	0	1	2	0	0	0	0	19	7	6	0	6
	2	09JUL96	15, -49	3	2	2	1	2	0	2	1	3	3	1	0	2	0	0	1	0	23	6	7	3	6
	3	16JUL96	22, -42	3	1	0	2	0	0	1	0	4	3	1	2	2	0	0	0	0	19	8	5	2	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.012.00221	4	23JUL96	29, -35	3	2	0	0	2	2	1	0	4	4	0	0	1	0	0	0	0	19	5	6	4	4
	5	30JUL96	36, -28	1	1	0	1	0	0	1	0	3	1	0	0	0	0	0	0	0	8	1	4	1	2
	6	09AUG96	46, -18	1	2	0	0	0	0	0	0	3	4	0	0	2	0	0	0	0	12	6	5	0	1
	8	19AUG96	56, -8	3	1	0	2	2	0	0	0	0	3	1	2	0	0	0	0	0	14	6	1	4	3
	8	27AUG96	64, 1	3	1	0	2	0	0	0	0	2	2	2	0	0	1	0	0	0	13	4	3	2	4
	12	23SEP96	91, 28	0	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	4	2	1	0	1
	16	21OCT96	119, 56	1	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	5	2	2	0	1
	20	04NOV96	133, 70	3	2	4	1	0	0	2	1	2	2	2	1	1	0	0	0	0	21	6	8	1	6
329.012.00223	SC	23AUG96	-7, .	4	2	0	2	2	0	3	0	0	3	2	0	1	0	0	0	0	19	6	2	4	7
	BL	30AUG96	1, .	4	2	0	2	2	0	3	0	0	4	3	0	1	0	0	0	0	21	8	2	4	7
	1	06SEP96	8, .	4	2	1	2	2	0	3	1	0	2	0	2	2	0	0	0	0	21	6	3	4	8
	2	16SEP96	18, .	2	2	0	2	2	1	2	1	0	2	0	0	2	0	2	0	1	19	7	2	5	5
	3	23SEP96	25, .	3	2	1	2	2	2	3	0	2	2	0	0	0	0	0	0	0	19	2	5	6	6
	5	01OCT96	33, .	3	2	3	2	2	0	0	0	2	3	2	0	0	0	0	0	0	19	5	7	4	3
329.012.00227	SC	12DEC96	-6, -75	4	2	3	1	0	0	2	2	2	3	1	1	1	1	0	1	0	24	6	7	1	9
	BL	18DEC96	1, -69	3	2	2	1	1	0	1	2	2	1	0	0	0	0	0	1	0	16	1	6	2	6
	1	27DEC96	10, -60	0	0	0	0	0	0	2	1	2	1	0	1	1	0	0	0	0	8	3	2	0	3
	3	06JAN97	20, -50	3	0	0	2	0	0	1	1	1	3	0	1	1	0	0	0	0	13	5	1	2	5
	4	15JAN97	29, -41	0	0	0	0	0	0	1	1	2	3	0	1	1	0	0	0	0	9	5	2	0	2
	5	24JAN97	38, -32	2	0	0	1	1	0	3	1	2	1	0	0	2	0	0	0	0	13	3	2	2	6
	7	04FEB97	49, -21	0	0	0	2	1	1	0	1	1	0	0	0	0	0	0	0	0	6	0	1	4	1
	8	14FEB97	59, -11	1	1	0	1	0	2	1	1	0	1	1	1	1	0	0	0	0	11	4	1	3	3
	8	20FEB97	65, -5	2	0	0	1	0	1	1	0	1	1	0	1	1	0	0	0	0	9	3	1	2	3
	8	25FEB97	70, 1	1	0	1	0	1	0	1	1	1	1	1	0	1	0	0	0	0	9	3	2	1	3
	16	27MAR97	100, 31	1	0	1	2	0	0	2	2	1	1	1	0	0	0	0	0	0	11	2	2	2	5
	20	25APR97	129, 60	1	0	0	2	0	0	1	0	2	1	1	0	0	1	0	0	1	10	3	2	2	3
	24	26MAY97	160, 91	1	1	0	0	0	0	1	0	2	1	1	0	0	0	0	0	1	8	3	3	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.012.00227	28	25JUN97	190, 121	1	0	0	1	1	0	0	0	1	0	1	1	0	0	0	1	0	7	2	1	2	1
	32	21JUL97	216, 147	1	1	0	1	0	0	1	0	1	0	0	0	0	0	0	0	0	5	0	2	1	2
	32	19AUG97	245, 176	1	1	0	0	0	0	2	1	2	1	0	1	0	0	0	0	0	9	2	3	0	4
329.012.00230	SC	20FEB97	-8, -77	4	1	2	2	0	1	3	1	0	4	0	0	1	0	0	0	1	20	6	3	3	8
	BL	28FEB97	1, -69	4	2	2	2	0	0	3	1	0	4	0	0	2	0	0	0	1	21	7	4	2	8
	1	07MAR97	8, -62	4	1	0	0	0	2	3	0	1	2	1	1	1	0	0	0	1	17	6	2	2	7
	2	14MAR97	15, -55	3	0	1	0	0	2	4	0	1	1	1	1	1	0	0	1	0	16	4	2	2	7
	3	24MAR97	25, -45	4	2	0	0	0	2	3	0	0	3	1	2	2	0	0	0	0	19	8	2	2	7
	5	03APR97	35, -35	4	2	1	0	0	2	3	1	0	3	0	2	2	0	0	0	0	20	7	3	2	8
	6	11APR97	43, -27	2	0	0	0	0	2	4	0	0	2	0	0	1	0	0	0	0	11	3	0	2	6
	8	23APR97	55, -15	2	2	0	0	0	0	3	0	1	3	0	0	1	0	0	0	0	12	4	3	0	5
	8	02MAY97	64, -6	1	0	0	0	0	0	3	1	0	0	1	0	1	0	0	0	0	7	2	0	0	5
	8	08MAY97	70, 1	1	0	0	1	0	0	3	0	1	1	0	1	0	0	0	0	0	8	2	1	1	4
	12	16MAY97	78, 9	3	0	0	0	0	0	3	1	0	1	1	1	0	0	0	1	0	11	3	0	0	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.001.00062	SC	06OCT94	-14, .	4	3	1	2	2	2	4	3	3	3	2	2	2	1	0	1	0	35	9	7	6	12
	BL	20OCT94	1, .	3	2	0	2	1	0	4	3	3	2	0	2	2	0	0	0	0	24	6	5	3	10
	1	27OCT94	8, .	0	0	0	2	1	0	3	2	3	2	3	0	2	0	0	0	0	18	7	3	3	5
	2	03NOV94	15, .	1	0	0	1	0	0	3	2	3	1	3	0	0	0	0	0	0	14	4	3	1	6
	3	10NOV94	22, .	0	0	0	2	0	0	2	1	3	0	0	0	0	0	0	0	1	9	1	3	2	3
329.001.00064	SC	04NOV94	-6, -60	4	0	0	1	0	0	4	3	1	0	0	1	2	0	0	0	0	16	3	1	1	11
	BL	10NOV94	1, -54	2	0	0	1	0	0	4	3	1	0	1	1	2	0	0	0	0	15	4	1	1	9
	1	16NOV94	7, -48	2	0	0	1	0	0	3	3	0	0	1	0	1	0	0	0	0	11	2	0	1	8
	2	22NOV94	13, -42	1	0	0	1	0	0	2	2	0	0	0	0	1	0	0	0	1	8	2	0	1	5
	3	29NOV94	20, -35	1	0	0	1	0	0	2	1	0	0	1	0	0	0	0	0	0	6	1	0	1	4
	4	06DEC94	27, -28	0	0	0	1	0	0	2	1	0	0	0	0	0	0	0	0	2	6	2	0	1	3
	5	13DEC94	34, -21	1	0	0	1	0	0	1	1	0	0	1	0	0	0	0	0	0	5	1	0	1	3
	6	20DEC94	41, -14	1	0	0	1	0	0	2	2	0	0	0	0	1	0	0	0	0	7	1	0	1	5
	7	27DEC94	48, -7	1	0	0	0	0	0	2	2	1	0	0	0	1	0	0	0	0	7	1	1	0	5
	8	03JAN95	55, 1	1	0	0	1	0	0	3	2	0	0	0	0	1	0	0	0	0	8	1	0	1	6
	12	31JAN95	83, 29	0	0	0	1	0	0	1	1	0	0	1	0	1	0	0	0	1	6	3	0	1	2
	16	28FEB95	111, 57	0	0	0	1	0	0	2	2	0	0	1	0	1	0	0	0	0	7	2	0	1	4
	20	28MAR95	139, 85	1	0	0	1	0	0	3	2	0	0	0	1	1	0	0	0	0	9	2	0	1	6
329.001.00069	SC	07FEB95	-9, .	4	2	2	2	0	2	4	3	2	0	2	0	2	0	2	0	0	27	6	6	4	11
	BL	16FEB95	1, .	3	0	0	1	0	2	4	3	3	1	2	0	2	0	1	0	0	22	6	3	3	10
	1	23FEB95	8, .	2	0	0	1	0	2	4	2	0	0	1	0	2	0	0	0	0	14	3	0	3	8
	2	02MAR95	15, .	2	0	0	1	1	0	3	2	1	0	0	0	1	0	0	0	1	12	2	1	2	7
	3	09MAR95	22, .	1	1	0	1	0	2	3	2	1	0	0	0	1	0	0	1	0	13	1	2	3	6
	4	16MAR95	29, .	0	0	0	0	0	0	1	2	2	0	0	0	1	0	0	0	0	6	1	2	0	3
	5	23MAR95	36, .	0	0	0	0	0	1	2	0	1	1	1	2	1	0	0	1	0	10	5	1	1	2
	6	30MAR95	43, .	3	1	2	1	0	2	2	2	1	1	1	1	1	0	0	0	0	18	4	4	3	7
	7	06APR95	50, .	3	0	1	1	1	0	4	3	1	2	1	1	2	0	0	0	0	20	6	2	2	10

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
					HAMD Scores																					
329.001.00069	8	13APR95	57,	.	1	0	2	0	0	0	3	2	2	1	0	0	1	0	0	0	0	12	2	4	0	6
329.001.00071	SC	02FEB95	-21,	.	3	0	2	2	2	0	4	3	2	4	4	0	2	0	0	0	0	28	10	4	4	10
	BL	23FEB95	1,	.	4	2	2	2	0	1	4	3	1	2	3	0	2	1	0	0	0	27	7	5	3	12
	1	02MAR95	8,	.	3	2	0	2	0	0	3	3	2	2	4	0	2	0	0	1	0	24	8	4	2	9
	2	09MAR95	15,	.	3	0	2	2	0	1	4	3	1	2	3	0	2	0	0	0	0	23	7	3	3	10
	3	16MAR95	22,	.	2	0	1	2	0	0	3	2	1	2	1	0	2	2	1	0	0	19	6	2	2	9
	4	23MAR95	29,	.	2	0	0	2	0	0	2	2	0	1	2	0	1	0	1	0	0	13	5	0	2	6
	5	30MAR95	36,	.	1	0	0	2	0	0	2	2	0	0	1	0	1	0	0	0	0	9	2	0	2	5
	6	06APR95	43,	.	3	0	2	2	0	0	4	3	0	2	3	0	2	1	0	0	0	22	7	2	2	11
	7	13APR95	50,	.	3	0	0	2	0	0	4	2	1	2	0	0	2	0	0	0	0	16	4	1	2	9
	8	20APR95	57,	.	2	0	0	2	0	0	4	3	1	2	4	0	2	0	0	0	0	20	8	1	2	9
329.001.00123	SC	14DEC95	-21,	.	4	2	2	2	1	2	4	2	0	2	3	0	2	0	1	0	0	27	8	4	5	10
	BL	04JAN96	1,	.	3	0	1	2	0	0	4	3	1	1	3	2	2	0	1	0	0	23	9	2	2	10
	1	12JAN96	9,	.	1	0	0	2	0	0	3	1	1	1	0	0	1	0	1	0	0	11	3	1	2	5
	2	18JAN96	15,	.	0	0	0	1	0	0	3	1	1	0	0	0	1	0	1	0	0	8	2	1	1	4
	3	25JAN96	22,	.	3	0	1	0	0	0	3	2	1	2	3	0	2	0	0	0	0	17	7	2	0	8
	4	01FEB96	29,	.	0	0	0	1	2	0	3	0	2	0	2	0	1	0	0	0	0	11	3	2	3	3
	5	08FEB96	36,	.	1	0	0	0	0	0	3	2	1	0	0	0	1	0	0	0	0	8	1	1	0	6
	6	15FEB96	43,	.	0	0	0	1	0	0	2	0	0	0	0	0	1	0	0	0	0	4	1	0	1	2
	7	22FEB96	50,	.	3	1	2	0	0	0	4	3	2	1	2	0	2	0	2	0	0	22	7	5	0	10
329.001.00207	SC	19FEB96	-9,	.	2	2	2	2	0	0	4	2	2	0	2	1	1	0	0	0	0	20	4	6	2	8
	BL	28FEB96	1,	.	3	1	2	1	0	0	4	2	3	0	0	0	2	0	0	0	0	18	2	6	1	9
	1	06MAR96	8,	.	1	0	0	0	0	0	3	0	3	2	0	0	1	0	0	0	1	11	4	3	0	4
	2	13MAR96	15,	.	0	0	0	1	1	0	2	0	1	0	0	0	1	0	0	0	0	6	1	1	2	2
	3	20MAR96	22,	.	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	4	26MAR96	28,	.	0	0	0	0	0	0	2	0	0	0	0	1	0	0	0	0	0	3	1	0	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.001.00207	5	03APR96	36, .	1	0	0	0	0	0	2	0	1	0	0	0	0	0	0	0	0	4	0	1	0	3
	6	10APR96	43, .	2	0	0	0	0	0	4	1	1	1	0	0	0	0	0	0	0	9	1	1	0	7
	7	17APR96	50, .	2	1	0	0	0	0	3	0	1	0	1	0	0	0	0	0	2	10	3	2	0	5
	8	24APR96	57, .	3	1	0	2	0	0	3	2	1	1	1	0	0	0	0	1	0	15	2	2	2	8
329.002.00049	SC	03MAR95	-6, .	4	0	0	0	2	1	3	1	0	1	3	0	2	2	0	0	2	21	8	0	3	10
	BL	08MAR95	-1, .	4	0	0	0	0	2	3	1	0	1	0	1	2	2	0	0	1	17	5	0	2	10
	1	15MAR95	7, .	4	0	0	0	0	0	3	1	0	0	0	0	2	2	0	0	1	13	3	0	0	10
	2	22MAR95	14, .	4	0	0	0	1	0	3	1	0	0	0	1	2	2	0	0	1	15	4	0	1	10
	3	29MAR95	21, .	2	0	0	0	1	0	3	0	0	1	0	1	2	2	0	0	0	12	4	0	1	7
	4	05APR95	28, .	4	0	0	0	1	1	3	2	0	0	0	1	1	2	0	0	0	15	2	0	2	11
	5	12APR95	35, .	3	0	0	0	1	1	3	0	0	0	0	1	1	0	0	0	0	10	2	0	2	6
	6	19APR95	42, .	4	0	0	0	0	0	3	1	0	0	0	1	1	2	0	0	0	12	2	0	0	10
	7	27APR95	50, .	2	0	0	1	0	0	3	0	0	0	0	1	1	2	0	1	0	11	2	0	1	7
	8	05MAY95	58, .	3	0	0	0	0	0	3	1	0	0	0	1	1	2	0	0	1	12	3	0	0	9
329.002.00059	SC	03NOV94	-7, .	2	0	0	2	1	0	3	2	0	3	2	1	2	0	2	0	1	21	11	0	3	7
	BL	10NOV94	1, .	2	0	0	0	0	0	2	1	0	3	2	1	2	0	1	0	1	15	10	0	0	5
	1	17NOV94	8, .	2	0	0	1	0	0	3	1	1	2	1	1	2	0	2	0	1	17	9	1	1	6
	2	23NOV94	14, .	1	0	0	0	0	0	3	0	0	2	0	1	1	0	1	0	1	10	6	0	0	4
	3	01DEC94	22, .	2	0	0	2	0	0	3	1	0	2	1	0	1	0	1	0	1	14	6	0	2	6
	4	08DEC94	29, .	1	0	0	2	0	0	3	1	0	1	1	0	1	0	2	0	1	13	6	0	2	5
	5	15DEC94	36, .	0	0	0	0	0	0	3	1	0	2	0	0	1	0	2	0	0	9	5	0	0	4
	6	22DEC94	43, .	1	0	0	1	0	0	3	2	0	2	1	0	1	0	2	0	0	13	6	0	1	6
	7	29DEC94	50, .	1	0	0	0	0	0	3	2	0	2	1	0	1	0	1	0	0	11	5	0	0	6
	8	05JAN95	57, .	3	0	0	2	0	0	3	2	0	3	0	0	1	0	2	0	0	16	6	0	2	8
329.002.00060	SC	24JAN95	-7, -63	3	2	1	2	0	0	3	2	1	3	2	1	2	0	0	2	0	24	8	4	2	8
	BL	31JAN95	1, -56	1	0	0	1	0	1	3	1	0	2	2	1	2	0	0	2	0	16	7	0	2	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00060	1	07FEB95	8, -49	2	0	0	0	1	1	3	1	0	2	2	1	2	0	0	0	0	15	7	0	2	6
	2	14FEB95	15, -42	2	0	0	0	1	0	3	1	0	2	0	0	1	0	0	0	0	10	3	0	1	6
	3	21FEB95	22, -35	2	0	0	0	1	0	3	1	0	3	2	0	1	0	0	0	0	13	6	0	1	6
	4	28FEB95	29, -28	2	1	0	1	1	0	3	1	0	3	2	1	1	0	0	0	0	16	7	1	2	6
	5	07MAR95	36, -21	1	0	0	0	0	0	3	0	0	1	2	1	2	0	0	0	0	10	6	0	0	4
	6	14MAR95	43, -14	0	0	0	0	0	0	2	0	0	0	1	0	1	0	0	0	0	4	2	0	0	2
	7	21MAR95	50, -7	0	0	0	0	1	0	2	0	0	0	2	0	1	0	0	0	0	6	3	0	1	2
	8	28MAR95	57, 1	1	0	0	0	1	0	3	0	0	1	2	0	1	0	0	0	0	9	4	0	1	4
	12	25APR95	85, 29	3	1	1	1	1	0	3	1	0	2	2	2	2	0	0	1	0	20	8	2	2	7
329.002.00097	SC	20DEC94	-14, -72	3	2	1	2	0	2	3	2	1	3	2	0	2	0	0	0	0	23	7	4	4	8
	BL	03JAN95	1, -58	3	2	1	2	0	2	3	2	1	3	2	0	2	0	0	0	0	23	7	4	4	8
	1	10JAN95	8, -51	3	1	0	0	0	0	1	1	1	2	2	0	1	0	0	0	0	12	5	2	0	5
	2	18JAN95	16, -43	2	0	0	1	0	2	3	0	1	1	1	1	1	1	0	0	0	14	4	1	3	6
	3	24JAN95	22, -37	2	1	0	1	0	0	1	1	1	1	1	0	1	0	0	0	0	10	3	2	1	4
	4	31JAN95	29, -30	2	1	0	2	0	1	1	1	1	2	2	0	2	0	0	0	0	15	6	2	3	4
	5	07FEB95	36, -23	3	1	0	0	2	1	2	1	1	2	1	0	1	0	0	0	0	15	4	2	3	6
	6	14FEB95	43, -16	2	1	0	1	1	1	2	0	1	1	1	0	1	0	0	0	0	12	3	2	3	4
	7	21FEB95	50, -9	2	1	0	1	0	0	1	0	1	1	0	0	1	0	0	0	0	8	2	2	1	3
	8	02MAR95	59, 1	2	0	1	1	0	1	1	1	1	2	1	0	1	0	0	0	0	12	4	2	2	4
	12	30MAR95	87, 29	2	1	1	2	0	2	1	0	0	3	1	0	0	0	0	0	0	13	4	2	4	3
	16	27APR95	115, 57	0	0	0	0	0	0	1	1	0	1	0	0	1	0	0	0	0	4	2	0	0	2
	20	23MAY95	141, 83	2	0	0	2	0	0	1	1	1	2	2	0	1	0	0	0	0	12	5	1	2	4
	24	29JUN95	178, 120	2	0	0	0	0	0	1	0	1	3	2	0	2	0	0	0	0	11	7	1	0	3
	28	01AUG95	211, 153	3	0	0	1	0	1	0	2	2	3	1	0	0	1	0	0	0	14	4	2	2	6
	32	05SEP95	246, 188	0	0	0	1	0	0	1	0	1	1	0	0	1	0	0	0	0	5	2	1	1	1
329.002.00101	SC	20MAR95	-8, -66	3	1	1	1	1	0	3	0	1	4	2	0	1	0	0	1	0	19	7	3	2	6
	BL	28MAR95	1, -58	3	1	1	1	1	0	3	0	1	4	2	0	1	0	0	1	0	19	7	3	2	6

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00101	1	04APR95	8, -51	2	1	0	2	2	1	3	0	1	2	2	1	1	0	0	1	0	19	6	2	5	5
	2	13APR95	17, -42	1	0	0	1	2	0	2	0	0	2	1	0	1	0	0	0	0	10	4	0	3	3
	3	20APR95	24, -35	1	1	1	0	2	0	3	0	1	2	1	0	1	0	0	0	0	13	4	3	2	4
	4	27APR95	31, -28	1	1	0	0	0	0	2	0	0	1	2	0	1	0	0	0	0	8	4	1	0	3
	5	04MAY95	38, -21	1	1	0	0	0	0	2	0	0	1	1	0	1	0	0	0	0	7	3	1	0	3
	6	11MAY95	45, -14	2	1	1	0	0	0	2	1	0	1	1	0	1	0	0	0	0	10	3	2	0	5
	7	18MAY95	52, -7	1	1	0	0	0	0	2	0	0	1	1	0	0	0	0	0	0	6	2	1	0	3
	8	25MAY95	59, 1	1	1	0	0	1	0	1	0	0	1	0	0	1	0	0	0	0	6	2	1	1	2
	12	22JUN95	87, 29	2	1	0	0	0	0	1	0	0	4	0	0	0	0	0	1	0	9	4	1	0	3
	12	27JUN95	92, 34	0	0	0	0	2	0	0	0	0	1	0	0	0	0	0	1	0	4	1	0	2	0
329.002.00107	SC	18JAN96	-7, -63	3	1	0	2	0	0	4	1	0	1	1	0	2	0	1	0	0	16	5	1	2	8
	BL	25JAN96	1, -56	3	1	1	1	0	0	4	1	0	3	2	0	2	0	1	0	0	19	8	2	1	8
	1	01FEB96	8, -49	1	0	0	0	0	0	4	1	0	3	2	0	2	0	1	0	0	14	8	0	0	6
	2	08FEB96	15, -42	2	1	0	1	0	0	4	0	0	3	1	0	1	0	0	0	0	13	5	1	1	6
	3	13FEB96	20, -37	1	0	0	0	0	0	4	0	0	3	1	0	1	0	0	0	0	10	5	0	0	5
	4	20FEB96	27, -30	1	0	0	1	0	0	1	0	0	0	2	0	0	0	0	0	0	5	2	0	1	2
	5	27FEB96	34, -23	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	3	1	0	0	2
	6	05MAR96	41, -16	3	1	0	0	1	0	0	0	0	1	2	0	0	0	0	0	0	8	3	1	1	3
	7	15MAR96	51, -6	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	8	21MAR96	57, 1	2	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	3	1	0	0	2
	12	23APR96	90, 34	1	1	0	0	0	0	0	1	0	1	1	0	0	1	1	0	0	7	3	1	0	3
	16	21MAY96	118, 62	1	1	1	2	0	0	1	0	1	1	1	0	1	1	1	0	0	12	4	3	2	3
	20	20JUN96	148, 92	1	1	1	0	0	0	0	0	0	2	1	0	0	0	0	1	0	7	3	2	0	1
	24	18JUL96	176, 120	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	32	29AUG96	218, 162	0	0	0	2	0	0	1	0	0	1	0	0	0	0	0	0	0	4	1	0	2	1
	32	26SEP96	246, 190	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	1	0	3	1	0	0	1
329.002.00241	SC	25JAN96	-12, -68	2	2	3	1	1	1	2	0	2	1	0	1	1	0	0	0	0	17	3	7	3	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00241	BL	06FEB96	1, -56	2	0	3	0	1	1	2	3	4	1	0	1	2	0	0	0	0	20	4	7	2	7
	1	13FEB96	8, -49	2	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	3	1	0	0	2
	2	22FEB96	17, -40	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	3	27FEB96	22, -35	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	4	05MAR96	29, -28	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	2	2	0	0	0
	5	12MAR96	36, -21	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	6	19MAR96	43, -14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	26MAR96	50, -7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	02APR96	57, 1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	12	30APR96	85, 29	3	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	0	7	1	1	1	4
329.002.00246	SC	01APR96	-17, .	4	2	2	0	1	0	3	1	3	4	2	0	2	1	1	0	0	26	9	7	1	9
	BL	18APR96	1, .	3	2	3	1	0	0	3	1	4	4	2	0	2	0	1	0	0	26	9	9	1	7
	1	25APR96	8, .	3	1	1	0	1	0	2	2	3	4	1	1	2	0	1	0	0	22	9	5	1	7
	2	02MAY96	15, .	1	0	0	1	0	0	2	0	3	1	2	0	1	0	1	0	0	12	5	3	1	3
	3	09MAY96	22, .	3	1	2	1	0	0	2	0	4	3	2	0	2	0	1	0	0	21	8	7	1	5
	4	16MAY96	29, .	2	1	1	1	0	0	1	1	3	3	2	0	2	0	1	0	0	18	8	5	1	4
	5	23MAY96	36, .	1	1	1	0	0	0	2	0	2	3	2	0	2	0	1	0	0	15	8	4	0	3
	6	30MAY96	43, .	0	1	1	0	0	0	3	0	1	3	2	0	2	0	1	0	0	14	8	3	0	3
	7	04JUN96	48, .	2	1	0	0	0	0	1	1	3	3	1	0	2	0	1	0	0	15	7	4	0	4
	8	18JUN96	62, .	3	1	1	0	0	0	3	2	1	4	2	0	2	0	1	0	0	20	9	3	0	8
329.002.00320	SC	09MAY96	-7, -68	3	2	1	2	2	2	2	1	2	3	3	0	1	0	1	0	0	25	8	5	6	6
	BL	16MAY96	1, -61	2	2	0	2	2	2	2	1	2	1	3	0	1	0	1	0	0	21	6	4	6	5
	1	23MAY96	8, -54	4	1	2	0	2	0	2	1	2	3	2	0	1	0	0	0	0	20	6	5	2	7
	2	30MAY96	15, -47	4	1	1	2	2	2	3	2	1	3	0	0	2	0	0	0	0	23	5	3	6	9
	3	04JUN96	20, -42	3	1	0	2	2	1	1	0	2	2	2	0	0	0	0	0	0	16	4	3	5	4
	5	18JUN96	34, -28	3	2	1	2	1	1	2	0	2	2	2	0	2	0	0	0	0	20	6	5	4	5
	6	25JUN96	41, -21	2	1	0	1	1	2	1	0	1	1	1	0	0	0	0	0	0	11	2	2	4	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.002.00320	7	02JUL96	48, -14	3	2	2	0	2	1	2	0	1	1	1	0	2	0	0	0	0	17	4	5	3	5
	8	09JUL96	55, -7	3	1	2	1	2	0	0	0	0	1	0	0	0	0	0	0	0	10	1	3	3	3
	8	16JUL96	62, 1	2	1	0	1	1	1	0	0	1	1	0	0	1	0	0	0	0	9	2	2	3	2
	12	13AUG96	90, 29	2	1	1	1	2	1	0	0	1	1	0	0	0	0	0	0	0	10	1	3	4	2
	16	17SEP96	125, 64	3	1	1	2	1	0	0	0	1	2	1	0	1	0	1	0	0	14	5	3	3	3
329.002.00323	SC	04NOV96	-8, -66	3	1	1	1	0	0	2	1	0	4	1	1	2	0	1	0	0	18	9	2	1	6
	BL	12NOV96	1, -58	3	1	1	1	0	0	2	1	0	3	1	1	2	0	1	0	0	17	8	2	1	6
	1	19NOV96	8, -51	1	1	0	1	0	0	1	1	0	3	1	0	2	0	1	0	0	12	7	1	1	3
	2	26NOV96	15, -44	2	1	0	0	0	0	1	1	0	2	1	1	2	0	1	0	0	12	7	1	0	4
	3	05DEC96	24, -35	1	0	0	0	0	0	1	1	0	3	1	0	2	0	0	0	0	9	6	0	0	3
	4	10DEC96	29, -30	1	0	0	0	0	0	2	1	0	3	1	0	2	0	1	0	0	11	7	0	0	4
	5	17DEC96	36, -23	0	1	0	0	0	0	2	1	0	1	1	0	2	0	0	0	0	8	4	1	0	3
	6	26DEC96	45, -14	0	0	0	0	0	0	0	0	0	2	1	0	0	0	1	0	0	4	4	0	0	0
	7	02JAN97	52, -7	0	0	0	0	0	0	1	1	0	2	1	0	1	0	0	0	0	6	4	0	0	2
	8	09JAN97	59, 1	0	0	0	1	0	0	1	0	0	2	2	0	2	0	0	0	0	8	6	0	1	1
	12	04FEB97	85, 27	2	0	0	0	0	0	1	1	0	1	1	0	2	0	0	0	0	8	4	0	0	4
	16	04MAR97	113, 55	1	0	0	0	0	0	1	1	0	1	1	0	1	0	0	0	0	6	3	0	0	3
	20	03APR97	143, 85	1	0	0	0	0	0	1	0	0	1	0	0	2	0	0	0	0	5	3	0	0	2
	24	30APR97	170, 112	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	28	27MAY97	197, 139	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	32	12JUN97	213, 155	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
329.003.00074	SC	18JAN95	-7, -63	3	0	1	0	0	0	3	2	3	4	2	0	2	0	1	0	0	21	9	4	0	8
	BL	25JAN95	1, -56	3	1	2	0	0	0	3	0	3	3	0	0	2	0	0	0	0	17	5	6	0	6
	1	01FEB95	8, -49	2	1	1	0	0	0	3	1	3	3	2	0	0	0	0	0	0	16	5	5	0	6
	2	08FEB95	15, -42	3	0	1	0	0	0	3	1	3	3	2	0	1	0	0	0	0	17	6	4	0	7
	3	15FEB95	22, -35	2	0	0	0	0	0	3	0	2	4	1	0	1	0	0	0	0	13	6	2	0	5
	4	21FEB95	28, -29	3	0	0	0	0	0	1	1	1	3	1	0	1	0	0	0	0	11	5	1	0	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00074	5	01MAR95	36, -21	2	1	0	0	0	0	1	0	2	3	2	0	1	0	0	0	0	12	6	3	0	3
	7	15MAR95	50, -7	2	0	0	0	0	0	1	0	1	2	1	0	0	0	0	0	0	7	3	1	0	3
	8	22MAR95	57, 1	2	0	0	0	0	0	1	0	1	2	1	0	0	0	0	0	0	7	3	1	0	3
	12	19APR95	85, 29	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	3	1	0	0	2
	16	17MAY95	113, 57	1	0	0	0	0	0	1	0	0	2	0	0	0	0	0	0	0	4	2	0	0	2
	20	19JUN95	146, 90	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	2	2	0	0	0
	24	24JUL95	181, 125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	30AUG95	218, 162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	11OCT95	260, 204	0	0	0	0	0	0	1	0	0	2	1	0	0	0	0	0	0	4	3	0	0	1
329.003.00078	SC	11APR95	-15, .	2	1	0	0	0	0	4	1	0	2	0	0	2	0	0	0	0	12	4	1	0	7
	BL	26APR95	1, .	2	1	0	0	0	0	4	1	1	1	0	0	2	0	0	0	0	12	3	2	0	7
	1	02MAY95	7, .	1	0	0	0	0	0	3	1	1	1	0	0	1	0	0	0	0	8	2	1	0	5
	2	10MAY95	15, .	1	0	0	0	0	0	3	1	0	2	2	0	2	0	0	0	0	11	6	0	0	5
	3	17MAY95	22, .	2	1	0	0	0	0	3	1	0	2	0	0	2	0	0	0	0	11	4	1	0	6
	4	24MAY95	29, .	2	0	0	0	0	0	3	1	0	1	0	0	2	0	0	0	0	9	3	0	0	6
	5	30MAY95	35, .	2	0	0	0	0	0	3	0	0	1	0	0	2	0	0	0	0	8	3	0	0	5
	6	07JUN95	43, .	2	0	0	0	0	0	3	1	0	0	0	0	2	0	0	0	0	8	2	0	0	6
	7	15JUN95	51, .	2	0	0	0	0	0	3	0	0	0	0	0	2	0	0	0	0	7	2	0	0	5
	8	21JUN95	57, .	2	0	0	0	0	0	2	0	0	0	0	0	2	0	0	0	0	6	2	0	0	4
329.003.00080	BL	27NOV95	1, .	4	2	1	2	0	0	3	1	0	1	0	0	1	1	0	0	0	16	2	3	2	9
	1	04DEC95	8, .	4	0	1	2	0	2	3	2	0	0	0	0	2	1	0	0	1	18	3	1	4	10
	1	07DEC95	11, .	4	2	0	2	0	0	3	1	0	0	0	0	1	1	0	0	0	14	1	2	2	9
	3	18DEC95	22, .	2	0	2	2	0	0	3	2	0	0	1	0	1	2	0	1	0	16	2	2	2	9
	5	04JAN96	39, .	3	0	2	2	0	0	3	2	0	0	0	0	2	1	0	0	0	15	2	2	2	9
	6	10JAN96	45, .	2	0	1	2	0	0	3	1	0	0	0	0	0	1	0	0	0	10	0	1	2	7
	7	17JAN96	52, .	2	0	1	2	0	0	3	2	0	0	0	0	2	1	0	0	0	13	2	1	2	8
	8	24JAN96	59, .	3	0	1	2	0	0	3	2	0	0	0	0	2	1	0	0	0	14	2	1	2	9

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00085	SC	26OCT94	-13, .	3	0	3	0	2	1	2	1	1	2	0	1	0	0	0	0	0	16	3	4	3	6
	BL	07NOV94	-1, .	2	0	3	2	2	2	3	2	2	1	0	0	0	2	0	0	0	21	1	5	6	9
	1	14NOV94	7, .	3	0	0	0	2	2	3	1	2	1	0	0	0	0	0	0	0	14	1	2	4	7
	2	21NOV94	14, .	3	0	1	0	2	2	3	1	2	2	0	0	0	0	0	0	0	16	2	3	4	7
	3	28NOV94	21, .	3	0	0	0	2	1	2	1	1	2	0	0	0	0	0	0	0	12	2	1	3	6
	4	05DEC94	28, .	4	0	0	0	2	2	2	2	0	1	0	0	0	0	0	0	0	13	1	0	4	8
	5	12DEC94	35, .	3	0	0	0	2	2	1	2	2	2	0	0	0	0	0	0	0	14	2	2	4	6
	6	19DEC94	42, .	2	0	0	0	2	2	2	2	0	2	0	0	0	0	0	1	0	13	2	0	4	6
	7	27DEC94	50, .	2	0	0	0	2	0	2	1	2	2	0	0	0	0	0	0	0	11	2	2	2	5
	8	03JAN95	57, .	2	0	0	0	2	2	2	1	2	0	0	0	0	0	0	0	0	11	0	2	4	5
329.003.00086	SC	09NOV94	-19, -76	2	1	3	1	0	0	3	1	2	2	2	0	1	0	0	0	0	18	5	6	1	6
	BL	21NOV94	-7, -64	3	0	3	0	0	0	3	2	0	0	1	1	1	1	0	0	0	15	3	3	0	9
	1	05DEC94	8, -50	2	1	0	2	0	0	2	2	2	3	1	1	1	0	0	0	0	17	6	3	2	6
	2	12DEC94	15, -43	2	2	0	0	0	0	2	1	2	2	2	1	1	2	2	0	0	19	8	4	0	7
	3	19DEC94	22, -36	2	3	0	0	0	0	2	2	1	2	1	1	1	0	1	0	0	16	6	4	0	6
	4	27DEC94	30, -28	2	2	0	0	2	0	2	2	2	2	2	0	1	0	0	0	0	17	5	4	2	6
	5	03JAN95	37, -21	1	1	0	0	0	0	2	1	0	1	1	0	1	0	0	0	0	8	3	1	0	4
	6	09JAN95	43, -15	1	1	0	0	0	0	1	0	0	1	1	0	1	0	0	0	0	6	3	1	0	2
	7	17JAN95	51, -7	1	1	0	0	0	0	0	0	0	0	0	1	1	0	0	1	0	5	2	1	0	1
	8	23JAN95	57, -1	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	3	2	0	0	1
	12	13FEB95	78, 21	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	16	28MAR95	121, 64	1	1	0	1	1	0	0	0	1	0	0	0	1	0	0	0	0	6	1	2	2	1
	20	25APR95	149, 92	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	28	30MAY95	184, 127	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1
	32	11JUL95	226, 169	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	32	17AUG95	263, 206	0	0	0	0	0	0	1	0	0	1	0	1	1	0	0	1	0	5	3	0	0	1
329.003.00094	BL	24OCT95	1, .	3	0	3	0	0	0	3	2	0	1	0	0	2	0	0	0	0	14	3	3	0	8

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00094	1	31OCT95	8,	.	3	1	3	0	0	0	3	0	2	0	0	0	2	0	0	0	0	14	2	6	0	6
	2	07NOV95	15,	.	3	1	3	0	0	0	3	0	2	0	0	0	2	0	0	0	0	14	2	6	0	6
	3	14NOV95	22,	.	2	1	2	1	0	0	2	1	1	1	0	0	2	0	0	0	0	13	3	4	1	5
	4	21NOV95	29,	.	1	1	0	0	0	0	2	0	1	2	0	0	1	0	0	0	0	8	3	2	0	3
	5	28NOV95	36,	.	2	2	2	1	0	0	2	1	1	2	0	0	2	0	0	0	0	15	4	5	1	5
	6	05DEC95	43,	.	2	1	2	1	0	0	1	1	1	2	0	0	1	0	0	0	0	12	3	4	1	4
	7	12DEC95	50,	.	3	2	3	0	0	0	3	3	1	3	0	1	2	0	0	0	0	21	6	6	0	9
	8	19DEC95	57,	.	2	1	2	2	0	0	3	1	1	3	1	0	2	0	0	0	0	18	6	4	2	6
329.003.00251	BL	27MAR96	-1,	.	2	2	2	2	0	1	3	1	1	3	0	1	2	0	0	0	0	20	6	5	3	6
	1	04APR96	8,	.	2	2	2	2	0	0	3	0	0	2	0	0	2	0	0	0	0	15	4	4	2	5
	2	09APR96	13,	.	1	0	0	2	0	0	3	0	0	1	0	0	2	0	0	0	0	9	3	0	2	4
329.003.00252	SC	19MAR96	-22,	.	3	1	1	0	0	0	3	2	1	3	0	0	2	0	0	0	0	16	5	3	0	8
	BL	09APR96	-1,	.	3	0	0	0	0	0	4	1	1	3	0	1	2	0	0	0	0	15	6	1	0	8
	1	16APR96	7,	.	2	0	0	0	0	0	3	2	1	3	0	0	2	0	0	0	0	13	5	1	0	7
	2	23APR96	14,	.	1	0	0	0	0	0	3	1	0	0	0	0	2	0	0	0	0	7	2	0	0	5
	3	30APR96	21,	.	2	1	0	0	0	0	3	1	1	1	0	0	2	0	0	0	0	11	3	2	0	6
	4	09MAY96	30,	.	1	0	0	0	0	0	2	1	1	1	0	0	2	0	0	0	0	8	3	1	0	4
	5	14MAY96	35,	.	1	0	0	0	0	0	1	1	0	0	0	0	1	0	0	0	0	4	1	0	0	3
	6	21MAY96	42,	.	2	1	0	0	0	0	1	0	1	1	0	0	2	0	0	0	0	8	3	2	0	3
	7	28MAY96	49,	.	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	8	04JUN96	56,	.	2	1	1	0	0	0	2	1	0	2	0	0	2	0	0	0	0	11	4	2	0	5
329.003.00291	BL	03JUL96	1,	-65	4	2	2	2	1	1	3	3	2	4	2	2	2	2	3	2	0	37	13	6	4	12
	2	15JUL96	13,	-53	3	2	1	1	1	1	3	2	1	3	2	1	2	1	2	0	0	26	10	4	3	9
	3	24JUL96	22,	-44	1	2	2	0	0	1	1	1	1	1	1	2	1	1	1	0	0	16	6	5	1	4
	4	31JUL96	29,	-37	1	1	1	2	0	0	1	1	1	1	1	0	0	0	0	0	0	10	2	3	2	3
	5	07AUG96	36,	-30	1	1	1	2	0	0	1	1	1	1	0	0	0	0	0	0	0	9	1	3	2	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.003.00291	6	14AUG96	43, -23	1	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	3	0	0	1	2
	7	21AUG96	50, -16	0	0	0	2	2	0	0	0	1	1	1	0	1	0	0	0	0	8	3	1	4	0
	8	28AUG96	57, -9	0	0	0	1	0	0	0	0	1	1	0	0	0	0	0	0	0	3	1	1	1	0
	8	04SEP96	64, -2	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	12	02OCT96	92, 27	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	16	30OCT96	120, 55	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
329.003.00315	BL	05NOV96	-7, .	3	1	0	2	0	0	3	3	0	0	0	0	2	0	0	0	0	14	2	1	2	9
	1	21NOV96	10, .	3	2	1	0	0	0	3	2	0	0	0	0	0	0	0	0	0	11	0	3	0	8
	2	26NOV96	15, .	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	3	0	1	0	2
	3	03DEC96	22, .	1	0	0	0	.	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	4	12DEC96	31, .	1	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	3	0	0	0	3
	5	17DEC96	36, .	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	6	23DEC96	42, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	07JAN97	57, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00316	BL	17DEC96	1, .	3	1	1	2	0	0	3	2	2	2	0	1	2	0	0	1	0	20	5	4	2	8
	1	23DEC96	7, .	3	1	0	0	0	0	3	2	2	0	0	1	2	0	0	0	0	14	3	3	0	8
	3	07JAN97	22, .	2	0	0	1	0	0	2	0	0	1	1	0	0	0	0	1	0	8	2	0	1	4
	4	14JAN97	29, .	3	1	2	1	1	0	3	2	1	3	0	0	2	0	0	0	0	19	5	4	2	8
	5	21JAN97	36, .	3	1	1	2	2	2	2	2	1	2	0	0	2	0	0	0	0	20	4	3	6	7
	6	28JAN97	43, .	3	2	2	2	2	0	3	2	1	3	1	0	2	0	0	0	0	23	6	5	4	8
	7	04FEB97	50, .	3	1	2	2	2	0	2	2	1	3	0	0	2	0	0	0	0	20	5	4	4	7
	8	11FEB97	57, .	3	2	2	2	2	0	2	1	1	3	0	0	2	0	0	0	0	20	5	5	4	6
329.004.00016	SC	01MAR95	-12, .	3	0	0	2	0	0	3	2	1	1	1	1	2	0	0	2	0	18	5	1	2	8
	BL	13MAR95	1, .	3	0	0	2	0	0	3	2	1	1	2	1	2	0	0	1	0	18	6	1	2	8
	1	20MAR95	8, .	3	0	0	2	0	0	3	2	1	2	0	1	2	0	0	2	0	18	5	1	2	8
	2	29MAR95	17, .	3	0	0	2	0	0	2	0	2	1	0	0	2	0	0	0	0	12	3	2	2	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.004.00016	3	05APR95	24, .	3	0	0	2	0	0	3	2	1	1	0	1	2	0	0	0	0	15	4	1	2	8
	4	12APR95	31, .	3	0	0	2	0	0	3	2	1	1	0	1	2	0	0	0	0	15	4	1	2	8
	5	19APR95	38, .	3	0	0	2	0	0	2	2	1	1	0	1	2	0	0	0	0	14	4	1	2	7
329.004.00018	SC	19APR95	-14, .	3	2	2	2	2	0	2	0	1	2	0	0	2	1	0	0	0	19	4	5	4	6
	BL	03MAY95	1, .	3	1	2	2	2	1	2	0	2	2	2	0	2	0	1	0	0	22	7	5	5	5
	1	11MAY95	9, .	3	1	1	2	2	2	3	0	2	2	2	1	2	0	0	0	0	23	7	4	6	6
	2	18MAY95	16, .	2	0	0	2	0	2	1	0	2	1	2	0	1	0	0	0	0	13	4	2	4	3
	3	25MAY95	23, .	3	1	1	1	1	2	2	0	1	1	1	0	2	0	0	0	0	16	4	3	4	5
	4	01JUN95	30, .	3	0	0	0	0	2	3	0	2	1	2	0	2	0	0	0	0	15	5	2	2	6
	5	08JUN95	37, .	3	1	2	0	0	1	2	0	1	1	2	1	0	0	1	0	0	15	5	4	1	5
	7	19JUN95	48, .	3	1	1	1	1	0	3	0	1	1	1	0	2	0	0	0	0	15	4	3	2	6
	7	22JUN95	51, .	3	0	1	0	0	1	2	0	1	1	1	0	2	0	0	0	0	12	4	2	1	5
	8	29JUN95	58, .	1	0	0	1	0	2	1	0	1	1	2	0	1	0	0	0	0	10	4	1	3	2
329.004.00020	SC	02NOV95	-7, .	3	2	2	1	1	0	3	0	2	1	0	0	2	1	0	0	0	18	3	6	2	7
	BL	09NOV95	1, .	3	2	2	2	0	0	2	0	2	1	1	0	2	1	1	0	0	19	5	6	2	6
	1	16NOV95	8, .	2	2	3	2	0	0	1	0	2	1	1	2	2	0	0	1	0	19	6	7	2	3
	2	24NOV95	16, .	2	1	2	2	0	0	2	0	2	2	1	1	2	0	0	0	0	17	6	5	2	4
329.004.00213	SC	18JUL96	-15, -69	2	2	1	2	1	0	3	0	2	1	2	1	2	0	1	0	0	20	7	5	3	5
	BL	01AUG96	-1, -55	2	0	2	0	0	0	3	0	1	1	1	2	1	0	0	1	0	14	5	3	0	5
	1	08AUG96	7, -48	2	0	3	2	0	0	3	0	0	1	2	1	2	0	0	0	0	16	6	3	2	5
	2	15AUG96	14, -41	4	0	2	2	0	0	3	0	0	1	0	1	2	0	0	0	0	15	4	2	2	7
	3	21AUG96	20, -35	1	0	1	1	0	0	1	0	1	1	0	1	0	0	0	0	0	7	2	2	1	2
	4	29AUG96	28, -27	1	0	0	1	0	0	1	0	1	1	1	0	1	0	0	0	0	7	3	1	1	2
	5	03SEP96	33, -22	0	0	0	0	0	0	1	0	1	1	1	0	1	0	0	0	0	5	3	1	0	1
	6	10SEP96	40, -15	1	0	0	0	0	0	0	0	1	1	1	0	1	0	0	1	0	6	3	1	0	1
	7	17SEP96	47, -8	1	0	0	0	0	0	0	0	1	1	1	1	1	0	0	1	0	7	4	1	0	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.004.00213	8	24SEP96	54, -1	3	0	3	0	0	0	0	0	0	1	0	0	0	0	0	0	0	7	1	3	0	3
	12	22OCT96	82, 28	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	16	19NOV96	110, 56	1	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	4	2	1	0	1
	20	20DEC96	141, 87	2	0	3	0	0	0	0	0	0	1	1	0	1	0	0	0	0	8	3	3	0	2
	24	21JAN97	173, 119	1	0	2	0	0	0	0	0	0	1	0	0	0	0	0	0	0	4	1	2	0	1
	28	18FEB97	201, 147	2	0	3	0	0	0	0	0	0	1	1	0	0	0	0	0	0	7	2	3	0	2
	32	19MAR97	230, 176	0	0	0	0	0	0	1	0	1	1	1	0	1	0	0	0	0	5	3	1	0	1
329.005.00001	SC	11APR94	-9, .	3	0	2	2	1	0	2	0	0	3	2	1	2	0	0	0	0	18	8	2	3	5
	BL	20APR94	1, .	3	0	2	2	0	0	2	1	0	4	2	1	2	0	0	0	0	19	9	2	2	6
	1	27APR94	8, .	3	0	2	1	0	0	2	2	0	2	0	1	2	0	0	1	0	16	5	2	1	7
	2	04MAY94	15, .	3	0	2	0	0	0	3	2	1	1	2	1	1	0	0	0	0	16	5	3	0	8
	3	11MAY94	22, .	3	0	2	0	0	0	3	1	0	2	0	1	1	0	0	0	0	13	4	2	0	7
	4	18MAY94	29, .	2	0	2	2	0	0	3	1	0	3	0	1	1	0	0	0	0	15	5	2	2	6
	5	25MAY94	36, .	2	0	2	2	0	0	3	1	0	3	3	1	1	0	0	0	0	18	8	2	2	6
	6	01JUN94	43, .	2	0	0	2	0	0	1	1	0	1	1	0	1	0	0	0	0	9	3	0	2	4
	7	08JUN94	50, .	2	0	0	0	0	0	1	1	0	3	3	0	2	0	0	0	1	13	9	0	0	4
	8	15JUN94	57, .	3	0	2	1	0	0	0	1	0	1	0	0	1	0	1	0	0	10	3	2	1	4
329.005.00005	SC	24OCT94	-8, .	3	0	2	2	1	0	3	2	0	1	2	0	1	0	0	0	1	18	5	2	3	8
	BL	01NOV94	1, .	2	0	2	2	0	1	2	1	0	0	2	0	0	0	0	0	0	12	2	2	3	5
	1	08NOV94	8, .	1	0	2	2	1	0	0	0	0	1	0	0	0	0	0	0	0	7	1	2	3	1
329.005.00010	SC	07DEC94	-6, -63	2	2	2	2	2	2	2	1	1	1	0	1	1	0	0	0	0	19	3	5	6	5
	BL	13DEC94	1, -57	2	2	1	2	2	2	2	1	1	1	0	1	1	0	0	0	0	18	3	4	6	5
	1	20DEC94	8, -50	2	1	0	2	0	2	1	1	1	1	0	0	0	0	0	1	0	12	1	2	4	4
	2	27DEC94	15, -43	0	2	0	0	0	0	0	0	2	1	0	0	0	0	0	1	0	6	1	4	0	0
	3	04JAN95	23, -35	1	0	0	0	1	0	0	0	1	1	1	0	1	0	0	0	0	6	3	1	1	1
	4	11JAN95	30, -28	0	0	0	2	2	2	1	0	1	1	0	0	1	0	0	0	0	10	2	1	6	1

* days relative to start of acute phase, days relative to start of continuation phase
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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00010	5	18JAN95	37, -21	1	0	0	2	0	2	1	0	1	1	0	1	2	1	0	0	0	12	4	1	4	3
	6	25JAN95	44, -14	1	0	0	0	0	0	1	1	1	1	0	1	1	0	0	2	0	9	3	1	0	3
	7	02FEB95	52, -6	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	2	0	0
	8	08FEB95	58, 1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	2	0	0
	12	10MAR95	88, 31	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	3	1	1	0	1
	16	13APR95	122, 65	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	2	0	1	0	0
	20	10MAY95	149, 92	1	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	3	0	1	1	1
	24	06JUN95	176, 119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	32	12JUL95	212, 155	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2	1	0	0	0
	32	09AUG95	240, 183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00012	SC	12DEC94	-7, -66	3	1	1	0	0	0	2	2	3	1	0	0	2	0	0	1	0	16	3	5	0	7
	BL	19DEC94	1, -59	3	1	0	0	0	0	3	2	3	1	0	0	1	0	0	1	0	15	2	4	0	8
	1	27DEC94	9, -51	1	0	0	0	1	2	3	2	4	0	1	1	1	0	0	0	0	16	3	4	3	6
	2	05JAN95	18, -42	2	0	1	0	1	2	1	1	2	1	0	0	1	0	0	0	0	12	2	3	3	4
	3	12JAN95	25, -35	1	0	0	0	0	0	1	1	2	0	0	0	1	0	0	0	0	6	1	2	0	3
	4	18JAN95	31, -29	1	0	0	0	0	0	1	1	2	1	0	0	0	0	0	0	0	6	1	2	0	3
	5	25JAN95	38, -22	1	0	0	0	0	1	1	0	1	0	0	0	1	0	0	0	0	5	1	1	1	2
	6	31JAN95	44, -16	2	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1	0	7	1	1	0	4
	7	08FEB95	52, -8	1	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	4	1	1	0	2
	8	16FEB95	60, 1	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	12	27MAR95	99, 40	1	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	5	2	1	0	2
	20	04MAY95	137, 78	1	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	4	1	1	0	2
	24	31MAY95	164, 105	2	0	0	2	0	0	1	0	0	0	0	0	0	0	0	1	0	6	0	0	2	3
329.005.00111	SC	05JAN95	-6, -62	2	0	1	2	1	0	2	3	1	1	0	0	1	0	1	0	0	15	3	2	3	7
	BL	11JAN95	1, -56	2	0	0	2	1	1	2	1	2	1	0	0	1	0	0	0	0	13	2	2	4	5
	1	18JAN95	8, -49	2	0	2	0	1	1	1	2	1	2	0	1	0	0	0	1	0	14	3	3	2	5
	2	25JAN95	15, -42	2	0	0	0	0	1	1	3	3	1	0	0	1	0	0	0	0	12	2	3	1	6

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.005.00111	3	01FEB95	22, -35	2	0	0	0	2	2	2	1	1	1	0	1	2	0	0	1	0	15	4	1	4	5
	4	08FEB95	29, -28	0	0	0	0	0	1	1	0	3	0	0	1	0	0	0	1	0	7	1	3	1	1
	5	15FEB95	36, -21	1	0	0	0	2	1	1	1	2	0	0	1	0	0	0	0	0	9	1	2	3	3
	6	22FEB95	43, -14	0	0	0	0	1	0	0	0	1	1	0	1	0	0	0	1	0	5	2	1	1	0
	7	01MAR95	50, -7	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	2	0	0
	8	08MAR95	57, 1	1	0	0	0	1	0	2	0	1	0	0	0	1	0	0	0	0	6	1	1	1	3
	12	05APR95	85, 29	0	0	0	0	1	0	1	0	1	0	0	1	0	0	1	1	0	6	2	1	1	1
	12	19APR95	99, 43	0	0	0	0	2	2	1	0	0	0	0	0	2	0	0	1	0	8	2	0	4	1
	16	03MAY95	113, 57	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
329.005.00114	SC	23JAN95	-8, -65	3	0	1	1	0	0	2	2	0	1	0	1	2	1	0	1	0	15	4	1	1	8
	BL	31JAN95	1, -57	1	0	0	1	1	2	2	1	2	1	0	1	0	0	0	1	0	13	2	2	4	4
	1	07FEB95	8, -50	3	0	0	1	0	0	0	3	2	1	0	1	0	0	0	0	0	11	2	2	1	6
	2	14FEB95	15, -43	3	0	0	1	1	0	0	2	2	0	0	1	0	0	0	0	0	10	1	2	2	5
	3	21FEB95	22, -36	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	4	28FEB95	29, -29	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1
	5	09MAR95	38, -20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6	15MAR95	44, -14	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	1	0	3	0	0	2	0
	7	22MAR95	51, -7	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	2	0	0
	8	29MAR95	58, 1	3	1	1	1	0	0	1	0	2	0	0	0	0	0	0	1	0	10	0	4	1	4
	12	26APR95	86, 29	3	0	1	0	0	0	2	1	1	1	0	0	0	0	0	0	0	9	1	2	0	6
	16	17MAY95	107, 50	3	0	0	2	0	0	2	1	0	1	0	0	0	1	0	0	0	10	1	0	2	7
329.005.00115	SC	27JAN95	-10, -81	3	1	0	2	2	1	2	1	1	1	0	1	2	2	2	2	0	23	6	2	5	8
	BL	06FEB95	1, -71	2	0	1	2	2	1	2	1	1	1	0	1	2	2	2	1	0	21	6	2	5	7
	1	13FEB95	8, -64	1	1	0	0	1	2	0	0	3	1	1	2	2	2	2	1	0	19	8	4	3	3
	2	20FEB95	15, -57	0	0	0	2	0	0	1	0	2	1	2	1	2	0	1	1	0	13	7	2	2	1
	3	02MAR95	25, -47	2	0	0	0	1	0	3	1	0	1	0	1	2	0	2	0	0	13	6	0	1	6
	5	10MAR95	33, -39	0	0	0	0	1	0	0	0	1	0	0	0	2	0	1	1	0	6	3	1	1	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00115	6	17MAR95	40, -32	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	7	28MAR95	51, -21	0	0	0	0	0	0	0	0	4	0	0	0	2	0	0	0	0	6	2	4	0	0
	8	10APR95	64, -8	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	8	18APR95	72, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0	0	0	0
	12	27APR95	81, 10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00120	SC	22AUG95	-8, .	3	0	2	0	0	0	3	1	0	1	0	0	2	0	0	0	2	14	5	2	0	7
	BL	30AUG95	1, .	3	0	0	1	0	0	3	2	0	2	0	0	0	0	0	0	1	12	3	0	1	8
	1	07SEP95	9, .	3	0	0	0	0	0	3	0	4	3	0	0	0	0	0	0	1	14	4	4	0	6
	2	14SEP95	16, .	2	0	0	0	0	0	3	0	0	0	0	0	1	0	0	0	1	7	2	0	0	5
	3	21SEP95	23, .	1	0	0	0	0	0	1	0	0	2	0	0	1	0	0	0	1	6	4	0	0	2
	4	28SEP95	30, .	2	1	0	1	0	0	1	0	0	2	0	0	0	0	0	0	1	8	3	1	1	3
	5	05OCT95	37, .	2	0	0	1	0	0	2	0	0	2	1	0	0	0	0	0	0	8	3	0	1	4
	6	12OCT95	44, .	2	1	1	1	0	0	1	0	0	3	0	0	1	0	0	0	0	10	4	2	1	3
	7	19OCT95	51, .	3	0	0	2	0	0	2	0	0	2	0	1	0	0	0	0	0	10	3	0	2	5
	8	26OCT95	58, .	1	0	0	2	0	0	1	0	0	2	0	0	0	0	0	0	0	6	2	0	2	2
329.005.00253	SC	31JAN96	-8, .	3	0	2	2	2	0	1	0	2	1	1	1	1	0	0	1	1	18	5	4	4	4
	BL	08FEB96	1, .	3	1	1	2	2	0	2	0	1	0	0	1	0	0	0	0	0	13	1	3	4	5
	1	14FEB96	7, .	3	0	1	2	1	0	2	1	1	0	0	1	1	0	0	0	0	13	2	2	3	6
	2	21FEB96	14, .	3	0	1	2	1	0	2	0	1	0	0	1	1	0	0	0	0	12	2	2	3	5
	3	28FEB96	21, .	3	0	2	2	1	0	3	1	1	1	0	1	1	0	0	0	0	16	3	3	3	7
	4	06MAR96	28, .	3	1	2	2	0	0	3	0	1	1	0	1	1	0	0	0	0	15	3	4	2	6
	5	14MAR96	36, .	3	1	2	1	1	0	2	0	1	1	0	0	1	0	0	0	0	13	2	4	2	5
	6	20MAR96	42, .	3	1	2	1	1	0	2	0	1	1	0	0	1	0	0	0	0	13	2	4	2	5
	7	28MAR96	50, .	3	0	2	2	2	0	1	1	2	1	0	0	1	0	0	0	0	15	2	4	4	5
	8	03APR96	56, .	3	1	1	1	1	0	2	0	1	1	1	1	1	0	0	0	0	14	4	3	2	5
329.005.00254	SC	08FEB96	-7, -62	3	2	2	0	0	0	3	2	0	2	2	1	1	0	0	1	0	19	6	4	0	8

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00254	BL	14FEB96	-1, -56	3	2	2	0	0	1	1	2	0	2	1	0	1	0	0	2	0	17	4	4	1	6
	1	21FEB96	7, -49	2	0	2	0	0	1	1	2	2	1	0	0	2	0	0	0	0	13	3	4	1	5
	2	28FEB96	14, -42	3	2	2	0	0	0	0	2	0	2	2	0	2	0	0	1	0	16	6	4	0	5
	3	06MAR96	21, -35	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	3	1	0	0	2
	4	13MAR96	28, -28	1	0	0	0	0	0	0	1	0	1	0	1	2	0	0	1	0	7	4	0	0	2
	5	20MAR96	35, -21	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	3	1	0	0	2
	6	27MAR96	42, -14	1	0	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0	4	2	0	0	2
	7	03APR96	49, -7	2	0	1	0	0	0	1	0	0	1	0	0	0	1	0	1	0	7	1	1	0	4
	8	10APR96	56, 1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	12	22MAY96	98, 43	1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1	0	4	1	0	0	2
	16	12JUN96	119, 64	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2	1	0	0	0
	20	10JUL96	147, 92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24	07AUG96	175, 120	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	12SEP96	211, 156	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0
	32	16OCT96	245, 190	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.005.00293	SC	06MAR97	-6, .	4	0	1	0	0	1	3	2	1	1	0	1	1	2	0	0	0	17	3	2	1	11
	BL	12MAR97	1, .	3	1	1	0	0	0	3	2	0	1	0	0	1	0	0	0	0	12	2	2	0	8
	1	19MAR97	8, .	4	1	0	0	0	0	3	2	0	1	0	0	2	0	0	0	0	13	3	1	0	9
	2	25MAR97	14, .	3	1	0	0	0	0	2	2	0	1	0	0	0	0	0	0	0	9	1	1	0	7
	3	02APR97	22, .	2	0	0	0	0	0	0	2	0	1	0	0	0	0	0	0	0	5	1	0	0	4
	4	09APR97	29, .	2	0	0	2	0	0	0	2	0	1	0	0	0	0	0	0	0	7	1	0	2	4
	5	16APR97	36, .	3	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	6	1	0	0	5
	6	23APR97	43, .	2	0	0	0	0	0	2	2	0	1	0	0	0	0	0	0	0	7	1	0	0	6
	7	30APR97	50, .	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	3	0	0	0	3
	8	07MAY97	57, .	1	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	4	1	0	0	3
329.005.00298	SC	15MAY96	-7, -63	3	0	2	1	1	1	2	2	1	1	0	0	1	0	0	0	0	15	2	3	3	7
	BL	22MAY96	1, -56	3	0	1	0	0	0	2	2	2	1	1	0	2	0	0	0	0	14	4	3	0	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.005.00298	1	30MAY96	9, -48	1	0	0	2	0	0	1	2	2	1	0	1	0	0	0	0	0	10	2	2	2	4
	2	06JUN96	16, -41	3	0	0	0	0	0	2	2	2	1	0	1	1	0	0	1	0	13	3	2	0	7
	3	12JUN96	22, -35	3	0	1	0	0	0	1	2	1	1	0	1	1	0	0	0	0	11	3	2	0	6
	4	19JUN96	29, -28	0	0	0	0	0	0	1	1	2	1	0	0	0	0	0	0	0	5	1	2	0	2
	5	26JUN96	36, -21	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	3	0	0	0	3
	6	03JUL96	43, -14	2	0	0	0	0	0	1	1	1	1	0	0	2	0	0	0	0	8	3	1	0	4
	7	10JUL96	50, -7	0	0	0	0	0	0	2	1	0	0	0	0	0	1	0	1	0	5	0	0	0	4
	8	17JUL96	57, 1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	12	07AUG96	78, 22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	19SEP96	121, 65	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	0	0	3	1	1	0	1
	20	17OCT96	149, 93	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	3	1	1	0	1
	24	14NOV96	177, 121	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	28	12DEC96	205, 149	1	1	0	0	0	0	0	0	0	1	0	0	2	0	0	0	0	5	3	1	0	1
	32	13JAN97	237, 181	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0	0	0	1
329.005.00331	SC	14NOV96	-7, .	4	2	2	2	2	2	3	2	3	2	2	1	2	0	1	0	0	30	8	7	6	9
	BL	21NOV96	1, .	3	2	0	2	2	2	1	2	3	2	2	1	2	0	0	0	0	24	7	5	6	6
	1	27NOV96	7, .	3	2	0	2	2	2	2	1	3	2	0	1	2	0	1	0	0	23	6	5	6	6
	2	04DEC96	14, .	3	2	3	2	2	2	2	1	2	2	0	1	2	0	0	0	0	24	5	7	6	6
	3	12DEC96	22, .	2	1	1	2	2	2	1	1	2	1	0	1	0	0	0	0	0	16	2	4	6	4
	4	19DEC96	29, .	1	1	0	2	1	1	1	0	1	1	0	1	0	0	0	1	0	11	2	2	4	2
	5	26DEC96	36, .	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	6	02JAN97	43, .	1	1	1	1	1	2	1	1	1	2	0	0	0	0	0	0	0	12	2	3	4	3
	7	10JAN97	51, .	1	0	0	2	1	0	0	1	1	1	0	1	0	0	0	1	0	9	2	1	3	2
	8	16JAN97	57, .	2	0	1	0	1	1	1	1	1	1	0	1	1	0	0	0	0	11	3	2	2	4
329.005.00334	SC	24JAN97	-7, .	3	1	3	2	0	0	2	1	2	1	0	1	0	0	0	0	0	16	2	6	2	6
	BL	29JAN97	-2, .	2	0	1	2	1	0	3	1	2	1	0	1	1	0	0	1	0	16	3	3	3	6
	1	06FEB97	7, .	3	0	1	0	2	0	2	1	2	1	0	1	1	0	0	0	0	14	3	3	2	6

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.005.00334	2	13FEB97	14, .	1	0	2	0	0	0	1	0	1	1	0	1	1	0	0	0	0	8	3	3	0	2
	3	21FEB97	22, .	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	4	26FEB97	27, .	1	0	1	1	1	1	0	1	3	1	0	2	0	0	0	2	0	14	3	4	3	2
	5	06MAR97	35, .	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	3	0	1	0	2
	6	13MAR97	42, .	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	3	0	1	1	1
	7	21MAR97	50, .	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	2	0	3	0	1	0	0
	8	27MAR97	56, .	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
329.006.00037	SC	20JAN95	-8, .	1	0	0	0	0	0	0	2	2	3	1	0	1	1	0	0	1	12	6	2	0	4
	BL	27JAN95	-1, .	2	1	1	0	0	0	2	0	1	0	0	0	1	0	3	0	1	12	5	3	0	4
	1	03FEB95	7, .	0	0	0	0	1	2	0	0	3	0	1	1	1	1	0	0	1	11	4	3	3	1
	2	13FEB95	17, .	1	1	0	2	1	1	1	0	3	1	2	1	1	1	2	1	1	20	8	4	4	3
	4	22FEB95	26, .	3	2	1	2	2	0	2	0	0	2	0	0	1	1	0	0	0	16	3	3	4	6
329.006.00042	SC	01DEC95	-6, -63	1	2	2	0	1	0	2	1	4	2	2	0	2	0	2	0	0	21	8	8	1	4
	BL	06DEC95	-1, -58	1	2	2	1	2	0	2	0	4	2	1	0	2	0	1	0	0	20	6	8	3	3
	1	13DEC95	7, -51	1	2	0	1	1	2	1	1	3	0	2	0	1	0	0	0	0	15	3	5	4	3
	2	20DEC95	14, -44	1	2	2	1	1	0	2	1	1	0	1	0	0	0	0	0	0	12	1	5	2	4
	3	27DEC95	21, -37	3	2	2	1	1	0	1	1	2	1	2	0	1	0	0	0	0	17	4	6	2	5
	4	03JAN96	28, -30	1	3	1	1	1	0	1	1	0	3	2	0	1	0	0	1	0	16	6	4	2	3
	5	10JAN96	35, -23	1	3	1	1	1	0	1	0	2	1	2	0	2	0	1	0	0	16	6	6	2	2
	6	17JAN96	42, -16	1	3	1	1	0	0	2	0	2	0	2	0	1	0	0	2	0	15	3	6	1	3
	7	23JAN96	48, -10	1	2	1	1	0	1	0	0	1	2	1	0	0	0	1	0	0	11	4	4	2	1
	8	02FEB96	58, 1	1	1	2	0	0	0	0	0	1	1	1	1	0	0	0	0	0	8	3	4	0	1
	12	29FEB96	85, 28	1	1	2	0	0	0	0	0	1	2	1	0	1	0	0	0	0	9	4	4	0	1
	16	26MAR96	111, 54	1	0	0	0	0	0	0	0	1	2	1	0	1	0	0	0	0	6	4	1	0	1
	20	23APR96	139, 82	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	1	1	0	0
	24	21MAY96	167, 110	1	2	0	0	0	0	0	4	0	0	1	0	0	0	0	0	0	8	1	2	0	5
	28	18JUN96	195, 138	1	0	0	1	0	2	0	0	4	1	1	0	1	0	0	0	0	11	3	4	3	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.006.00042	32	16JUL96	223, 166	1	2	1	0	0	1	0	0	2	0	3	0	0	0	0	2	0	12	3	5	1	1
329.006.00259	SC	22APR96	-32, .	3	0	1	1	1	1	3	0	0	1	0	1	2	0	0	1	0	15	4	1	3	6
	BL	22MAY96	-2, .	3	0	1	1	0	1	3	0	1	0	0	0	2	0	1	2	1	16	4	2	2	6
	1	30MAY96	7, .	1	0	0	2	0	0	3	0	2	0	0	0	2	0	1	1	1	13	4	2	2	4
	2	06JUN96	14, .	0	0	0	2	1	2	3	1	1	1	0	0	2	0	1	0	1	15	5	1	5	4
	3	13JUN96	21, .	0	0	0	0	0	0	2	0	0	1	0	0	1	0	3	2	1	10	6	0	0	2
	4	20JUN96	28, .	1	0	1	0	0	1	2	0	2	1	0	0	2	0	0	1	1	12	4	3	1	3
	5	27JUN96	35, .	1	0	0	0	1	1	0	0	2	0	0	0	2	0	3	0	1	11	6	2	2	1
	6	03JUL96	41, .	1	0	1	0	0	0	1	0	4	1	0	0	1	0	0	0	1	10	3	5	0	2
	7	10JUL96	48, .	1	0	1	1	1	1	0	0	4	1	0	0	1	0	0	0	1	12	3	5	3	1
	8	17JUL96	55, .	0	0	0	0	1	1	1	0	2	0	0	0	2	0	0	0	0	7	2	2	2	1
329.007.00141	SC	14SEP95	-7, .	3	2	0	2	1	0	2	3	2	2	1	0	1	0	0	1	2	22	6	4	3	8
	BL	21SEP95	1, .	3	1	1	1	0	2	3	2	1	3	2	1	1	0	2	0	0	23	9	3	3	8
	1	28SEP95	8, .	3	1	0	0	0	0	1	3	0	3	0	0	0	0	0	0	2	13	5	1	0	7
	2	05OCT95	15, .	2	1	0	0	1	0	1	2	1	1	0	0	0	0	0	0	1	10	2	2	1	5
	3	12OCT95	22, .	3	1	0	0	1	0	1	1	1	3	0	0	0	0	0	0	2	13	5	2	1	5
329.007.00144	SC	30NOV95	-7, -63	4	2	2	0	1	0	2	2	1	3	0	0	0	0	0	0	1	18	4	5	1	8
	BL	07DEC95	1, -56	3	2	2	0	1	0	2	2	1	2	1	0	1	0	2	0	1	20	7	5	1	7
	1	14DEC95	8, -49	3	2	2	0	2	0	3	0	2	3	2	1	2	0	1	0	0	23	9	6	2	6
	2	21DEC95	15, -42	2	1	0	1	0	0	1	0	2	2	1	0	0	0	0	0	1	11	4	3	1	3
	3	28DEC95	22, -35	1	1	2	0	1	0	2	1	2	2	2	0	2	0	2	1	0	19	8	5	1	4
	4	04JAN96	29, -28	1	1	0	1	0	0	0	0	2	1	1	0	0	0	0	0	1	8	3	3	1	1
	5	11JAN96	36, -21	1	1	0	0	2	0	1	0	1	0	0	1	0	0	2	0	0	9	3	2	2	2
	6	18JAN96	43, -14	1	0	0	0	0	0	0	0	1	1	1	0	1	0	0	0	1	6	4	1	0	1
	7	25JAN96	50, -7	1	1	0	0	0	0	0	0	1	2	0	0	0	0	0	0	1	6	3	2	0	1
	8	01FEB96	57, 1	1	1	0	0	0	0	1	0	1	1	1	1	0	0	0	0	1	8	4	2	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.007.00266	SC	29FEB96	-7, .	4	2	0	2	0	0	3	0	2	3	0	0	0	0	0	2	2	20	5	4	2	7
	BL	07MAR96	1, .	3	1	0	2	1	0	3	1	2	3	0	1	1	0	0	0	2	20	7	3	3	7
	1	14MAR96	8, .	1	1	0	0	0	0	1	0	2	2	0	0	0	0	0	0	1	8	3	3	0	2
	3	25MAR96	19, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	28MAR96	22, .	1	0	0	0	0	0	2	0	2	1	0	0	0	0	0	0	0	6	1	2	0	3
	4	04APR96	29, .	3	2	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	7	0	3	1	3
	5	11APR96	36, .	2	0	0	2	0	0	1	1	2	1	0	0	0	0	0	0	0	9	1	2	2	4
	6	18APR96	43, .	2	0	0	1	0	0	1	0	2	1	0	0	0	0	0	0	0	7	1	2	1	3
	8	29APR96	54, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8	02MAY96	57, .	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
329.007.00267	SC	29FEB96	-7, .	4	1	0	1	0	0	3	3	1	3	0	0	0	0	0	0	2	18	5	2	1	10
	BL	07MAR96	1, .	4	1	0	2	0	0	3	3	1	3	0	0	0	0	0	0	1	18	4	2	2	10
	1	14MAR96	8, .	3	0	0	0	0	0	2	2	1	1	0	0	0	0	0	0	2	11	3	1	0	7
	2	21MAR96	15, .	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	3	28MAR96	22, .	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	4	04APR96	29, .	2	0	0	2	0	0	1	1	0	0	0	0	0	0	0	1	0	7	0	0	2	4
	5	11APR96	36, .	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
	6	18APR96	43, .	2	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	4	0	0	0	4
	7	25APR96	50, .	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	0	0	3	0	1	2	0
	8	02MAY96	57, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.007.00311	SC	26SEP96	-7, -67	4	2	0	0	2	0	3	1	0	3	0	0	0	0	0	0	0	15	3	2	2	8
	BL	03OCT96	1, -60	3	1	0	0	2	2	3	0	2	3	0	0	0	0	0	0	0	16	3	3	4	6
	1	10OCT96	8, -53	0	0	0	0	2	0	2	0	0	1	1	1	0	0	0	1	0	8	3	0	2	2
	2	17OCT96	15, -46	2	0	0	0	2	0	0	0	1	2	0	0	0	0	0	0	0	7	2	1	2	2
	4	28OCT96	26, -35	1	0	0	0	2	0	0	0	1	2	0	1	0	0	0	0	0	7	3	1	2	1
	4	31OCT96	29, -32	1	0	0	0	2	0	1	0	0	1	0	0	0	0	0	0	0	5	1	0	2	2
	5	07NOV96	36, -25	0	0	0	0	2	0	0	0	1	2	0	0	0	0	0	0	0	5	2	1	2	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.007.00311	6	14NOV96	43, -18	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0
	7	22NOV96	51, -10	2	1	0	0	2	0	1	1	0	2	0	1	0	0	0	0	0	10	3	1	2	4
	8	02DEC96	61, 1	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	2	1
	12	02JAN97	92, 32	2	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	0	5	1	0	2	2
	16	30JAN97	120, 60	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	2	1
	24	13MAR97	162, 102	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	3	0	1	1	1
	28	11APR97	191, 131	3	1	0	1	2	0	2	0	1	2	0	0	0	0	0	0	0	12	2	2	3	5
329.008.00158	SC	06SEP95	-7, -69	2	1	2	2	1	0	3	2	0	3	0	1	1	0	0	0	0	18	5	3	3	7
	BL	13SEP95	1, -62	3	0	0	2	1	1	3	3	0	0	1	0	1	0	1	1	0	17	3	0	4	9
	1	19SEP95	7, -56	3	1	2	2	1	0	0	2	0	0	1	0	1	0	0	0	0	13	2	3	3	5
	2	27SEP95	15, -48	3	0	0	2	2	1	2	2	0	2	0	0	2	0	1	1	0	18	5	0	5	7
	3	03OCT95	21, -42	2	0	0	1	0	0	2	1	0	1	0	0	0	0	1	0	0	8	2	0	1	5
	4	10OCT95	28, -35	1	0	0	0	0	0	2	0	0	1	0	1	0	0	1	0	0	6	3	0	0	3
	5	16OCT95	34, -29	2	0	0	1	0	0	1	2	0	1	0	0	2	0	1	0	0	10	4	0	1	5
	6	24OCT95	42, -21	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	7	31OCT95	49, -14	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	0	1
	8	14NOV95	63, 1	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	2	1	0	0	1
	16	26DEC95	105, 43	2	0	0	1	0	0	3	1	0	1	0	0	1	0	0	0	0	9	2	0	1	6
	20	23JAN96	133, 71	2	0	3	2	0	0	3	1	0	0	0	0	2	0	3	0	0	16	5	3	2	6
329.008.00162	SC	26OCT95	-6, -71	4	2	3	2	2	0	3	2	0	3	0	0	2	0	1	2	0	26	6	5	4	9
	BL	01NOV95	1, -65	1	2	1	2	2	1	2	2	1	1	0	0	1	0	1	0	0	17	3	4	5	5
	1	10NOV95	10, -56	4	1	2	2	2	0	3	2	1	1	2	1	2	1	1	1	0	26	7	4	4	10
	3	20NOV95	20, -46	3	2	2	2	0	0	3	2	1	2	1	0	2	0	0	0	0	20	5	5	2	8
	4	29NOV95	29, -37	2	2	2	2	1	0	3	2	0	2	0	0	0	0	0	0	0	16	2	4	3	7
	5	07DEC95	37, -29	1	2	0	2	0	0	3	2	0	0	0	1	1	0	0	0	0	12	2	2	2	6
	6	14DEC95	44, -22	0	2	0	2	1	0	0	0	0	2	1	0	0	0	0	0	0	8	3	2	3	0
	7	20DEC95	50, -16	0	2	0	2	0	0	3	0	0	0	0	1	0	0	0	0	0	8	1	2	2	3

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.008.00162	8	27DEC95	57, -9	1	2	0	2	0	0	3	0	0	2	2	0	0	0	2	0	0	14	6	2	2	4
	8	05JAN96	66, 1	1	1	1	2	1	0	3	1	0	1	0	0	1	0	0	0	0	12	2	2	3	5
	16	09FEB96	101, 36	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	3	0	0	0	3
	20	08MAR96	129, 64	1	0	0	2	0	0	0	1	0	1	2	1	0	0	0	0	0	8	4	0	2	2
	24	11APR96	163, 98	0	0	0	1	1	0	1	0	0	0	0	0	0	0	0	0	0	3	0	0	2	1
	24	01MAY96	183, 118	0	0	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	3	0	0	2	1
	32	05JUN96	218, 153	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0	0	0	3	1	0	2	0
	32	02JUL96	245, 180	0	0	0	2	0	1	3	0	0	1	2	0	1	0	0	0	0	10	4	0	3	3
329.008.00191	SC	12JAN96	-20, -81	4	2	3	2	2	0	3	2	0	2	0	0	0	0	1	2	0	23	3	5	4	9
	BL	01FEB96	1, -61	4	2	2	2	2	0	3	2	0	2	0	0	0	0	1	0	0	20	3	4	4	9
	2	12FEB96	12, -50	0	2	2	0	0	0	1	1	0	2	0	1	1	0	0	0	0	10	4	4	0	2
	3	20FEB96	20, -42	1	1	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	5	0	1	2	2
	4	27FEB96	27, -35	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	2	0	1	1	0
	5	05MAR96	34, -28	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	6	12MAR96	41, -21	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	1	0	0
	7	18MAR96	47, -15	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	1	0	0	0
	8	26MAR96	55, -7	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0
	8	02APR96	62, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	01MAY96	91, 30	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1
	16	05JUN96	126, 65	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	2	1	0	1	0
	20	12JUN96	133, 72	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.009.00128	SC	05APR95	-6, .	3	2	2	2	0	0	2	1	2	3	2	0	2	0	2	0	0	23	9	6	2	6
	BL	11APR95	1, .	3	1	2	2	1	0	2	1	2	3	2	1	2	0	2	0	0	24	10	5	3	6
	1	18APR95	8, .	3	2	1	1	1	0	2	2	2	3	2	1	1	0	2	0	1	24	10	5	2	7
	2	25APR95	15, .	3	1	1	2	1	0	2	2	2	2	2	1	1	0	2	0	1	23	9	4	3	7
329.009.00129	SC	22MAR95	-20, .	4	3	2	1	2	2	3	2	2	2	2	0	2	1	1	0	0	29	7	7	5	10

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00129	BL	11APR95	1,	.	3	1	1	2	1	1	3	2	3	3	2	1	2	1	1	0	0	27	9	5	4	9
	1	18APR95	8,	.	4	2	1	2	2	0	2	2	2	2	2	1	1	0	1	0	0	24	7	5	4	8
	2	25APR95	15,	.	3	2	1	2	1	0	2	1	2	2	2	1	1	0	1	0	0	21	7	5	3	6
	3	02MAY95	22,	.	3	2	1	2	1	1	2	1	1	2	2	1	1	0	1	0	1	22	8	4	4	6
	4	09MAY95	29,	.	4	2	2	2	1	1	2	2	3	2	2	1	1	0	1	1	0	27	7	7	4	8
	5	16MAY95	36,	.	4	2	1	2	1	0	2	2	2	1	2	0	1	0	1	0	0	21	5	5	3	8
329.009.00135	SC	25SEP95	-7,	.	4	2	0	1	0	1	4	3	0	2	2	2	2	1	3	0	0	27	11	2	2	12
	BL	02OCT95	1,	.	4	3	1	1	0	0	4	3	1	3	2	1	2	1	1	0	0	27	9	5	1	12
	1	09OCT95	8,	.	4	3	1	1	0	0	4	3	1	3	2	1	2	1	1	0	0	27	9	5	1	12
	2	16OCT95	15,	.	4	3	1	1	0	0	4	3	2	1	3	1	2	1	1	0	0	27	8	6	1	12
	3	23OCT95	22,	.	4	2	1	1	0	0	4	3	1	2	2	1	2	1	1	0	0	25	8	4	1	12
	4	30OCT95	29,	.	4	3	1	1	0	0	4	3	1	1	2	1	2	1	1	0	0	25	7	5	1	12
	5	06NOV95	36,	.	4	2	1	1	0	0	4	3	0	3	0	1	2	1	2	0	0	24	8	3	1	12
329.009.00136	SC	26SEP95	-7,	.	4	0	3	2	2	1	4	1	0	2	3	0	2	0	0	0	0	24	7	3	5	9
	BL	03OCT95	1,	.	4	2	1	2	2	1	3	2	1	1	1	0	1	0	1	0	0	22	4	4	5	9
	1	10OCT95	8,	.	4	2	1	2	2	1	3	2	2	1	2	0	1	0	1	0	0	24	5	5	5	9
	2	17OCT95	15,	.	3	2	1	2	2	1	2	2	1	2	2	0	1	0	2	0	0	23	7	4	5	7
	3	24OCT95	22,	.	3	2	1	2	2	1	2	2	1	1	2	1	1	0	0	0	0	21	5	4	5	7
	4	03NOV95	32,	.	3	1	0	2	2	0	2	2	2	2	1	0	1	0	1	0	0	19	5	3	4	7
	5	07NOV95	36,	.	3	1	0	2	1	0	1	1	2	1	1	0	0	0	2	0	0	15	4	3	3	5
	6	14NOV95	43,	.	3	1	2	2	1	2	2	2	2	2	1	0	1	0	1	0	0	22	5	5	5	7
	7	21NOV95	50,	.	3	2	1	2	2	0	2	2	2	2	1	0	1	0	1	0	0	21	5	5	4	7
	8	28NOV95	57,	.	3	2	1	2	2	0	3	2	2	2	1	0	1	0	1	0	1	23	6	5	4	8
329.009.00169	SC	25OCT95	-6,	-71	4	3	3	1	2	2	3	0	3	3	1	1	0	0	0	1	0	27	5	9	5	7
	BL	31OCT95	1,	-65	3	2	2	2	2	1	2	2	1	2	1	2	1	0	1	1	0	25	7	5	5	7
	1	07NOV95	8,	-58	3	2	2	1	2	1	2	2	2	2	1	2	1	0	1	1	0	25	7	6	4	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00169	2	14NOV95	15, -51	1	1	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	4	1	1	0	2
	3	21NOV95	22, -44	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	2	0	1	1	0
	4	28NOV95	29, -37	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	5	05DEC95	36, -30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6	12DEC95	43, -23	1	1	0	0	0	0	1	0	2	1	1	0	0	0	0	0	0	7	2	3	0	2
	7	19DEC95	50, -16	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	2	0	1	1	0
	8	27DEC95	58, -8	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	2	0	1	0	0
	12	23JAN96	85, 20	0	0	0	0	0	0	1	0	2	0	0	0	0	0	0	0	0	3	0	2	0	1
329.009.00174	SC	14NOV95	-7, -64	1	1	2	2	1	0	3	0	2	1	0	0	1	0	0	0	0	14	2	5	3	4
	BL	21NOV95	1, -57	2	1	2	2	1	0	3	0	3	1	0	1	2	0	1	0	1	20	6	6	3	5
	1	28NOV95	8, -50	2	1	0	2	0	0	3	0	2	1	0	0	2	0	1	0	1	15	5	3	2	5
	2	05DEC95	15, -43	3	1	0	2	0	0	3	1	1	1	1	2	2	0	2	0	1	20	9	2	2	7
	3	12DEC95	22, -36	3	1	0	1	0	0	3	1	1	1	1	1	2	0	1	0	1	17	7	2	1	7
	4	19DEC95	29, -29	1	0	0	0	0	0	2	0	1	1	0	0	1	0	0	0	1	7	3	1	0	3
	5	27DEC95	37, -21	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	6	02JAN96	43, -15	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	7	09JAN96	50, -8	1	0	0	1	0	0	1	1	0	1	0	0	0	0	0	0	0	5	1	0	1	3
	8	17JAN96	58, 1	2	1	0	0	0	0	1	0	2	1	0	0	1	0	0	0	0	8	2	3	0	3
	12	31JAN96	72, 15	2	1	0	0	0	0	4	1	1	1	2	1	2	0	1	0	1	17	8	2	0	7
329.009.00197	SC	20DEC95	-9, -63	4	2	1	1	0	0	3	2	2	2	2	1	2	0	0	0	2	24	9	5	1	9
	BL	29DEC95	1, -54	4	2	2	1	1	0	3	2	2	1	2	0	2	0	1	0	1	24	7	6	2	9
	1	02JAN96	5, -50	3	2	2	1	1	0	3	2	2	1	2	0	2	0	1	0	1	23	7	6	2	8
	1	08JAN96	11, -44	2	2	2	0	1	0	2	2	2	1	2	0	2	0	1	0	1	20	7	6	1	6
	3	16JAN96	19, -36	3	2	0	0	0	0	2	2	1	1	1	0	1	0	1	0	2	16	6	3	0	7
	4	23JAN96	26, -29	1	1	0	1	0	0	1	1	2	1	1	1	2	0	1	0	1	14	7	3	1	3
	5	30JAN96	33, -22	1	0	0	0	0	0	1	1	1	1	1	0	0	0	1	0	1	8	4	1	0	3
	6	06FEB96	40, -15	0	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	4	0	2	0	2

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00197	7	13FEB96	47, -8	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	20FEB96	54, -1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	19MAR96	82, 28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	23APR96	117, 63	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	20	21MAY96	145, 91	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24	25JUN96	180, 126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	16JUL96	201, 147	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	32	20AUG96	236, 182	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.009.00198	SC	19DEC95	-14, .	4	1	2	2	2	2	3	0	2	2	2	2	2	2	1	2	0	31	9	5	6	9
	BL	02JAN96	1, .	4	2	2	2	2	1	3	2	1	3	2	2	1	0	1	2	1	31	10	5	5	9
	1	08JAN96	7, .	4	2	2	1	2	1	3	2	1	3	2	2	2	0	2	1	1	31	12	5	4	9
	2	16JAN96	15, .	4	2	1	2	2	1	3	1	3	2	2	2	2	0	1	0	1	29	10	6	5	8
	3	23JAN96	22, .	4	2	1	2	2	1	3	1	3	2	2	2	2	0	1	0	1	29	10	6	5	8
	4	30JAN96	29, .	4	2	1	2	0	0	3	2	2	2	2	2	2	0	2	1	0	27	10	5	2	9
	5	06FEB96	36, .	3	2	0	2	1	1	3	2	2	2	1	1	2	0	2	0	0	24	8	4	4	8
	6	13FEB96	43, .	3	2	1	2	1	1	3	2	1	2	1	1	2	0	2	1	0	25	8	4	4	8
	7	20FEB96	50, .	4	2	1	2	1	1	3	2	1	2	1	2	1	0	2	1	0	26	8	4	4	9
	8	27FEB96	57, .	4	2	1	2	1	1	3	2	2	2	2	2	2	1	1	1	0	29	9	5	4	10
329.009.00200	SC	17JAN96	-6, .	4	0	2	2	0	0	4	2	2	1	0	0	2	2	0	0	1	22	4	4	2	12
	BL	23JAN96	1, .	4	2	1	2	2	1	3	2	1	2	2	1	2	0	2	0	2	29	11	4	5	9
	1	02FEB96	11, .	4	1	1	1	1	0	4	2	1	2	1	1	2	0	0	0	2	23	8	3	2	10
	2	06FEB96	15, .	4	1	1	2	1	0	3	2	2	2	1	1	2	0	0	0	1	23	7	4	3	9
	3	13FEB96	22, .	4	1	1	2	1	0	4	2	2	2	1	1	1	0	0	1	1	24	6	4	3	10
	4	20FEB96	29, .	4	1	1	2	1	0	3	2	2	2	1	1	2	0	0	1	1	24	7	4	3	9
	5	28FEB96	37, .	4	1	1	2	1	0	4	2	2	2	1	1	2	0	1	0	1	25	8	4	3	10
	6	08MAR96	46, .	4	1	1	2	1	1	4	2	3	2	1	1	2	0	2	0	1	28	9	5	4	10

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
					HAMD Scores																					
329.009.00202	SC	14FEB96	-6,	.	2	2	2	2	2	2	3	1	3	2	1	2	2	0	0	2	0	28	7	7	6	6
	BL	20FEB96	1,	.	4	2	1	2	2	1	3	2	2	2	2	2	2	0	2	2	2	33	12	5	5	9
	1	27FEB96	8,	.	4	2	1	2	1	1	3	1	2	2	2	2	2	0	3	0	1	29	12	5	4	8
	2	08MAR96	18,	.	4	2	1	2	1	0	2	1	1	2	2	2	2	0	2	0	1	25	11	4	3	7
	4	19MAR96	29,	.	2	1	1	2	1	1	2	1	1	1	0	0	0	0	0	0	1	14	2	3	4	5
	5	26MAR96	36,	.	1	1	0	1	1	0	2	1	2	2	1	0	0	0	0	0	0	12	3	3	2	4
329.009.00237	SC	04NOV96	-7,	.	1	2	0	2	1	0	3	1	1	1	0	0	0	0	0	0	2	14	3	3	3	5
	BL	11NOV96	1,	.	3	1	0	2	0	0	3	2	0	1	0	1	2	0	0	1	0	16	4	1	2	8
	1	18NOV96	8,	.	3	1	0	2	1	0	3	2	1	1	0	1	2	0	0	0	0	17	4	2	3	8
329.009.00238	SC	28OCT96	-15,	.	2	2	1	2	2	0	3	1	1	2	2	0	2	1	0	2	0	23	6	4	4	7
	BL	12NOV96	1,	.	2	2	3	2	1	0	2	1	1	2	1	0	2	0	1	0	0	20	6	6	3	5
	1	19NOV96	8,	.	3	2	2	1	0	0	2	1	1	1	0	0	1	1	0	0	0	15	2	5	1	7
	2	26NOV96	15,	.	2	1	1	2	2	1	2	0	1	1	0	0	0	0	0	0	0	13	1	3	5	4
	3	03DEC96	22,	.	3	1	0	2	0	0	2	1	1	2	1	1	2	0	0	0	0	16	6	2	2	6
	4	10DEC96	29,	.	1	0	0	0	0	0	1	0	1	1	0	1	0	0	0	1	0	6	2	1	0	2
	5	17DEC96	36,	.	1	1	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	6	2	2	0	2
	6	23DEC96	42,	.	2	1	0	0	0	0	1	0	0	0	0	0	2	0	0	0	0	6	2	1	0	3
	7	31DEC96	50,	.	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2
	8	07JAN97	57,	.	3	1	0	2	0	0	1	2	0	1	0	0	2	0	0	0	0	12	3	1	2	6
329.009.00276	SC	17JAN97	-4,	.	2	0	3	1	2	0	4	2	2	2	2	1	2	0	0	1	0	24	7	5	3	8
	BL	21JAN97	1,	.	4	1	3	2	2	1	3	1	3	2	2	1	2	0	0	0	1	28	8	7	5	8
	1	28JAN97	8,	.	3	1	1	2	2	1	2	0	1	1	0	1	1	0	0	2	1	19	4	3	5	5
	2	04FEB97	15,	.	3	1	1	2	1	0	3	1	1	2	0	1	2	0	0	0	0	18	5	3	3	7
	3	11FEB97	22,	.	3	1	2	2	0	0	3	0	1	1	0	1	2	1	0	1	1	19	5	4	2	7
	4	18FEB97	29,	.	2	0	1	1	1	0	2	1	0	0	0	0	2	0	0	0	1	11	3	1	2	5
	5	25FEB97	36,	.	2	0	1	2	0	0	2	0	1	1	0	0	1	0	0	0	0	10	2	2	2	4

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.009.00276	6	04MAR97	43,	.	2	0	0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	6	0	0	2	4
	7	13MAR97	52,	.	2	0	0	2	0	0	1	0	0	1	0	0	1	0	0	0	0	7	2	0	2	3
	8	18MAR97	57,	.	2	0	0	2	0	0	2	1	0	1	0	1	2	0	0	1	0	12	4	0	2	5
329.009.00302	SC	20MAR96	-7,	.	3	1	1	2	0	0	3	2	0	2	0	0	1	1	0	0	1	17	4	2	2	9
	BL	27MAR96	1,	.	3	1	1	0	0	0	3	2	1	1	1	1	2	1	0	1	0	18	5	3	0	9
	1	03APR96	8,	.	3	2	0	1	0	0	3	0	1	2	0	1	1	0	0	0	0	14	4	3	1	6
	2	10APR96	15,	.	2	2	0	0	0	0	2	1	1	1	0	1	0	0	0	0	0	10	2	3	0	5
329.009.00306	SC	03JUN96	-8,	.	3	0	2	2	1	0	3	2	0	2	0	0	1	0	0	0	1	17	4	2	3	8
	BL	11JUN96	1,	.	3	2	2	2	1	1	3	2	1	2	1	1	0	0	0	0	1	22	5	5	4	8
	1	18JUN96	8,	.	3	2	2	2	1	1	3	2	0	2	1	1	0	0	0	0	1	21	5	4	4	8
	2	25JUN96	15,	.	4	2	1	2	1	1	4	3	2	2	0	2	1	0	0	1	1	27	6	5	4	11
	3	02JUL96	22,	.	3	2	1	2	2	2	2	2	2	2	1	1	2	0	1	0	1	26	8	5	6	7
	4	09JUL96	29,	.	2	2	1	1	1	1	2	2	1	2	1	1	1	0	0	0	0	18	5	4	3	6
	5	16JUL96	36,	.	1	1	0	1	1	0	2	1	2	1	1	1	2	0	0	0	0	14	5	3	2	4
	6	23JUL96	43,	.	1	1	0	0	0	0	2	1	0	1	1	0	2	0	0	0	0	9	4	1	0	4
	7	30JUL96	50,	.	3	1	0	1	0	0	3	2	0	0	0	0	2	0	0	0	1	13	3	1	1	8
	8	06AUG96	57,	.	2	1	0	0	0	0	2	1	0	0	0	1	1	0	0	0	1	9	3	1	0	5
329.009.00312	SC	30OCT96	-5,	.	2	1	1	0	2	0	3	1	0	4	2	0	2	1	1	0	0	20	9	2	2	7
	BL	04NOV96	1,	.	4	2	1	0	1	1	3	2	1	2	2	0	2	0	1	0	0	22	7	4	2	9
	2	15NOV96	12,	.	4	2	0	0	1	1	3	2	1	1	1	0	2	0	1	0	1	20	6	3	2	9
	2	18NOV96	15,	.	3	2	0	1	1	0	2	2	1	1	1	0	1	0	0	0	1	16	4	3	2	7
	4	02DEC96	29,	.	3	2	0	2	1	1	4	2	1	1	2	0	2	0	1	0	1	23	7	3	4	9
	5	09DEC96	36,	.	3	1	0	2	2	1	2	2	1	1	1	1	2	0	1	0	1	21	7	2	5	7
	6	16DEC96	43,	.	3	1	0	0	0	0	3	2	0	1	0	0	1	0	1	0	1	13	4	1	0	8
	8	27DEC96	54,	.	3	2	0	1	1	0	3	2	1	2	1	0	2	0	1	0	1	20	7	3	2	8
	8	30DEC96	57,	.	3	1	1	0	0	0	3	2	1	1	0	0	2	0	0	0	2	16	5	3	0	8

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
					HAMD Scores																					
329.009.00312	8	06JAN97	64,	.	3	2	0	0	1	0	3	2	0	2	1	0	2	0	1	0	1	18	7	2	1	8
329.009.00327	SC	09SEP96	-7,	.	3	2	2	2	2	1	3	2	3	2	2	1	2	1	1	1	0	30	8	7	5	9
	BL	16SEP96	1,	.	4	2	1	2	2	0	3	2	2	3	2	1	2	0	1	0	0	27	9	5	4	9
	1	23SEP96	8,	.	4	2	1	2	2	1	3	2	1	2	2	2	1	0	1	1	0	27	8	4	5	9
	2	30SEP96	15,	.	4	2	1	2	1	1	3	2	1	2	2	2	2	0	1	1	0	27	9	4	4	9
	3	07OCT96	22,	.	4	2	1	2	2	1	3	2	1	2	2	2	2	0	1	1	0	28	9	4	5	9
	4	14OCT96	29,	.	4	2	1	2	1	1	3	1	1	2	2	1	2	0	1	1	0	25	8	4	4	8
	5	21OCT96	36,	.	4	1	1	2	2	1	3	2	1	2	2	1	2	0	1	1	0	26	8	3	5	9
329.009.00330	SC	15OCT96	-6,	.	3	2	3	1	2	1	3	1	4	4	2	1	1	0	0	1	0	29	8	9	4	7
	BL	21OCT96	1,	.	3	1	2	2	1	1	2	2	1	1	0	1	1	0	0	1	2	21	5	4	4	7
	1	28OCT96	8,	.	2	0	1	0	1	1	1	2	1	1	0	1	2	0	0	1	2	16	6	2	2	5
	2	04NOV96	15,	.	2	1	1	1	1	1	2	1	2	2	1	1	2	0	2	0	1	21	9	4	3	5
329.010.00183	SC	21NOV95	-12,	.	3	0	3	0	0	0	3	0	2	0	0	1	2	0	0	2	1	17	4	5	0	6
	BL	28NOV95	-5,	.	3	0	0	0	2	0	3	0	2	1	1	1	2	0	0	0	1	16	6	2	2	6
	1	05DEC95	3,	.	2	0	0	0	2	0	2	0	3	2	0	0	1	0	0	0	1	13	4	3	2	4
	2	19DEC95	17,	.	1	0	0	0	0	0	2	0	3	1	0	0	0	0	0	0	1	8	2	3	0	3
329.010.00263	SC	24JUL96	-16,	.	4	2	0	2	0	0	3	2	0	2	1	0	0	0	1	1	0	18	4	2	2	9
	BL	09AUG96	1,	.	3	1	0	2	0	0	3	1	0	2	2	0	1	0	2	0	1	18	8	1	2	7
	1	14AUG96	6,	.	3	1	0	1	0	0	2	1	0	2	0	0	1	0	2	0	1	14	6	1	1	6
	2	21AUG96	13,	.	1	1	0	1	0	0	2	1	0	2	0	0	1	0	2	0	1	12	6	1	1	4
	3	28AUG96	20,	.	1	0	0	0	0	0	1	1	0	2	0	0	0	0	2	0	1	8	5	0	0	3
	4	04SEP96	27,	.	0	0	0	0	0	0	1	0	0	1	0	0	1	0	1	0	1	5	4	0	0	1
	5	11SEP96	34,	.	1	0	0	0	0	0	1	1	0	1	0	0	1	0	2	0	0	7	4	0	0	3
	6	18SEP96	41,	.	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	0	0	3	1	0	0	2
	7	25SEP96	48,	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.010.00263	8	09OCT96	62, .	1	0	0	1	0	0	2	1	0	1	0	0	0	0	1	0	0	7	2	0	1	4
329.010.00277	SC	23FEB96	-7, -63	2	0	0	0	0	0	3	1	4	0	3	0	2	1	0	0	1	17	6	4	0	7
	BL	01MAR96	1, -56	2	1	0	0	0	0	3	1	4	0	2	0	2	1	0	0	1	17	5	5	0	7
	1	08MAR96	8, -49	1	0	0	0	0	0	3	1	4	0	0	0	2	1	0	0	1	13	3	4	0	6
	2	18MAR96	18, -39	1	0	0	0	0	0	3	1	2	0	1	2	0	1	0	0	1	12	4	2	0	6
	3	22MAR96	22, -35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0
	4	29MAR96	29, -28	1	0	0	0	0	0	2	0	1	0	0	1	1	1	0	0	1	8	3	1	0	4
	6	15APR96	46, -11	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	2	0	1	0	1
	7	19APR96	50, -7	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	2	2	0	0	0
	8	26APR96	57, 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	24MAY96	85, 29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	21JUN96	113, 57	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	24	07AUG96	160, 104	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.010.00282	SC	19JUL96	-7, .	3	0	0	0	0	0	2	1	3	1	0	0	1	0	3	0	1	15	6	3	0	6
	BL	26JUL96	1, .	3	0	0	0	0	0	2	0	3	1	0	0	1	0	3	0	1	14	6	3	0	5
	1	02AUG96	8, .	3	0	0	0	0	0	2	0	2	1	0	0	0	0	2	0	1	11	4	2	0	5
	2	09AUG96	15, .	2	0	0	0	0	0	2	0	2	1	0	0	0	0	2	0	1	10	4	2	0	4
	3	16AUG96	22, .	2	0	0	0	0	0	3	0	1	1	0	0	1	0	2	0	1	11	5	1	0	5
	4	26AUG96	32, .	1	0	0	0	0	0	2	0	0	1	0	0	0	0	2	0	1	7	4	0	0	3
	6	03SEP96	40, .	1	0	0	0	0	0	2	0	1	1	0	0	1	0	1	0	1	8	4	1	0	3
	7	13SEP96	50, .	0	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	3	2	1	0	0
	8	19SEP96	56, .	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	3	1	0	0	2
	8	27SEP96	64, .	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
329.011.00164	SC	15DEC95	-7, .	3	0	0	1	1	0	3	1	1	2	1	1	1	0	0	1	0	16	5	1	2	7
	BL	21DEC95	-1, .	3	0	0	2	2	0	4	1	2	3	1	0	1	0	0	0	0	19	5	2	4	8
	1	28DEC95	7, .	3	0	0	0	2	1	3	1	3	1	2	0	2	0	0	0	0	18	5	3	3	7

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
				HAMD Scores																					
329.011.00164	2	04JAN96	14, .	2	0	0	2	1	0	4	0	3	1	1	0	1	0	0	0	0	15	3	3	3	6
	3	11JAN96	21, .	2	0	0	2	1	0	3	1	2	1	0	0	1	0	0	0	0	13	2	2	3	6
	4	18JAN96	28, .	3	0	0	2	1	0	3	1	2	1	0	0	2	0	0	0	0	15	3	2	3	7
	5	25JAN96	35, .	2	0	0	2	1	0	3	0	2	1	1	0	1	0	0	0	0	13	3	2	3	5
329.011.00210	SC	13SEP96	-15, -81	3	0	2	2	1	2	1	0	1	2	1	1	1	0	0	0	1	18	6	3	5	4
	BL	27SEP96	-1, -67	3	0	1	2	2	1	2	0	2	1	0	1	1	0	0	0	2	18	5	3	5	5
	1	03OCT96	6, -61	2	0	1	1	1	0	2	0	2	1	0	0	1	0	0	0	0	11	2	3	2	4
	2	09OCT96	12, -55	4	2	2	0	0	0	3	0	2	3	2	0	2	0	1	0	0	21	8	6	0	7
	3	17OCT96	20, -47	3	0	0	1	1	0	2	1	2	2	1	1	1	0	0	1	0	16	5	2	2	6
	4	24OCT96	27, -40	0	0	0	2	1	0	1	0	2	1	0	0	1	0	0	0	0	8	2	2	3	1
	5	04NOV96	38, -29	1	0	0	1	0	0	1	0	1	1	1	0	1	1	0	0	0	8	3	1	1	3
	6	12NOV96	46, -21	0	2	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	4	0	4	0	0
	8	22NOV96	56, -11	0	1	0	0	0	0	0	0	2	1	0	1	0	0	0	0	0	5	2	3	0	0
	8	02DEC96	66, -1	0	1	0	0	0	0	1	0	2	1	0	1	1	0	0	1	0	8	3	3	0	1
329.011.00285	SC	08MAY96	-10, .	3	2	2	2	2	2	3	1	0	3	1	1	1	0	2	0	0	25	8	4	6	7
	BL	17MAY96	-1, .	3	1	2	2	2	2	3	1	0	3	1	1	1	0	2	0	0	24	8	3	6	7
	1	27MAY96	10, .	3	0	0	2	2	2	3	1	2	2	1	1	1	0	0	0	0	20	5	2	6	7
	2	03JUN96	17, .	3	2	2	2	1	2	3	1	0	3	1	0	1	0	1	0	0	22	6	4	5	7
	3	10JUN96	24, .	3	0	2	2	2	1	3	0	1	2	1	1	1	0	0	0	0	19	5	3	5	6
	5	21JUN96	35, .	4	0	1	2	1	0	2	1	2	2	0	1	1	0	1	0	0	18	5	3	3	7
	6	28JUN96	42, .	3	0	2	2	0	0	2	1	2	3	1	1	1	0	0	1	0	19	6	4	2	6
	7	08JUL96	52, .	3	1	2	2	2	0	3	1	2	1	1	1	1	0	0	0	0	20	4	5	4	7
	8	18JUL96	62, .	3	0	0	2	1	0	1	1	2	2	0	0	1	0	0	1	0	14	3	2	3	5
	8	24JUL96	68, .	3	0	0	2	1	0	1	1	2	2	0	0	1	0	0	0	0	13	3	2	3	5
329.011.00287	SC	25JUN96	-8, .	3	2	2	2	1	0	2	0	2	2	1	0	1	0	0	0	0	18	4	6	3	5
	BL	02JUL96	-1, .	3	1	2	1	0	0	1	1	2	1	0	1	1	0	0	0	1	15	4	5	1	5

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.011.00287	1	09JUL96	7,	.	2	0	2	2	1	0	1	0	2	1	1	0	1	0	0	0	0	13	3	4	3	3
	2	17JUL96	15,	.	1	1	1	2	1	0	1	0	2	2	0	1	1	0	0	1	0	14	4	4	3	2
	3	23JUL96	21,	.	2	0	0	2	1	0	1	0	2	1	0	1	1	0	0	1	1	13	4	2	3	3
	4	30JUL96	28,	.	2	0	2	1	1	0	2	0	2	1	0	1	1	0	0	0	0	13	3	4	2	4
	5	06AUG96	35,	.	1	0	1	1	1	1	1	0	2	1	0	1	1	0	0	0	0	11	3	3	3	2
	6	13AUG96	42,	.	1	1	1	1	1	0	1	0	2	1	0	0	0	0	0	0	0	9	1	4	2	2
	7	20AUG96	49,	.	1	0	0	1	0	1	1	0	2	1	0	1	1	0	0	0	0	9	3	2	2	2
	8	27AUG96	56,	.	2	0	0	1	1	1	1	0	1	1	0	0	1	0	0	0	0	9	2	1	3	3
329.012.00027	SC	23NOV95	-13,	.	4	2	1	2	1	2	3	2	0	1	0	2	2	0	0	0	0	22	5	3	5	9
	BL	06DEC95	1,	.	4	1	1	2	1	1	3	2	0	1	0	2	2	0	0	0	0	20	5	2	4	9
	1	12DEC95	7,	.	2	2	0	0	1	1	3	2	1	1	0	0	2	0	0	0	0	15	3	3	2	7
	2	19DEC95	14,	.	3	2	1	0	2	2	3	0	0	4	2	1	1	0	1	0	0	22	9	3	4	6
	3	27DEC95	22,	.	4	1	1	2	1	1	3	0	1	4	2	1	2	0	3	0	0	26	12	3	4	7
	4	02JAN96	28,	.	3	1	0	2	2	1	3	0	0	2	1	1	2	0	3	0	1	22	10	1	5	6
329.012.00217	SC	14MAY96	-7,	.	4	2	2	2	2	1	3	1	4	1	3	2	2	1	0	1	0	31	8	8	5	9
	BL	21MAY96	1,	.	4	2	2	2	2	1	3	1	1	1	3	2	2	1	0	0	0	27	8	5	5	9
	1	31MAY96	11,	.	4	2	1	2	2	2	3	2	0	1	1	1	1	0	0	0	0	22	4	3	6	9
	2	07JUN96	18,	.	3	2	1	2	1	1	3	0	0	2	1	1	1	0	0	0	0	18	5	3	4	6
	3	14JUN96	25,	.	3	0	1	2	0	1	1	1	0	1	0	2	2	0	0	0	0	14	5	1	3	5
	4	19JUN96	30,	.	4	2	2	2	2	0	4	0	2	3	0	1	1	0	0	0	0	23	5	6	4	8
329.012.00218	SC	04JUN96	-12,	-70	4	1	2	2	1	0	3	2	0	2	0	2	2	0	1	0	0	22	7	3	3	9
	BL	14JUN96	-2,	-60	3	2	1	2	1	0	2	1	0	2	0	2	1	0	1	0	0	18	6	3	3	6
	1	21JUN96	6,	-53	2	2	1	2	0	0	2	0	0	2	0	1	2	0	0	0	0	14	5	3	2	4
	2	28JUN96	13,	-46	1	2	2	1	0	0	1	0	0	3	0	2	0	0	0	0	0	12	5	4	1	2
	3	05JUL96	20,	-39	0	1	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	6	2	1	1	1
	4	12JUL96	27,	-32	0	0	0	0	0	0	1	0	0	1	0	1	1	0	0	0	0	4	3	0	0	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Paroxetine - Protocol 329
Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.012.00218	5	19JUL96	34, -25	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1
	6	29JUL96	44, -15	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0
	7	06AUG96	52, -7	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	8	13AUG96	59, 1	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	3	3	0	0	0
	12	18SEP96	95, 37	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2	1	0	0	1
329.012.00224	SC	30AUG96	-17, -83	4	2	2	2	2	2	3	2	0	3	0	2	1	0	0	0	0	25	6	4	6	9
	BL	16SEP96	1, -66	3	2	2	2	2	1	2	1	0	3	0	2	1	0	0	0	0	21	6	4	5	6
	1	24SEP96	9, -58	3	2	1	2	2	1	2	0	2	3	0	1	1	0	0	0	0	20	5	5	5	5
	2	03OCT96	18, -49	1	1	0	0	0	1	0	0	2	2	0	0	0	0	0	0	0	7	2	3	1	1
	3	10OCT96	25, -42	1	1	0	0	0	1	0	0	1	1	0	0	0	0	0	0	0	5	1	2	1	1
	4	17OCT96	32, -35	0	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	4	2	2	0	0
	6	25OCT96	40, -27	0	2	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	5	2	3	0	0
	7	04NOV96	50, -17	0	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	4	2	2	0	0
	8	12NOV96	58, -9	1	2	0	1	0	0	0	0	0	2	0	0	0	0	0	0	0	6	2	2	1	1
	8	20NOV96	66, -1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
	12	19DEC96	95, 29	1	1	0	0	0	0	1	0	1	2	0	0	0	0	0	1	0	7	2	2	0	2
	16	20JAN97	127, 61	0	2	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	6	4	2	0	0
	24	18FEB97	156, 90	0	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	3	0	3	0	0
329.012.00225	SC	19NOV96	-7, -71	4	2	0	1	0	0	3	2	2	1	1	1	0	0	0	1	1	19	4	4	1	9
	BL	26NOV96	1, -64	4	0	0	0	1	0	4	2	0	3	0	2	2	0	0	1	1	20	8	0	1	10
	1	03DEC96	8, -57	4	2	0	0	0	0	3	2	2	2	1	1	1	0	0	0	1	19	6	4	0	9
	2	10DEC96	15, -50	2	1	0	0	0	1	2	1	0	0	0	1	0	0	0	0	0	8	1	1	1	5
	3	20DEC96	25, -40	0	0	0	1	0	0	1	1	0	0	0	0	1	0	0	0	0	4	1	0	1	2
	4	27DEC96	32, -33	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	2	0	0	1	1
	6	06JAN97	42, -23	2	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	1	6	2	1	0	3
	7	13JAN97	49, -16	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0	0	3	2	0	0	1
	8	21JAN97	57, -8	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.2
Listing of HAMD Scores by Factor by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	HAMD Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total	Anx/Som	Cog.Dis	Sleep	Retard.
329.012.00225	8	29JAN97	65, 1	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	3	1	0	0	2
	12	24FEB97	91, 27	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
	16	20MAR97	115, 51	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	1	0	3	1	1	0	0
	20	21APR97	147, 83	1	0	0	0	0	0	1	0	1	1	0	0	1	0	0	0	0	5	2	1	0	2
	24	26MAY97	182, 118	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	3	2	0	0	1
	32	30JUN97	217, 153	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	0	3	1	0	0	1
	32	30JUL97	247, 183	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2	1	1	0	0

* days relative to start of acute phase, days relative to start of continuation phase
Anxiety/Somatization: items 10, 11, 12, 13, 15, 17; Cognitive Disturbance: items 2, 3, 9; Sleep: items 4, 5, 6;
Retardation: items 1, 7, 8, 14

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.001.00063	SC	02NOV94	-6 , .	5	4	5	5	4	5	4	4	2	38
	BL	08NOV94	1 , .	5	4	5	4	4	4	1	4	3	34
	2	22NOV94	15 , .	1	1	5	4	1	2	4	4	1	23
	4	06DEC94	29 , .	1	1	1	1	3	2	5	4	1	19
329.001.00065	SC	07NOV94	-10 , .	5	4	5	5	5	4	3	5	1	37
	BL	17NOV94	1 , .	6	3	4	6	5	4	3	5	1	37
329.001.00068	SC	01FEB95	-7 , .	6	3	5	5	4	5	3	5	3	39
	BL	08FEB95	1 , .	6	1	5	6	4	5	4	5	2	38
	2	22FEB95	15 , .	6	1	5	5	4	5	1	4	3	34
	4	08MAR95	29 , .	3	1	4	4	4	4	3	4	1	28
	6	22MAR95	43 , .	4	1	3	4	4	4	3	5	1	29
	8	05APR95	57 , .	4	2	4	5	4	4	3	5	1	32
329.001.00072	SC	07MAR95	-13 , .	5	1	5	5	4	4	3	4	1	32
	BL	20MAR95	1 , .	4	2	5	4	4	5	4	5	1	34
	2	03APR95	15 , .	2	1	2	3	4	3	1	1	1	18
329.001.00121	SC	22MAR95	-13 ,-69	5	3	5	4	5	5	3	4	4	38
	BL	04APR95	1 ,-56	5	1	5	4	5	4	4	4	1	33
	2	18APR95	15 ,-42	3	1	5	4	3	4	3	4	1	28
	4	02MAY95	29 ,-28	4	1	4	4	4	4	3	4	1	29
	6	16MAY95	43 ,-14	1	2	2	3	4	3	3	4	1	23
	8	30MAY95	57 , 1	1	1	2	3	3	3	1	3	1	18
	12	27JUN95	85 , 29	1	1	1	2	3	3	4	4	1	20
	16	24JUL95	112 , 56	4	1	4	4	3	3	4	4	1	28
	20	21AUG95	140 , 84	4	3	1	4	3	4	6	4	1	30

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.001.00205	SC	29JAN96	-9 , .	5	3	4	5	3	4	1	3	1	29
	BL	07FEB96	1 , .	5	1	5	4	4	3	1	3	1	27
329.001.00206	SC	12FEB96	-9 , .	6	4	5	5	1	5	6	4	1	37
	BL	21FEB96	1 , .	6	1	5	5	1	5	6	4	1	34
	2	06MAR96	15 , .	6	1	5	5	1	5	5	4	1	33
	4	20MAR96	29 , .	4	4	4	5	2	5	2	3	1	30
	6	03APR96	43 , .	3	1	4	5	1	4	5	4	1	28
	8	17APR96	57 , .	5	1	5	5	3	5	6	4	1	35
329.002.00055	SC	09JUN94	-15 ,-70	4	4	4	5	2	3	3	4	5	34
	BL	23JUN94	-1 ,-56	4	4	4	5	1	3	3	4	5	33
	2	07JUL94	14 ,-42	4	4	4	4	1	4	6	1	3	31
	4	21JUL94	28 ,-28	2	2	2	2	1	2	5	1	1	18
	6	04AUG94	42 ,-14	2	1	2	2	1	2	3	1	1	15
	8	18AUG94	56 , 1	1	1	3	2	2	3	5	4	1	22
	12	15SEP94	84 , 29	1	1	2	1	1	3	2	1	1	13
	16	13OCT94	112 , 57	1	1	1	1	1	2	1	2	1	11
	20	10NOV94	140 , 85	4	4	4	4	1	4	4	3	3	31
329.002.00058	SC	08SEP94	-12 ,-70	6	4	5	3	3	3	1	5	3	33
	BL	20SEP94	1 ,-58	6	4	5	3	3	3	1	5	3	33
	2	07OCT94	18 ,-41	2	2	2	3	3	1	1	1	1	16
	4	20OCT94	31 ,-28	1	1	1	3	2	1	1	1	1	12
	6	03NOV94	45 ,-14	1	1	2	3	3	2	1	1	1	15
	8	17NOV94	59 , 1	2	1	2	3	3	1	1	1	1	15
	12	15DEC94	87 , 29	2	1	1	4	4	2	1	1	1	17
	16	13JAN95	116 , 58	2	1	3	1	3	1	1	1	1	14

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.002.00099	SC	23FEB95	-7 ,-62	4	5	5	4	3	1	1	3	1	27
	BL	02MAR95	1 ,-55	4	5	5	4	3	1	1	3	1	27
	2	14MAR95	13 ,-43	2	3	3	3	3	1	1	3	1	20
	4	28MAR95	27 ,-29	1	1	1	2	2	1	1	2	1	12
	6	11APR95	41 ,-15	3	2	1	1	3	1	1	2	1	15
	8	25APR95	55 , -1	3	1	1	2	3	1	1	1	1	14
	12	23MAY95	83 , 28	1	1	2	1	2	1	3	3	1	15
	16	27JUN95	118 , 63	2	1	1	3	2	1	2	4	1	17
	20	01AUG95	153 , 98	1	1	1	1	3	1	1	1	1	11
	24	31AUG95	183 ,128	1	1	1	1	2	1	1	3	1	12
	28	28SEP95	211 ,156	1	1	2	3	2	1	1	1	1	13
	32	26OCT95	239 ,184	6	4	4	5	2	2	3	3	3	32
329.002.00102	SC	03APR95	-10 ,-64	4	2	4	3	3	1	1	3	1	22
	2	25APR95	13 ,-42	3	1	2	2	4	1	1	4	1	19
	4	09MAY95	27 ,-28	3	1	2	1	4	1	1	3	1	17
	6	23MAY95	41 ,-14	1	1	2	1	2	1	1	2	1	12
	8	06JUN95	55 , 1	2	1	1	1	4	1	2	2	1	15
	12	13JUL95	92 , 38	1	1	1	1	3	1	1	1	1	11
	16	10AUG95	120 , 66	1	1	1	1	4	2	1	2	1	14
	20	12SEP95	153 , 99	1	1	1	1	2	1	1	1	1	10
	24	10OCT95	181 ,127	1	1	1	1	2	1	1	1	1	10
	28	09NOV95	211 ,157	2	1	1	1	4	1	1	1	1	13
	32	05DEC95	237 ,183	2	1	1	1	3	1	1	1	1	12
329.002.00105	SC	20JUL95	-7 , .	3	2	1	5	2	3	3	4	4	27
	BL	27JUL95	1 , .	3	2	1	5	2	3	3	4	1	24
	2	10AUG95	15 , .	1	1	1	3	2	2	2	2	1	15

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.002.00106	SC	20JUL95	-7 , .	5	3	4	4	2	2	4	4	2	30
	2	08AUG95	13 , .	2	1	3	2	1	2	1	2	1	15
	4	24AUG95	29 , .	3	2	4	1	1	2	1	3	1	18
	6	05SEP95	41 , .	2	2	2	2	1	2	1	2	2	16
329.002.00242	SC	26JAN96	-12 ,-70	5	1	5	5	1	1	1	1	1	21
	2	21FEB96	15 ,-44	4	1	4	5	1	2	1	1	1	20
	4	06MAR96	29 ,-30	2	1	1	2	2	2	1	1	1	13
	6	20MAR96	43 ,-16	1	1	3	2	1	1	1	1	1	12
	8	05APR96	59 , 1	1	1	1	1	1	1	1	1	1	9
	12	08MAY96	92 , 34	1	1	1	1	1	1	1	1	1	9
	16	05JUN96	120 , 62	1	1	1	1	1	1	1	4	1	12
	20	10JUL96	155 , 97	1	1	1	1	1	1	1	1	1	9
329.002.00245	SC	21MAR96	-7 , .	3	4	2	4	3	3	1	3	2	25
	BL	28MAR96	1 , .	3	4	3	4	3	3	1	3	1	25
329.002.00319	SC	23APR96	-7 ,-63	6	2	3	2	3	3	1	4	3	27
	2	14MAY96	15 ,-42	3	3	1	3	1	2	1	3	1	18
	4	28MAY96	29 ,-28	4	2	2	1	1	3	1	3	2	19
	6	11JUN96	43 ,-14	3	1	2	2	2	2	1	2	1	16
	8	25JUN96	57 , 1	1	1	1	1	1	1	1	2	1	10
	12	23JUL96	85 , 29	1	1	1	1	1	2	1	2	1	11
	16	15AUG96	108 , 52	1	1	2	1	1	2	1	2	1	12
	20	24SEP96	148 , 92	2	1	2	1	1	1	1	1	1	11
	24	22OCT96	176 ,120	4	2	2	1	1	2	1	1	1	15
	28	19NOV96	204 ,148	2	1	1	1	1	1	1	1	1	10
	32	17DEC96	232 ,176	2	1	1	1	1	1	1	1	1	10

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00075	SC	18JAN95	-7 ,-63	3	1	4	5	1	1	5	1	4	25
	BL	25JAN95	1 ,-56	4	1	3	5	1	1	6	1	1	23
	2	08FEB95	15 ,-42	3	1	2	2	1	1	5	1	2	18
	4	21FEB95	28 ,-29	2	1	1	1	1	1	4	1	3	15
	6	08MAR95	43 ,-14	4	3	4	4	1	3	4	1	4	28
	8	22MAR95	57 , 1	3	1	3	2	1	1	4	1	3	19
	12	19APR95	85 , 29	2	1	2	2	2	1	5	1	1	17
	16	17MAY95	113 , 57	2	1	2	4	1	1	1	1	1	14
	24	12JUL95	169 ,113	3	1	1	1	1	1	1	1	2	12
	28	09AUG95	197 ,141	3	2	3	2	1	1	1	1	3	17
	32	13SEP95	232 ,176	3	1	1	1	1	1	1	1	2	12
329.003.00077	SC	01MAR95	-5 ,-64	6	3	5	5	4	5	1	5	2	36
	BL	06MAR95	1 ,-59	4	1	4	5	4	5	5	3	3	34
	2	20MAR95	15 ,-45	5	3	1	1	0	4	4	1	1	20
	4	05APR95	31 ,-29	1	1	1	1	3	1	5	1	1	15
	6	19APR95	45 ,-15	5	1	1	1	3	1	4	4	1	21
	8	03MAY95	59 , -1	1	1	1	1	1	1	1	3	1	11
	12	07JUN95	94 , 35	1	1	1	2	1	1	5	3	1	16
329.003.00081	BL	11DEC95	1 , .	7	4	6	0	3	0	1	5	4	30
	2	28DEC95	18 , .	4	1	1	5	3	5	4	1	1	25
	4	10JAN96	31 , .	5	1	5	4	4	1	1	4	1	26
	6	24JAN96	45 , .	1	1	3	5	1	1	1	1	2	16
	8	07FEB96	59 , .	4	1	6	0	1	1	1	4	1	19
329.003.00087	SC	23JAN95	-8 , .	3	1	4	2	4	3	0	2	1	20
	BL	30JAN95	-1 , .	5	5	5	5	3	1	3	0	4	31

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00089	SC	24FEB95	-11 , .	4	2	2	3	3	2	0	1	0	17
	BL	07MAR95	1 , .	7	1	4	3	3	1	1	1	2	23
	2	21MAR95	15 , .	3	3	1	2	1	1	1	4	2	18
	4	04APR95	29 , .	2	1	1	2	1	3	1	3	2	16
	6	18APR95	43 , .	1	1	1	0	5	1	1	5	1	16
	8	02MAY95	57 , .	0	1	1	1	1	1	0	0	1	6
329.003.00091	SC	14MAR95	-10 ,-64	5	2	3	3	1	4	1	4	2	25
	BL	24MAR95	1 ,-54	4	2	1	1	1	1	1	3	2	16
	2	04APR95	12 ,-43	1	2	1	2	1	1	1	1	1	11
	4	18APR95	26 ,-29	0	1	1	4	3	1	1	1	1	13
	6	02MAY95	40 ,-15	1	1	1	2	1	1	1	1	1	10
	8	16MAY95	54 , -1	2	1	1	1	1	1	1	1	1	10
	12	16JUN95	85 , 31	1	1	1	1	1	1	1	1	1	9
	16	14JUL95	113 , 59	1	1	1	1	1	1	1	1	1	9
	20	10AUG95	140 , 86	1	1	1	1	1	1	1	1	1	9
	24	05SEP95	166 ,112	1	1	1	1	1	1	1	1	1	9
	28	03OCT95	194 ,140	1	1	1	1	1	1	1	1	1	9
	32	07NOV95	229 ,175	1	1	1	1	1	1	1	1	1	9
329.003.00248	SC	14FEB96	-16 , .	5	1	5	4	1	5	3	5	3	32
	BL	22FEB96	-8 , .	5	1	2	5	2	3	3	4	3	28
	2	12MAR96	12 , .	4	1	1	3	3	1	1	3	1	18
	4	26MAR96	26 , .	3	1	1	3	1	1	1	4	1	16
	6	11APR96	42 , .	7	1	4	4	1	5	1	5	1	29
	8	23APR96	54 , .	4	1	3	4	4	3	1	1	2	23
329.003.00250	SC	05MAR96	-9 ,-66	5	1	6	5	1	4	1	5	4	32
	BL	14MAR96	1 ,-57	6	1	5	5	1	4	1	4	4	31

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00250	4	12APR96	30 ,-28	2	1	1	0	1	1	1	1	1	9
	6	23APR96	41 ,-17	7	1	2	3	4	1	6	4	4	32
	8	09MAY96	57 , -1	3	1	1	.	1	0	4	4	2	18
329.003.00292	SC	02AUG96	-5 ,-63	4	4	4	5	2	1	1	5	1	27
	BL	07AUG96	1 ,-58	4	4	4	5	3	5	1	5	1	32
	2	21AUG96	15 ,-44	4	5	0	1	1	1	1	1	1	15
	4	04SEP96	29 ,-30	1	4	1	1	1	1	1	4	1	15
	6	18SEP96	43 ,-16	1	2	1	1	1	1	1	1	1	10
	8	04OCT96	59 , 1	1	3	3	1	1	1	1	1	2	14
329.003.00313	SC	08MAY96	-9 , .	7	5	6	6	1	5	6	5	4	45
	BL	17MAY96	1 , .	6	5	5	6	1	5	6	5	4	43
	2	28MAY96	12 , .	7	5	4	6	1	5	4	5	4	41
329.004.00015	SC	30NOV94	-8 ,-65	5	2	5	3	3	1	3	4	1	27
	BL	07DEC94	-1 ,-58	5	2	5	3	3	1	3	4	1	27
	2	21DEC94	14 ,-44	4	3	3	2	3	1	1	4	1	22
	4	04JAN95	28 ,-30	3	1	4	1	2	1	1	4	1	18
	6	18JAN95	42 ,-16	1	2	2	2	3	1	1	1	1	14
	8	03FEB95	58 , 1	1	1	3	1	1	1	1	1	1	11
	12	27FEB95	82 , 25	2	3	1	2	2	1	3	3	3	20
	16	22MAR95	105 , 48	3	3	1	1	3	1	1	3	1	17
	20	19APR95	133 , 76	2	1	2	2	3	1	1	1	1	14
	24	17MAY95	161 ,104	3	1	1	1	2	1	1	1	1	12
	28	14JUN95	189 ,132	2	1	1	1	1	1	1	1	1	10
329.004.00017	SC	15MAR95	-7 ,-63	5	4	5	3	3	2	1	4	3	30
	BL	22MAR95	1 ,-56	4	4	5	1	2	1	1	4	1	23

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.004.00017	2	06APR95	16 ,-41	4	3	5	5	4	1	1	4	1	28
	4	20APR95	30 ,-27	4	1	4	2	4	2	1	4	2	24
	6	03MAY95	43 ,-14	4	1	4	3	1	2	1	4	1	21
	8	17MAY95	57 , 1	3	1	2	1	3	1	1	4	1	17
	12	14JUN95	85 , 29	3	1	3	1	2	1	1	4	2	18
	16	13JUL95	114 , 58	2	1	3	3	3	1	1	3	1	18
	20	10AUG95	142 , 86	3	1	3	1	3	1	1	3	3	19
	24	06SEP95	169 ,113	1	1	3	1	3	1	1	4	1	16
	28	04OCT95	197 ,141	2	3	2	1	1	1	1	2	1	14
	32	01NOV95	225 ,169	2	1	2	1	1	1	1	2	1	12
329.004.00019	SC	24MAY95	-7 , .	4	4	5	3	3	3	6	5	1	34
	BL	31MAY95	1 , .	5	3	5	4	3	3	5	5	1	34
	2	14JUN95	15 , .	4	1	4	3	3	2	4	4	1	26
329.004.00212	SC	24MAY96	-10 , .	5	5	5	4	1	1	1	5	2	29
	BL	03JUN96	1 , .	5	4	5	4	1	1	1	5	3	29
	3	21JUN96	19 , .	6	4	6	5	1	1	6	1	3	33
329.004.00214	SC	27SEP96	-7 ,-67	4	4	4	4	3	3	1	1	3	27
	BL	04OCT96	1 ,-60	3	4	5	5	4	4	.	1	1	30
	2	15OCT96	12 ,-49	3	3	4	5	5	4	2	4	1	31
	4	01NOV96	29 ,-32	0	3	4	5	4	3	2	3	0	24
	6	18NOV96	46 ,-15	4	0	3	5	4	4	3	0	0	23
	8	03DEC96	61 , 1	3	1	4	4	4	1	2	2	1	22
	12	30DEC96	88 , 28	0	3	3	3	3	3	2	1	1	19
329.005.00002	SC	20MAY94	-5 ,-61	4	1	4	5	4	1	1	4	1	25
	BL	25MAY94	1 ,-56	4	1	4	5	3	1	1	5	1	25

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00002	2	08JUN94	15 ,-42	5	1	3	5	4	2	1	5	1	27
	4	23JUN94	30 ,-27	5	1	3	5	4	1	1	5	1	26
	6	07JUL94	44 ,-13	4	1	3	4	2	1	1	4	1	21
	8	20JUL94	57 , 1	2	1	2	2	2	1	1	3	1	15
	12	17AUG94	85 , 29	3	1	1	3	1	1	1	4	1	16
	16	15SEP94	114 , 58	3	1	4	4	1	1	1	3	1	19
	20	18OCT94	147 , 91	3	1	3	1	1	1	1	5	1	17
329.005.00004	SC	22SEP94	-18 ,-77	4	4	1	4	1	4	1	4	1	24
	BL	10OCT94	1 ,-59	4	3	2	4	3	4	1	4	1	26
	2	27OCT94	18 ,-42	3	2	3	2	3	2	1	3	3	22
	4	10NOV94	32 ,-28	2	1	1	2	2	1	1	1	1	12
	6	23NOV94	45 ,-15	2	1	1	2	3	2	1	1	1	14
	8	08DEC94	60 , 1	1	1	1	1	1	1	1	1	1	9
	12	05JAN95	88 , 29	1	1	1	1	1	1	1	1	1	9
329.005.00008	SC	10NOV94	-6 ,-61	4	1	1	5	4	4	1	4	1	25
	BL	16NOV94	1 ,-55	4	1	1	5	4	4	1	4	1	25
	2	30NOV94	15 ,-41	2	1	2	2	4	2	1	1	1	16
	4	14DEC94	29 ,-27	1	1	2	2	3	1	2	1	1	14
	6	28DEC94	43 ,-13	1	1	1	1	2	1	1	4	1	13
	8	10JAN95	56 , 1	1	1	1	1	1	1	4	1	1	12
	12	06FEB95	83 , 28	2	3	1	2	2	1	1	4	1	17
	16	08MAR95	113 , 58	1	2	1	2	2	1	1	1	1	12
	24	10MAY95	176 ,121	1	1	1	1	1	1	1	1	1	9
329.005.00011	SC	06DEC94	-7 ,-63	5	1	5	4	4	4	3	5	1	32
	BL	13DEC94	1 ,-56	5	1	5	4	4	4	2	5	2	32
	2	27DEC94	15 ,-42	3	1	2	4	4	1	2	2	1	20

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00011	4	09JAN95	28 ,-29	3	1	2	3	3	3	1	3	1	20
	6	23JAN95	42 ,-15	1	1	1	3	3	1	2	3	1	16
	8	07FEB95	57 , 1	1	1	1	2	2	1	1	3	1	13
	12	09MAR95	87 , 31	1	1	1	2	2	1	1	1	1	11
	16	06APR95	115 , 59	1	1	1	2	2	1	1	2	1	12
	20	03MAY95	142 , 86	1	1	1	2	1	1	4	1	1	13
329.005.00109	SC	22DEC94	-8 ,-61	5	1	6	6	1	4	1	4	1	29
	BL	30DEC94	1 ,-53	1	3	2	3	2	1	1	1	1	15
	2	12JAN95	14 ,-40	.	1	1	3	1	1	4	1	1	15
	4	26JAN95	28 ,-26	3	1	2	1	2	1	2	1	1	14
	6	08FEB95	41 ,-13	2	1	1	2	1	1	1	1	1	11
	8	21FEB95	54 , 1	1	1	1	2	2	1	2	1	1	12
	12	23MAR95	84 , 31	1	1	1	1	1	1	1	1	1	9
	16	24APR95	116 , 63	1	1	1	1	1	1	1	1	1	9
	20	25MAY95	147 , 94	1	1	1	1	1	1	1	1	1	9
329.005.00112	SC	17JAN95	-9 ,-64	4	3	5	5	1	1	1	1	1	22
	BL	26JAN95	1 ,-55	4	1	4	4	2	3	6	1	1	26
	2	08FEB95	14 ,-42	2	3	2	1	3	1	1	4	1	18
	4	23FEB95	29 ,-27	1	1	1	2	1	1	1	2	1	11
	6	08MAR95	42 ,-14	3	1	1	5	1	1	1	5	1	19
	8	22MAR95	56 , 1	2	1	1	1	1	1	1	2	1	11
	12	19APR95	84 , 29	1	1	1	1	1	1	1	1	1	9
	20	21JUN95	147 , 92	1	1	1	1	1	1	2	1	1	10
329.005.00116	SC	30JAN95	-8 ,-66	4	2	3	4	3	4	3	3	2	28
	BL	07FEB95	1 ,-58	4	2	2	4	3	4	3	3	1	26
	2	20FEB95	14 ,-45	3	1	1	3	3	1	1	2	1	16

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00116	4	09MAR95	31 ,-28	1	2	1	1	2	1	1	1	1	11
	6	23MAR95	45 ,-14	2	1	1	1	2	1	1	2	1	12
	8	06APR95	59 , 1	1	1	1	1	2	1	1	1	1	10
	12	04MAY95	87 , 29	1	1	1	1	2	1	1	1	1	10
	16	31MAY95	114 , 56	1	1	1	1	2	1	1	2	1	11
	20	28JUN95	142 , 84	3	3	1	1	2	1	1	1	1	14
	24	26JUL95	170 ,112	1	2	1	2	3	1	1	1	1	13
329.005.00119	SC	27JUN95	-14 ,-73	4	1	3	3	1	3	3	4	1	23
	BL	11JUL95	1 ,-59	4	1	4	3	1	3	4	4	1	25
	2	26JUL95	16 ,-44	4	1	4	3	1	3	4	4	1	25
	4	08AUG95	29 ,-31	2	1	1	1	1	1	2	1	1	11
	6	23AUG95	44 ,-16	1	1	1	1	1	1	1	1	1	9
	8	08SEP95	60 , 1	1	1	1	1	1	1	1	1	1	9
	12	03OCT95	85 , 26	2	1	1	1	1	1	1	4	1	13
	16	30OCT95	112 , 53	1	1	1	1	1	1	1	1	1	9
	20	28NOV95	141 , 82	1	1	1	1	1	1	1	1	1	9
	24	02JAN96	176 ,117	1	1	1	1	1	1	1	1	1	9
329.005.00151	SC	29AUG95	-8 ,-65	3	4	3	2	3	1	1	4	1	22
	BL	06SEP95	1 ,-57	4	2	4	3	1	1	6	1	1	23
	2	20SEP95	15 ,-43	3	1	2	3	2	1	1	3	1	17
	4	03OCT95	28 ,-30	3	1	1	3	4	1	1	1	2	17
	6	19OCT95	44 ,-14	2	1	2	3	1	1	1	1	1	13
	8	02NOV95	58 , 1	3	1	2	1	1	1	1	1	1	12
	12	28NOV95	84 , 27	5	1	1	5	1	1	2	2	2	20
	16	02JAN96	119 , 62	4	1	3	2	1	1	1	1	2	16
	20	31JAN96	148 , 91	3	1	1	1	2	1	1	1	3	14
	24	27FEB96	175 ,118	4	1	1	1	1	1	1	1	3	14

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00151	28	27MAR96	204 ,147	3	1	1	2	1	1	1	1	1	12
	32	01MAY96	239 ,182	3	1	1	1	1	1	1	1	1	11
329.005.00152	SC	12OCT95	-14 , .	5	2	4	5	4	2	1	2	1	26
	BL	23OCT95	-3 , .	5	1	5	3	1	3	1	2	1	22
329.005.00257	SC	05MAR96	-6 ,-62	5	1	4	4	1	4	1	1	2	23
	BL	11MAR96	1 ,-56	4	4	5	4	1	1	1	1	1	22
	2	25MAR96	15 ,-42	2	1	3	4	1	3	1	2	1	18
	4	08APR96	29 ,-28	2	1	2	2	1	1	1	1	1	12
	6	22APR96	43 ,-14	2	1	2	2	1	1	1	1	1	12
	8	06MAY96	57 , 1	2	1	1	1	1	1	1	1	1	10
	12	03JUN96	85 , 29	2	1	1	1	1	1	1	1	1	10
	16	08JUL96	120 , 64	2	1	1	1	1	1	1	1	1	10
	20	07AUG96	150 , 94	1	1	1	1	1	1	1	2	1	10
	24	27AUG96	170 ,114	1	1	1	1	1	1	1	1	1	9
	28	01OCT96	205 ,149	1	1	1	1	1	1	1	1	1	9
	32	21OCT96	225 ,169	2	1	1	1	1	1	1	1	1	10
329.005.00258	SC	06FEB96	-35 , .	4	1	4	1	1	3	1	3	1	19
	BL	20FEB96	-21 , .	4	0	4	1	1	3	1	1	1	16
	2	26MAR96	15 , .	3	0	3	1	1	1	1	1	1	12
	4	09APR96	29 , .	3	1	3	1	1	1	2	1	1	14
	6	23APR96	43 , .	1	1	3	1	1	3	1	1	1	13
	8	07MAY96	57 , .	2	0	3	1	1	1	1	1	1	11
329.005.00299	SC	28MAY96	-11 ,-71	5	1	5	4	1	4	1	4	1	26
	BL	04JUN96	-4 ,-64	4	1	3	3	1	4	1	3	1	21
	2	25JUN96	18 ,-43	1	1	1	1	1	1	3	1	1	11

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00299	5	10JUL96	33 ,-28	1	1	1	1	1	1	1	1	1	9
	6	22JUL96	45 ,-16	1	1	1	1	1	1	1	1	1	9
	8	07AUG96	61 , 1	1	1	1	1	1	1	1	1	1	9
	12	03SEP96	88 , 28	1	1	1	1	1	1	1	1	1	9
	16	01OCT96	116 , 56	1	1	3	3	1	3	1	2	1	16
	20	29OCT96	144 , 84	4	1	1	3	1	1	1	1	2	15
	20	05NOV96	151 , 91	4	1	4	5	2	3	1	1	2	23
329.005.00300	SC	12SEP96	-7 , .	5	1	5	1	1	4	1	3	3	24
	BL	19SEP96	1 , .	4	1	4	1	3	4	1	3	3	24
	2	03OCT96	15 , .	3	1	1	3	3	1	1	3	1	17
	4	17OCT96	29 , .	2	2	1	2	3	2	1	1	2	16
	6	31OCT96	43 , .	2	1	1	1	3	3	1	1	2	15
	8	14NOV96	57 , .	4	1	2	0	4	5	1	1	3	21
329.005.00333	SC	15JAN97	-8 , .	5	3	3	4	1	4	1	2	3	26
	BL	23JAN97	1 , .	4	1	3	4	1	3	1	1	1	19
	2	06FEB97	15 , .	6	1	3	4	3	3	6	1	3	30
	4	20FEB97	29 , .	3	1	1	3	3	2	1	2	2	18
329.005.00336	SC	26FEB97	-6 , .	4	1	4	4	4	3	4	4	2	30
	BL	04MAR97	1 , .	4	2	3	4	3	3	4	4	1	28
	2	19MAR97	16 , .	3	1	1	2	2	1	1	3	1	15
	4	02APR97	30 , .	3	1	1	2	2	1	1	4	1	16
	6	16APR97	44 , .	1	1	1	1	1	1	1	2	1	10
	8	30APR97	58 , .	2	1	1	2	2	1	1	2	2	14
329.006.00038	SC	01FEB95	-14 , .	3	5	5	3	1	3	1	4	2	27
	BL	08FEB95	-7 , .	4	5	4	4	1	3	1	4	1	27

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.006.00038	2	03MAR95	17 , .	3	2	2	1	1	1	1	1	1	13
	4	15MAR95	29 , .	3	3	2	1	1	2	1	3	1	17
	6	29MAR95	43 , .	2	1	1	1	1	1	1	3	1	12
329.006.00039	SC	03FEB95	-5 ,-66	4	4	5	1	1	4	1	5	2	27
	BL	10FEB95	3 ,-59	5	5	5	2	1	3	1	4	3	29
	2	22FEB95	15 ,-47	6	4	5	1	2	2	5	3	3	31
	4	08MAR95	29 ,-33	4	4	5	1	1	4	1	3	3	26
	6	22MAR95	43 ,-19	4	4	4	1	1	3	4	1	3	25
	8	05APR95	57 , -5	4	4	5	1	1	3	1	3	3	25
	12	01MAY95	83 , 22	6	4	5	1	1	4	1	3	1	26
329.006.00260	SC	12JUL96	-6 ,-64	3	2	1	2	3	3	1	1	3	19
	BL	18JUL96	1 ,-58	4	4	2	4	3	3	1	1	1	23
	2	01AUG96	15 ,-44	3	3	2	3	2	1	1	1	1	17
	4	14AUG96	28 ,-31	4	3	1	1	2	1	1	1	1	15
	6	28AUG96	42 ,-17	4	4	1	1	1	1	1	1	1	15
	8	18SEP96	63 , 5	4	4	2	2	2	1	1	1	1	18
	12	09OCT96	84 , 26	3	3	1	1	2	1	1	1	1	14
	16	06NOV96	112 , 54	4	4	1	1	2	1	1	1	1	16
329.006.00261	SC	07NOV96	-19 ,-77	5	5	4	5	4	4	1	4	1	33
	BL	22NOV96	-4 ,-62	5	4	4	4	4	4	1	2	1	29
	2	10DEC96	15 ,-44	3	3	2	4	4	4	3	1	1	25
	4	24DEC96	29 ,-30	6	4	4	3	2	4	4	2	3	32
	6	09JAN97	45 ,-14	3	4	2	2	3	2	1	1	1	19
	8	23JAN97	59 , 1	5	4	3	4	3	4	3	4	2	32
	12	20FEB97	87 , 29	1	1	2	1	2	3	3	1	1	15
	20	02APR97	128 , 70	4	4	1	4	2	3	4	1	1	24

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.007.00140	SC	07SEP95	-8 ,-63	5	4	4	4	3	2	1	4	1	28
	BL	14SEP95	-1 ,-56	4	2	4	4	3	3	1	4	3	28
	2	28SEP95	14 ,-42	1	1	1	1	1	1	1	1	1	9
	4	12OCT95	28 ,-28	1	1	1	1	1	1	2	1	1	10
	6	26OCT95	42 ,-14	1	1	1	1	1	1	1	1	1	9
	8	09NOV95	56 , 1	1	1	1	1	1	1	1	1	1	9
	8	22NOV95	69 , 14	1	1	1	1	1	1	1	1	1	9
329.007.00142	SC	12OCT95	-6 , .	5	3	5	4	2	3	3	4	1	30
	BL	18OCT95	1 , .	5	3	5	5	3	5	6	1	1	34
	2	02NOV95	16 , .	4	3	5	4	1	4	4	1	1	27
	4	16NOV95	30 , .	4	1	4	4	1	4	1	4	1	24
	6	30NOV95	44 , .	5	3	5	5	1	5	4	3	3	34
	8	21DEC95	65 , .	5	1	5	3	1	4	1	5	1	26
329.007.00145	SC	04JAN96	-7 ,-63	4	4	4	4	1	5	4	4	1	31
	BL	11JAN96	1 ,-56	3	1	1	2	2	4	4	2	1	20
	2	25JAN96	15 ,-42	4	3	4	4	1	2	5	1	1	25
	4	08FEB96	29 ,-28	2	3	3	3	3	4	3	3	1	25
	6	21FEB96	42 ,-15	1	1	1	1	1	1	1	1	1	9
	8	07MAR96	57 , 1	2	3	5	3	3	4	1	1	1	23
	12	04APR96	85 , 29	2	1	4	1	1	1	1	1	1	13
	16	02MAY96	113 , 57	1	1	3	1	1	1	1	3	1	13
	20	30MAY96	141 , 85	1	1	1	1	1	1	1	1	1	9
	24	27JUN96	169 ,113	1	1	1	1	1	1	1	1	1	9
	28	25JUL96	197 ,141	1	1	1	1	1	1	1	1	1	9
	32	23AUG96	226 ,170	1	1	1	1	1	1	1	2	1	10
329.007.00265	SC	25JAN96	-7 , .	4	4	4	4	3	5	1	5	1	31

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.007.00265	BL	01FEB96	1 , .	4	4	4	4	5	5	1	4	1	32
329.007.00268	SC	21MAR96	-11 ,-70	5	4	4	5	1	5	4	3	4	35
	BL	01APR96	1 ,-59	4	3	4	3	4	1	2	3	1	25
	2	18APR96	18 ,-42	3	4	1	4	4	1	1	4	1	23
	4	02MAY96	32 ,-28	4	1	3	1	1	4	1	4	1	20
	6	16MAY96	46 ,-14	4	1	4	3	1	4	4	2	2	25
	8	30MAY96	60 , 1	2	1	1	1	4	1	1	1	1	13
	12	27JUN96	88 , 29	3	3	1	1	4	1	1	3	1	18
	16	01AUG96	123 , 64	3	1	3	3	3	1	1	4	1	20
	20	30AUG96	152 , 93	2	1	1	1	1	1	1	1	1	10
	24	30SEP96	183 ,124	2	1	2	1	3	3	1	4	1	18
	32	07NOV96	221 ,162	2	2	1	1	2	1	1	3	1	14
	32	05DEC96	249 ,190	1	1	1	1	2	1	1	1	1	10
329.007.00294	SC	20FEB97	-8 , .	6	4	6	5	4	4	1	5	1	36
	BL	27FEB97	-1 , .	6	4	6	5	4	4	1	4	1	35
	2	17MAR97	18 , .	3	1	5	4	4	3	1	4	1	26
	5	03APR97	35 , .	3	1	5	5	3	4	1	5	1	28
329.007.00309	SC	02JUL96	-13 ,-65	6	4	4	4	4	5	1	4	2	34
	BL	15JUL96	1 ,-52	6	5	5	3	4	4	1	4	3	35
	1	25JUL96	11 ,-42	2	1	3	1	4	1	1	1	1	15
	3	08AUG96	25 ,-28	2	3	1	1	1	3	1	3	2	17
	6	23AUG96	40 ,-13	2	2	1	1	3	1	1	3	1	15
	7	05SEP96	53 , 1	1	2	1	1	1	1	1	2	1	11
	12	03OCT96	81 , 29	4	1	1	1	1	3	1	1	1	14
	16	31OCT96	109 , 57	2	3	1	1	2	1	2	2	1	15
	20	13DEC96	152 ,100	3	2	1	2	1	1	1	5	2	18

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.007.00309	24	09JAN97	179 ,127	2	1	1	1	2	1	1	2	1	12
	28	10FEB97	211 ,159	2	2	2	3	4	1	1	2	1	18
	32	13MAR97	242 ,190	5	3	1	5	4	3	1	4	2	28
329.007.00310	SC	19SEP96	-7 ,-67	4	4	3	5	5	4	1	3	2	31
	BL	26SEP96	1 ,-60	4	2	4	5	3	1	1	4	1	25
	2	10OCT96	15 ,-46	2	1	1	1	3	1	1	3	1	14
	5	28OCT96	33 ,-28	2	1	1	1	1	1	1	1	1	10
	6	08NOV96	44 ,-17	1	1	1	1	2	1	1	1	1	10
	8	25NOV96	61 , 1	1	1	1	1	1	1	1	1	1	9
	12	02JAN97	99 , 39	2	1	1	1	1	1	1	1	1	10
	20	14FEB97	142 , 82	1	1	1	1	1	1	1	1	1	9
	24	13MAR97	169 ,109	1	1	1	1	1	1	1	1	1	9
	28	17APR97	204 ,144	1	1	1	1	1	1	1	1	1	9
	32	15MAY97	232 ,172	1	1	1	1	1	1	1	1	1	9
	32	12JUN97	260 ,200	1	1	1	1	1	1	1	1	1	9
329.007.00318	SC	22NOV96	-10 , .	4	3	4	1	4	1	1	4	1	23
	BL	02DEC96	1 , .	3	1	4	1	4	1	1	4	1	20
329.008.00157	SC	16AUG95	-14 ,-69	5	4	3	4	4	1	4	3	1	29
	BL	29AUG95	-1 ,-56	5	1	4	5	4	1	4	1	1	26
	2	12SEP95	14 ,-42	3	1	2	2	3	2	1	1	1	16
	4	26SEP95	28 ,-28	2	1	1	1	1	1	1	1	1	10
	6	10OCT95	42 ,-14	2	1	1	1	1	1	1	1	1	10
	8	24OCT95	56 , 1	1	1	1	1	1	1	1	1	1	9
	12	23NOV95	86 , 31	2	1	1	1	1	1	1	1	1	10
	16	15DEC95	108 , 53	1	1	1	1	1	1	1	1	1	9
	20	23JAN96	147 , 92	1	1	1	1	1	1	1	1	1	9

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.008.00157	24	20FEB96	175 ,120	1	1	1	3	1	1	1	1	1	11
329.008.00160	SC	25OCT95	-7 ,-73	4	4	4	5	3	4	4	4	3	35
	BL	01NOV95	1 ,-66	4	4	4	4	4	3	1	4	3	31
	3	20NOV95	20 ,-47	3	4	3	4	4	1	1	1	1	22
	5	05DEC95	35 ,-32	3	1	2	3	1	1	2	2	2	17
	7	20DEC95	50 ,-17	1	1	1	1	1	1	3	3	1	13
	8	05JAN96	66 , -1	1	1	1	3	1	1	1	1	1	11
	12	31JAN96	92 , 26	1	1	1	1	1	1	1	1	1	9
	16	05MAR96	126 , 60	4	1	1	1	1	3	1	1	2	15
	24	09APR96	161 , 95	1	1	1	1	1	1	1	1	1	9
	28	16MAY96	198 ,132	1	1	1	1	3	1	1	1	1	11
	32	18JUN96	231 ,165	1	1	1	1	1	1	1	1	1	9
	32	23JUL96	266 ,200	1	1	1	1	1	1	1	1	1	9
329.008.00188	SC	14DEC95	-21 , .	5	4	4	5	1	4	1	4	4	32
	BL	04JAN96	1 , .	4	3	4	4	4	3	4	4	1	31
	2	17JAN96	14 , .	4	3	4	4	3	3	3	3	1	28
	4	31JAN96	28 , .	4	2	4	4	3	4	4	4	3	32
	6	14FEB96	42 , .	3	1	2	3	2	2	4	3	2	22
	8	27FEB96	55 , .	4	4	4	5	3	2	1	4	3	30
329.008.00271	SC	25JAN96	-46 ,***	4	3	4	4	1	4	1	4	1	26
	BL	11MAR96	1 ,-64	4	4	4	5	1	4	1	4	1	28
	2	25MAR96	15 ,-50	3	5	5	4	1	4	1	4	1	28
	4	08APR96	29 ,-36	2	4	3	2	2	3	1	1	1	19
	6	22APR96	43 ,-22	2	3	4	4	1	1	1	1	1	18
	8	14MAY96	65 , 1	4	1	3	4	3	3	1	1	1	21
	12	10JUN96	92 , 28	3	3	1	4	1	2	2	1	1	18

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.008.00271	16	12JUL96	124 , 60	3	3	1	2	1	1	1	3	1	16
	20	09AUG96	152 , 88	3	3	1	1	1	2	1	2	1	15
	24	06SEP96	180 ,116	3	2	1	2	3	1	1	4	1	18
	28	07OCT96	211 ,147	6	3	1	4	2	1	1	5	1	24
	32	05NOV96	240 ,176	6	5	2	4	1	4	1	4	1	28
329.008.00275	SC	30APR96	-8 ,-63	5	4	2	5	3	2	2	4	1	28
	BL	07MAY96	-1 ,-56	5	3	4	5	4	3	3	5	1	33
	2	21MAY96	14 ,-42	4	3	3	3	3	2	3	4	1	26
	4	04JUN96	28 ,-28	2	1	1	2	1	1	1	1	1	11
	7	25JUN96	49 , -7	2	1	4	2	3	3	1	1	1	18
	8	02JUL96	56 , 1	2	1	2	1	1	1	1	1	1	11
	12	23JUL96	77 , 22	1	1	1	1	1	1	1	1	1	9
	16	20AUG96	105 , 50	1	1	1	1	1	1	1	1	1	9
	20	16SEP96	132 , 77	4	1	1	2	1	1	1	1	1	13
	24	21OCT96	167 ,112	3	1	2	1	2	1	1	1	1	13
	28	25NOV96	202 ,147	2	1	1	1	2	1	1	1	1	11
	32	16DEC96	223 ,168	1	1	1	1	1	1	1	1	1	9
329.009.00130	SC	12APR95	-6 ,-62	4	4	2	2	5	2	1	5	3	28
	BL	18APR95	1 ,-56	4	2	4	4	4	3	1	4	1	27
	2	02MAY95	15 ,-42	4	2	4	4	4	3	1	4	1	27
	4	16MAY95	29 ,-28	2	1	2	3	4	1	1	1	1	16
	6	30MAY95	43 ,-14	4	2	3	3	4	3	1	1	1	22
	8	13JUN95	57 , 1	1	1	1	1	2	1	1	1	1	10
	16	07AUG95	112 , 56	2	1	3	1	3	1	2	4	3	20
	20	19SEP95	155 , 99	1	1	1	2	2	1	1	1	1	11
	24	03OCT95	169 ,113	4	3	3	4	4	2	1	4	1	26

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00131	SC	26APR95	-6 ,-62	5	5	3	4	4	3	1	5	4	34
	BL	02MAY95	1 ,-56	5	4	5	5	4	4	1	5	3	36
	2	16MAY95	15 ,-42	5	4	4	4	4	3	1	4	1	30
	4	30MAY95	29 ,-28	3	3	3	3	3	2	1	3	2	23
	6	13JUN95	43 ,-14	1	2	1	1	1	2	1	1	1	11
	8	27JUN95	57 , 1	2	1	1	1	1	1	1	1	1	10
	12	25JUL95	85 , 29	2	2	1	1	2	2	1	2	1	14
	16	24AUG95	115 , 59	2	3	3	3	3	1	3	1	1	20
	20	26SEP95	148 , 92	3	4	1	3	2	2	3	3	1	22
329.009.00133	SC	07JUN95	-6 , .	5	1	5	4	2	3	1	4	2	27
	BL	13JUN95	1 , .	5	4	5	5	4	4	3	5	3	38
	2	27JUN95	15 , .	5	4	5	5	4	4	3	5	1	36
	4	11JUL95	29 , .	5	4	5	5	4	4	3	5	3	38
	6	27JUL95	45 , .	5	4	5	5	4	4	3	5	3	38
329.009.00138	SC	02OCT95	-8 , .	4	4	4	5	3	4	1	4	3	32
	BL	10OCT95	1 , .	4	3	4	4	4	3	2	4	2	30
329.009.00170	SC	26OCT95	-12 ,-69	4	1	5	4	4	1	1	3	3	26
	BL	07NOV95	1 ,-57	5	2	6	4	1	4	1	4	2	29
	2	21NOV95	15 ,-43	4	3	4	4	2	4	1	4	1	27
	4	05DEC95	29 ,-29	4	3	4	4	1	4	1	4	1	26
	6	21DEC95	45 ,-13	3	2	3	2	1	3	1	4	1	20
	8	03JAN96	58 , 1	2	2	2	2	2	2	1	2	1	16
	12	29JAN96	84 , 27	2	1	2	1	1	2	1	1	1	12
	16	26FEB96	112 , 55	1	1	2	1	2	2	1	1	1	12
	20	01APR96	147 , 90	1	1	2	1	2	1	1	3	1	13
	24	22APR96	168 ,111	1	1	2	1	2	1	1	2	1	12

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00170	28	23MAY96	199 ,142	1	1	1	1	3	1	1	1	1	11
	32	24JUN96	231 ,174	1	1	1	1	1	1	1	1	1	9
329.009.00173	SC	08NOV95	-12 ,-75	6	5	4	5	4	1	1	5	3	34
	BL	20NOV95	1 ,-63	6	4	5	5	3	4	1	4	3	35
	2	04DEC95	15 ,-49	6	4	5	5	3	4	1	3	3	34
	4	18DEC95	29 ,-35	5	4	5	5	3	4	2	2	1	31
	7	08JAN96	50 ,-14	4	4	5	5	3	4	4	3	1	33
	8	22JAN96	64 , 1	3	2	3	2	1	2	1	2	1	17
	12	26FEB96	99 , 36	2	2	3	3	1	2	2	2	2	19
329.009.00193	SC	21NOV95	-7 , .	5	4	5	5	4	4	1	5	4	37
	BL	28NOV95	1 , .	5	4	5	5	4	4	4	5	4	40
	2	12DEC95	15 , .	5	4	5	5	4	4	4	5	4	40
	4	27DEC95	30 , .	4	4	4	4	4	4	3	5	1	33
	6	09JAN96	43 , .	5	4	5	4	4	5	3	5	3	38
	8	24JAN96	58 , .	5	4	5	4	4	5	3	5	3	38
329.009.00196	SC	11DEC95	-7 , .	5	5	5	5	2	3	1	3	3	32
	BL	18DEC95	1 , .	5	4	5	4	1	4	1	5	4	33
	2	02JAN96	16 , .	4	3	4	4	1	3	1	5	2	27
	4	15JAN96	29 , .	4	3	4	3	1	3	2	3	1	24
	6	29JAN96	43 , .	3	3	3	3	1	1	5	2	1	22
	8	12FEB96	57 , .	3	3	3	1	1	2	2	1	1	17
329.009.00201	SC	31JAN96	-6 , .	4	3	4	4	3	4	1	4	2	29
	BL	06FEB96	1 , .	4	2	5	4	5	4	1	4	3	32
	2	20FEB96	15 , .	3	2	3	3	4	3	1	2	1	22
	4	05MAR96	29 , .	1	1	1	2	3	2	1	3	1	15

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00201	6	19MAR96	43 , .	1	1	1	1	2	2	1	3	1	13
	8	02APR96	57 , .	1	1	1	3	2	2	1	3	1	15
329.009.00204	SC	13MAR96	-6 ,-62	4	3	4	4	3	4	1	4	1	28
	BL	19MAR96	1 ,-56	5	3	4	4	4	4	1	4	1	30
	2	02APR96	15 ,-42	4	3	4	4	3	4	1	4	1	28
	4	16APR96	29 ,-28	2	2	3	3	3	3	1	3	1	21
	6	30APR96	43 ,-14	1	1	1	2	2	2	1	2	1	13
	8	14MAY96	57 , 1	1	1	1	1	1	2	1	1	1	10
	12	11JUN96	85 , 29	1	1	1	1	1	2	1	1	1	10
	16	09JUL96	113 , 57	1	1	1	1	1	1	1	1	1	9
	20	13AUG96	148 , 92	1	1	1	1	1	1	1	1	1	9
	24	10SEP96	176 ,120	1	1	1	1	1	1	1	1	1	9
	28	14OCT96	210 ,154	1	1	1	1	2	2	1	1	1	11
329.009.00235	SC	10DEC96	-8 ,-62	5	2	4	4	3	4	1	3	1	27
	BL	17DEC96	-1 ,-55	4	3	4	4	3	4	1	3	3	29
	2	30DEC96	13 ,-42	3	1	3	2	1	2	1	1	1	15
	4	15JAN97	29 ,-26	1	1	1	1	1	2	1	1	1	10
	6	27JAN97	41 ,-14	1	1	1	1	1	2	1	1	1	10
	8	10FEB97	55 , 1	1	1	1	1	1	1	1	1	1	9
	12	17MAR97	90 , 36	1	1	1	1	2	2	1	1	1	11
	16	14APR97	118 , 64	4	1	4	1	3	2	1	2	3	21
329.009.00240	SC	03JAN97	-11 , .	6	4	6	5	1	4	1	5	5	37
	BL	10JAN97	-4 , .	5	2	5	5	1	4	1	5	4	32
	2	28JAN97	15 , .	4	1	4	4	1	3	1	4	2	24
	4	11FEB97	29 , .	3	1	3	3	2	3	1	3	1	20
	6	25FEB97	43 , .	3	2	3	3	1	3	4	4	1	24

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00303	SC	25MAR96	-8 ,-64	4	4	4	5	3	4	1	4	3	32
	BL	02APR96	1 ,-56	5	4	4	4	2	4	1	4	3	31
	2	16APR96	15 ,-42	4	3	3	4	2	2	1	4	1	24
	4	30APR96	29 ,-28	3	1	2	2	1	2	1	2	1	15
	6	14MAY96	43 ,-14	2	1	1	1	1	2	1	1	1	11
	8	28MAY96	57 , 1	2	1	1	1	1	1	1	1	1	10
	12	25JUN96	85 , 29	1	1	1	1	1	1	1	1	1	9
	16	30JUL96	120 , 64	1	1	1	1	1	1	1	1	1	9
	20	27AUG96	148 , 92	1	1	1	1	1	1	1	1	1	9
	24	25SEP96	177 ,121	1	1	1	1	1	1	1	1	1	9
	32	30OCT96	212 ,156	1	1	1	2	1	1	1	1	1	10
	32	10DEC96	253 ,197	1	1	1	1	1	1	1	2	1	10
329.009.00304	SC	03APR96	-6 ,-62	5	4	4	5	3	4	1	4	2	32
	BL	09APR96	1 ,-56	4	3	4	5	3	4	1	3	2	29
	2	23APR96	15 ,-42	5	4	5	5	4	5	2	3	3	36
	4	07MAY96	29 ,-28	4	3	4	4	3	4	2	2	1	27
	6	21MAY96	43 ,-14	3	3	3	2	2	3	1	2	1	20
	8	04JUN96	57 , 1	3	2	1	1	1	2	1	1	1	13
	12	02JUL96	85 , 29	1	1	1	1	1	2	1	1	1	10
	16	30JUL96	113 , 57	3	2	3	3	1	3	2	3	1	21
	20	27AUG96	141 , 85	1	1	2	2	1	3	1	1	1	13
	24	23SEP96	168 ,112	4	3	3	4	3	4	2	2	1	26
	28	21OCT96	196 ,140	1	1	3	3	3	4	1	1	1	18
329.009.00324	SC	21OCT96	-7 , .	4	4	4	5	4	2	1	4	3	31
	BL	28OCT96	1 , .	5	4	4	5	3	3	1	5	3	33
	2	11NOV96	15 , .	3	1	2	3	2	2	1	4	1	19
	4	25NOV96	29 , .	1	1	1	1	2	2	1	1	1	11

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00324	6	09DEC96	43 , .	1	1	1	1	1	1	1	1	1	9
	8	27DEC96	61 , .	1	1	1	1	1	1	1	1	1	9
329.009.00328	SC	30SEP96	-7 , .	3	4	4	5	4	1	1	3	1	26
	BL	07OCT96	1 , .	4	3	4	5	4	3	1	4	1	29
329.009.00329	SC	01OCT96	-8 , .	4	3	4	4	4	4	1	2	1	27
	BL	09OCT96	1 , .	4	2	5	5	1	4	2	1	1	25
	2	23OCT96	15 , .	4	2	5	5	1	4	2	1	1	25
	4	05NOV96	28 , .	5	2	4	4	4	5	1	1	1	27
	6	19NOV96	42 , .	4	1	4	3	3	4	1	1	1	22
	8	03DEC96	56 , .	3	1	4	3	1	3	1	1	1	18
329.010.00182	SC	05DEC95	-14 , .	6	3	5	6	5	4	4	5	5	43
	BL	19DEC95	1 , .	6	1	5	6	5	4	4	5	3	39
	4	19JAN96	32 , .	4	1	5	3	3	1	2	1	1	21
329.010.00278	SC	02FEB96	-7 ,-63	5	5	4	5	4	4	1	5	2	35
	BL	09FEB96	1 ,-56	5	5	5	5	4	4	1	5	2	36
	2	23FEB96	15 ,-42	4	1	4	5	3	3	2	4	1	27
	4	08MAR96	29 ,-28	4	3	4	4	3	1	1	2	1	23
	6	22MAR96	43 ,-14	4	1	3	3	2	3	1	4	2	23
	8	05APR96	57 , 1	3	1	1	2	2	1	1	3	1	15
	12	03MAY96	85 , 29	1	1	1	1	2	4	2	4	1	17
	20	27JUN96	140 , 84	2	1	2	3	2	1	1	1	1	14
	24	25JUL96	168 ,112	4	1	1	1	1	1	1	6	3	19
	28	22AUG96	196 ,140	1	1	1	1	1	1	1	4	1	12
	32	19SEP96	224 ,168	1	1	1	1	1	1	1	2	1	10

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.010.00280	SC	10MAY96	-7 ,-62	4	4	4	5	3	1	1	2	1	25
	BL	17MAY96	1 ,-55	4	3	4	5	1	1	2	3	1	24
	4	14JUN96	29 ,-27	4	1	3	5	5	1	6	5	1	31
	6	27JUN96	42 ,-14	2	1	1	1	2	1	3	1	1	13
	8	11JUL96	56 , 1	1	1	1	2	2	1	1	1	1	11
	12	21AUG96	97 , 42	2	1	2	2	2	2	4	1	1	17
329.011.00283	SC	30JAN96	-9 ,-66	4	4	3	5	1	4	6	2	4	33
	BL	07FEB96	-1 ,-58	4	2	2	3	1	3	3	3	1	22
	2	21FEB96	14 ,-44	2	2	1	4	3	1	2	1	1	17
	4	07MAR96	29 ,-29	2	2	1	3	4	2	1	1	1	17
	6	22MAR96	44 ,-14	1	1	1	1	2	1	1	1	1	10
	8	04APR96	57 , -1	2	1	1	1	1	1	1	1	1	10
329.011.00288	SC	01JUL96	-24 , .	5	1	3	5	4	1	1	3	4	27
	BL	18JUL96	-7 , .	4	1	3	4	2	1	1	1	1	18
	2	09AUG96	16 , .	3	1	1	2	1	1	2	1	1	13
	5	29AUG96	36 , .	3	1	1	1	1	1	1	1	1	11
329.012.00025	SC	17OCT95	-7 , .	4	1	5	4	1	1	2	3	5	26
	BL	24OCT95	1 , .	5	1	5	5	1	3	2	4	3	29
	2	07NOV95	15 , .	4	1	4	5	1	4	2	5	1	27
	4	21NOV95	29 , .	4	1	3	3	1	3	5	1	1	22
	6	05DEC95	43 , .	4	1	4	3	1	1	3	2	1	20
	8	19DEC95	57 , .	4	2	4	3	1	1	3	4	1	23
329.012.00220	SC	04JUN96	-13 ,-73	5	3	4	3	1	2	6	6	4	34
	BL	14JUN96	-3 ,-63	5	1	4	5	4	1	1	4	3	28
	2	28JUN96	12 ,-49	4	3	4	2	3	1	1	4	2	24

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.012.00220	4	12JUL96	26 ,-35	3	3	3	3	1	1	1	3	1	19
	6	29JUL96	43 ,-18	1	2	1	3	1	1	1	1	1	12
	8	16AUG96	61 , 1	1	1	1	1	1	1	1	1	1	9
	12	13SEP96	89 , 29	1	1	1	1	1	1	1	1	1	9
	16	11OCT96	117 , 57	1	3	1	2	3	1	1	3	1	16
	20	08NOV96	145 , 85	1	2	1	1	1	1	1	3	1	12
	24	06DEC96	173 ,113	3	3	2	2	3	1	1	3	2	20
329.012.00222	SC	18JUN96	-10 ,-73	5	4	5	4	1	3	1	4	4	31
	BL	28JUN96	1 ,-63	5	4	4	3	1	2	1	4	4	28
	2	12JUL96	15 ,-49	4	3	4	3	1	1	1	4	2	23
	4	29JUL96	32 ,-32	2	1	2	1	2	1	1	3	2	15
	7	13AUG96	47 ,-17	3	2	2	1	1	1	1	3	1	15
	8	30AUG96	64 , 1	1	1	1	1	1	1	1	1	1	9
	12	27SEP96	92 , 29	1	1	1	1	1	1	1	1	1	9
329.012.00226	SC	26NOV96	-7 , .	5	2	5	5	3	3	3	4	4	34
	BL	03DEC96	1 , .	5	1	5	5	3	3	3	4	4	33
	2	20DEC96	18 , .	5	1	5	5	3	3	3	4	4	33
329.012.00228	SC	04MAR97	-15 , .	4	4	4	4	2	1	2	4	1	26
	BL	19MAR97	1 , .	4	4	4	3	3	1	1	4	2	26
329.012.00231	SC	26FEB97	-9 ,-70	5	4	4	4	3	1	3	1	3	28
	BL	07MAR97	1 ,-61	5	4	4	4	3	1	3	1	1	26
	2	24MAR97	18 ,-44	4	3	4	3	2	1	4	1	1	23
	5	09APR97	34 ,-28	3	1	3	3	3	1	3	1	1	19
	7	25APR97	50 ,-12	4	4	3	4	3	1	3	1	1	24
	8	07MAY97	62 , 1	3	1	1	1	2	2	3	1	1	15

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.012.00231	12	04JUN97	90 , 29	3	1	1	4	3	1	2	3	1	19
	16	30JUN97	116 , 55	3	1	3	2	2	3	3	3	1	21
	20	05AUG97	152 , 91	3	3	3	3	3	1	1	3	1	21

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.001.00061	SC	19JUL94	-10 , .	6	5	5	4	4	5	4	4	2	39
	BL	29JUL94	1 , .	3	3	4	4	4	5	4	4	1	32
	2	11AUG94	14 , .	4	1	4	4	2	5	6	3	1	30
	4	25AUG94	28 , .	1	1	2	1	2	2	4	4	1	18
329.001.00066	SC	14NOV94	-8 , .	5	4	5	4	4	4	3	4	2	35
	BL	21NOV94	-1 , .	5	3	5	4	3	4	3	4	1	32
	2	05DEC94	14 , .	2	1	2	3	3	3	3	3	1	21
329.001.00067	SC	15NOV94	-7 , .	6	4	5	5	5	4	2	4	1	36
	BL	22NOV94	1 , .	5	1	5	4	4	4	2	4	2	31
	2	06DEC94	15 , .	5	1	4	5	5	2	3	3	1	29
329.001.00070	SC	14FEB95	-8 , .	6	5	5	5	3	5	3	4	2	38
	BL	22FEB95	1 , .	5	3	6	5	3	5	3	4	1	35
	2	08MAR95	15 , .	3	1	4	3	3	3	3	4	1	25
329.001.00122	SC	13JUN95	-7 ,-64	5	3	5	5	4	5	3	4	4	38
	BL	20JUN95	1 ,-57	4	1	3	4	1	4	3	4	1	25
	2	05JUL95	16 ,-42	2	1	4	4	4	3	1	4	1	24
	4	18JUL95	29 ,-29	1	1	3	4	2	4	3	2	1	21
	6	01AUG95	43 ,-15	1	1	1	1	4	2	2	3	1	16
	8	16AUG95	58 , 1	1	2	3	2	3	2	1	2	1	17
	12	12SEP95	85 , 28	1	1	2	3	4	2	3	4	1	21
	16	10OCT95	113 , 56	1	1	3	2	3	2	1	2	1	16
	20	07NOV95	141 , 84	3	1	3	1	4	2	2	4	1	21
	24	05DEC95	169 ,112	3	1	2	4	4	2	3	4	1	24
329.002.00050	SC	10MAR95	-13 , .	4	1	5	5	1	3	1	5	1	26

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.002.00050	BL	22MAR95	-1 , .	5	1	5	4	1	5	1	5	1	28
	2	05APR95	14 , .	5	1	5	1	1	4	1	1	1	20
	5	28APR95	37 , .	4	1	5	4	1	4	4	4	1	28
329.002.00056	SC	24JUN94	-25 , .	6	3	5	5	3	4	6	1	4	37
	BL	19JUL94	1 , .	5	2	4	3	2	3	6	1	1	27
	2	02AUG94	15 , .	2	1	4	1	1	1	5	1	1	17
	4	16AUG94	29 , .	1	1	3	2	2	1	1	1	1	13
329.002.00057	SC	11AUG94	-28 ,-85	5	2	6	6	5	4	1	5	3	37
	BL	08SEP94	1 ,-57	5	2	6	6	5	4	1	5	2	36
	2	22SEP94	15 ,-43	4	1	4	3	2	2	3	1	2	22
	4	06OCT94	29 ,-29	1	1	1	1	2	1	1	1	1	10
	6	20OCT94	43 ,-15	1	1	1	1	2	1	1	1	1	10
	8	03NOV94	57 , -1	1	1	1	1	1	2	1	1	1	10
	12	01DEC94	85 , 28	1	1	1	1	1	1	1	1	1	9
	16	29DEC94	113 , 56	1	1	1	1	1	1	1	1	1	9
329.002.00098	SC	03JAN95	1 , .	4	3	4	4	1	3	1	4	2	26
	2	18JAN95	16 , .	4	4	4	3	1	2	1	3	1	23
	4	31JAN95	29 , .	4	1	4	3	1	3	1	2	1	20
	6	14FEB95	43 , .	4	2	3	3	3	1	1	3	1	21
	8	02MAR95	59 , .	5	3	4	4	3	3	1	4	1	28
329.002.00100	SC	16FEB95	-19 ,-77	5	1	4	5	3	1	2	3	2	26
	BL	07MAR95	1 ,-58	5	1	4	5	3	3	2	3	2	28
	2	21MAR95	15 ,-44	4	1	3	5	3	2	1	2	1	22
	4	04APR95	29 ,-30	4	1	2	1	3	2	2	1	1	17
	6	18APR95	43 ,-16	2	1	1	2	2	1	1	1	1	12

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.002.00100	8	04MAY95	59 , 1	2	1	4	1	2	2	5	1	1	19
	12	30MAY95	85 , 27	5	1	5	2	3	1	1	1	1	20
	16	27JUN95	113 , 55	1	1	1	1	3	1	1	3	1	13
	16	06JUL95	122 , 64	1	1	2	1	3	2	1	1	1	13
329.002.00103	SC	11APR95	-9 ,-65	5	4	3	4	3	2	3	2	1	27
	BL	20APR95	1 ,-56	5	4	3	4	4	2	2	2	2	28
	2	02MAY95	13 ,-44	4	4	3	4	2	1	4	2	1	25
	4	16MAY95	27 ,-30	2	1	1	1	2	1	1	1	1	11
	6	30MAY95	41 ,-16	2	1	2	2	1	1	1	1	1	12
	8	15JUN95	57 , 1	1	1	2	1	1	1	1	1	1	10
	12	13JUL95	85 , 29	1	1	1	1	1	1	3	1	1	11
	16	10AUG95	113 , 57	3	2	3	1	3	1	1	3	1	18
329.002.00104	SC	28APR95	-6 ,-62	4	4	4	4	1	3	1	4	2	27
	2	18MAY95	15 ,-42	4	1	4	4	1	4	1	4	1	24
	4	01JUN95	29 ,-28	3	1	3	4	4	2	1	3	0	21
	6	16JUN95	44 ,-13	3	1	3	3	1	2	2	4	1	20
	8	29JUN95	57 , 1	4	1	2	1	1	2	1	1	1	14
	12	25JUL95	83 , 27	2	1	1	1	1	1	1	1	1	10
	16	29AUG95	118 , 62	2	1	2	1	1	2	1	1	1	12
	20	03OCT95	153 , 97	2	1	2	1	1	2	1	1	1	12
	28	06NOV95	187 ,131	2	1	1	1	1	1	1	2	1	11
	32	06DEC95	217 ,161	2	1	2	1	1	2	1	3	1	14
	32	02JAN96	244 ,188	2	1	2	1	1	1	1	2	1	12
329.002.00243	SC	27FEB96	-16 , .	3	2	5	2	3	4	1	4	3	27
	2	28MAR96	15 , .	6	5	6	3	3	3	4	5	2	37

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.002.00244	SC	14MAR96	-7 ,-64	5	4	5	2	1	3	4	4	1	29
	BL	21MAR96	1 ,-57	4	4	5	2	1	3	4	4	3	30
	2	04APR96	15 ,-43	6	2	4	1	1	4	1	1	1	21
	4	18APR96	29 ,-29	4	2	3	1	1	3	2	2	1	19
	6	02MAY96	43 ,-15	4	2	3	1	1	3	1	1	1	17
	8	16MAY96	57 , -1	3	3	1	1	1	2	2	2	1	16
329.002.00321	SC	15MAY96	-8 , .	5	2	4	5	4	4	1	4	3	32
329.002.00322	SC	06JAN97	-3 , .	2	3	4	4	3	3	1	4	4	28
	2	23JAN97	15 , .	2	1	4	4	3	4	1	4	1	24
	4	04FEB97	27 , .	2	2	4	4	1	3	1	4	1	22
329.003.00073	SC	11JAN95	-8 , .	5	3	4	6	5	4	0	6	1	34
	BL	18JAN95	-1 , .	5	3	5	5	3	4	3	5	1	34
	4	14FEB95	27 , .	4	1	4	4	5	3	0	5	1	27
329.003.00076	SC	24JAN95	-7 ,-62	7	1	5	6	3	4	0	1	5	32
	BL	31JAN95	1 ,-55	5	3	3	5	3	3	1	3	4	30
	2	14FEB95	15 ,-41	4	1	2	1	4	3	0	4	1	20
	4	27FEB95	28 ,-28	3	1	1	1	4	3	1	1	1	16
	6	13MAR95	42 ,-14	3	1	1	1	1	1	1	1	1	11
	8	27MAR95	56 , 1	1	1	1	1	1	1	1	1	1	9
	12	03MAY95	93 , 38	1	1	1	1	1	1	1	1	1	9
	16	31MAY95	121 , 66	1	1	1	1	1	1	1	1	1	9
	20	28JUN95	149 , 94	1	1	1	1	1	1	1	1	1	9
	28	02AUG95	184 ,129	1	1	1	1	1	1	1	1	1	9
	32	06SEP95	219 ,164	1	1	1	1	1	1	1	1	1	9
	32	11OCT95	254 ,199	1	1	1	1	1	1	1	1	1	9

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00079	SC	14APR95	-19 , .	5	1	5	5	1	4	1	4	2	28
	BL	03MAY95	1 , .	4	3	4	5	2	4	4	2	2	30
	2	19MAY95	17 , .	4	1	4	5	1	3	3	4	1	26
329.003.00082	SC	11DEC95	1 , .	7	1	5	5	3	1	1	5	2	30
329.003.00088	SC	06FEB95	-22 , .	6	5	5	4	3	4	1	2	1	31
	BL	28FEB95	1 , .	5	4	5	5	3	1	4	1	4	32
	2	14MAR95	15 , .	6	4	6	6	5	4	0	1	1	33
	4	30MAR95	31 , .	5	3	4	4	4	3	2	2	2	29
329.003.00090	SC	08MAR95	-6 , .	5	5	4	4	2	2	3	1	1	27
	BL	14MAR95	1 , .	4	5	5	5	5	2	1	3	1	31
	5	18APR95	36 , .	4	2	1	1	3	1	1	5	1	19
	8	16MAY95	64 , .	7	3	6	6	3	4	1	4	3	37
329.003.00092	SC	13APR95	-20 ,-78	4	1	1	3	2	1	1	5	1	19
	BL	02MAY95	-1 ,-59	4	1	1	3	3	1	1	3	1	18
	2	16MAY95	14 ,-45	1	1	1	1	1	1	1	1	1	9
	4	02JUN95	31 ,-28	1	1	1	1	1	1	1	2	1	10
	6	13JUN95	42 ,-17	1	1	1	1	1	1	1	1	1	9
	8	30JUN95	59 , 1	1	1	1	1	1	1	1	1	1	9
	12	08AUG95	98 , 40	1	1	1	1	1	1	1	1	1	9
	16	05SEP95	126 , 68	1	1	1	1	1	1	1	1	1	9
	20	26SEP95	147 , 89	2	1	1	1	1	1	1	1	1	10
	28	07NOV95	189 ,131	1	1	1	1	1	1	1	1	1	9
	32	05DEC95	217 ,159	1	1	1	1	1	1	1	1	1	9
	32	02JAN96	245 ,187	1	1	1	1	1	1	1	1	1	9

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00093	SC	08JUN95	-13 ,-76	6	4	5	6	3	3	1	2	3	33
	BL	20JUN95	-1 ,-64	5	4	4	5	3	1	4	4	3	33
	2	06JUL95	16 ,-48	6	1	1	4	1	4	1	1	3	22
	5	25JUL95	35 ,-29	5	1	3	3	3	3	1	2	2	23
	7	10AUG95	51 ,-13	2	1	1	1	1	1	1	1	1	10
	8	22AUG95	63 , -1	2	2	1	1	1	1	1	1	1	11
	16	03OCT95	105 , 42	1	1	1	1	1	1	1	1	1	9
329.003.00247	SC	05JAN96	-27 ,-81	4	4	4	5	4	4	1	4	1	31
	BL	30JAN96	-2 ,-56	3	3	2	4	2	4	1	4	1	24
	2	13FEB96	13 ,-42	1	1	2	1	1	1	1	1	0	9
	4	27FEB96	27 ,-28	2	1	1	1	1	1	1	1	1	10
	6	12MAR96	41 ,-14	1	1	1	1	1	1	1	1	1	9
	8	26MAR96	55 , 1	1	1	4	1	1	1	1	1	1	12
	12	30APR96	90 , 36	1	1	1	1	1	1	1	1	1	9
329.003.00249	SC	01MAR96	-6 , .	7	4	4	5	3	4	3	4	4	38
	BL	07MAR96	1 , .	5	4	5	5	1	4	4	1	4	33
	2	19MAR96	13 , .	6	4	4	5	3	4	3	4	2	35
	4	02APR96	27 , .	4	5	5	3	4	4	1	2	1	29
	8	30APR96	55 , .	5	3	2	4	3	1	1	1	1	21
329.003.00289	SC	12FEB96	-16 ,-72	5	5	6	5	4	0	1	4	1	31
	BL	28FEB96	1 ,-56	5	5	6	5	1	1	.	4	1	32
	2	13MAR96	15 ,-42	4	4	2	2	3	1	1	5	1	23
	6	10APR96	43 ,-14	3	3	3	1	1	1	1	1	1	15
	8	24APR96	57 , 1	1	1	1	1	1	1	1	1	1	9
	12	22MAY96	85 , 29	1	1	1	1	1	1	1	1	1	9
	24	16AUG96	171 ,115	1	1	1	1	1	1	1	1	1	9

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00289	28	13SEP96	199 ,143	1	1	2	1	1	1	1	1	1	10
	32	11OCT96	227 ,171	1	1	1	1	1	1	1	1	1	9
329.003.00290	SC	06MAR96	-5 , .	6	4	5	4	1	4	1	4	2	31
	BL	11MAR96	1 , .	5	1	5	4	1	4	1	4	2	27
329.003.00314	5	26NOV96	36 , .	3	1	3	0	4	1	4	4	1	21
	7	10DEC96	50 , .	2	5	3	2	3	2	1	3	1	22
	8	23DEC96	63 , .	2	1	1	2	1	1	1	1	1	11
329.003.00317	SC	12DEC96	-7 , .	6	5	5	5	4	5	1	3	2	36
	4	14JAN97	27 , .	4	4	4	4	1	4	1	3	1	26
	6	28JAN97	41 , .	5	4	6	5	1	5	1	3	1	31
	8	11FEB97	55 , .	4	5	6	3	4	4	1	2	1	30
329.004.00013	SC	05JUL94	-14 ,-73	4	3	3	4	3	3	1	1	1	23
	BL	19JUL94	1 ,-59	3	1	2	2	3	4	1	3	1	20
	2	02AUG94	15 ,-45	3	2	2	3	2	2	1	1	1	17
	4	15AUG94	28 ,-32	1	2	1	2	1	1	2	2	1	13
	6	31AUG94	44 ,-16	1	1	1	1	1	1	1	1	1	9
	8	16SEP94	60 , 1	1	1	1	2	1	1	1	1	1	10
	12	11OCT94	85 , 26	2	1	1	1	1	1	1	1	1	10
	16	08NOV94	113 , 54	2	1	1	1	1	2	1	1	1	11
	20	06DEC94	141 , 82	2	1	1	1	1	1	1	1	1	10
	24	10JAN95	176 ,117	1	1	1	1	1	1	1	1	1	9
	28	07FEB95	204 ,145	1	1	1	1	1	1	1	1	1	9
	32	10MAR95	235 ,176	1	1	1	1	1	1	1	1	1	9
329.004.00014	SC	22NOV94	-7 , .	5	3	5	5	1	1	1	4	1	26

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.004.00014	BL	29NOV94	1 , .	5	3	5	5	1	1	2	4	1	27
	2	13DEC94	15 , .	4	1	5	5	3	1	1	4	1	25
329.004.00211	SC	24JAN96	-9 , .	4	3	4	2	4	1	1	4	3	26
	BL	01FEB96	-1 , .	4	3	4	4	4	1	1	3	3	27
	2	16FEB96	15 , .	4	2	2	2	3	1	1	2	1	18
	4	29FEB96	28 , .	1	1	3	1	3	1	1	1	1	13
	6	14MAR96	42 , .	1	1	1	1	3	1	1	4	1	14
	7	25MAR96	53 , .	1	1	1	1	3	1	1	1	1	11
329.004.00215	SC	12MAR97	-8 , .	4	3	4	5	3	4	5	1	3	32
	BL	20MAR97	1 , .	4	1	4	4	3	4	5	3	1	29
	2	03APR97	15 , .	2	1	3	4	2	2	1	1	1	17
	4	15APR97	27 , .	1	1	2	3	2	1	3	1	1	15
	6	29APR97	41 , .	1	3	1	4	1	1	1	4	1	17
329.005.00003	SC	12SEP94	-8 , .	4	4	5	5	1	3	4	4	1	31
	BL	20SEP94	1 , .	4	4	4	5	1	3	4	1	1	27
	2	04OCT94	15 , .	3	3	4	5	1	1	4	1	1	23
329.005.00006	SC	27OCT94	-8 ,-68	5	3	1	5	1	4	1	1	2	23
	BL	03NOV94	-1 ,-61	4	2	1	5	3	4	1	1	2	23
	2	21NOV94	18 ,-43	4	2	1	3	2	3	1	1	2	19
	4	05DEC94	32 ,-29	3	1	1	2	2	1	1	1	1	13
	6	19DEC94	46 ,-15	3	2	1	2	2	2	1	1	1	15
	8	03JAN95	61 , 1	1	2	1	1	1	1	1	1	1	10
	12	02FEB95	91 , 31	1	4	1	2	3	1	1	2	3	18
	16	27FEB95	116 , 56	2	1	1	1	3	1	1	4	3	17
	20	05APR95	153 , 93	1	3	1	1	2	1	1	1	1	12

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00007	SC	02NOV94	-7 ,-70	5	1	6	5	4	4	6	1	3	35
	BL	09NOV94	1 ,-63	5	1	6	5	4	3	6	2	1	33
	3	30NOV94	22 ,-42	4	1	6	5	4	1	4	4	3	32
	5	14DEC94	36 ,-28	4	1	4	5	4	1	1	3	2	25
	7	28DEC94	50 ,-14	1	1	2	5	3	1	1	4	1	19
	8	11JAN95	64 , 1	1	1	2	2	3	1	1	4	1	16
	12	15FEB95	99 , 36	2	1	1	2	2	2	1	4	1	16
	20	22MAR95	134 , 71	1	1	1	1	2	1	1	3	1	12
	24	19APR95	162 , 99	2	1	1	1	2	1	1	1	3	13
	28	17MAY95	190 ,127	2	1	1	1	2	1	1	3	1	13
329.005.00009	SC	07DEC94	-5 , .	5	3	5	4	5	4	1	5	4	36
	BL	12DEC94	1 , .	5	1	5	4	5	4	1	5	4	34
	2	27DEC94	16 , .	4	1	3	4	1	4	1	4	3	25
	4	11JAN95	31 , .	3	1	2	4	3	4	1	4	2	24
	6	25JAN95	45 , .	4	1	2	5	3	3	1	4	3	26
	8	07FEB95	58 , .	4	1	2	3	3	1	1	4	3	22
329.005.00110	SC	04JAN95	-7 , .	4	2	4	3	4	4	1	4	3	29
	BL	11JAN95	1 , .	3	2	2	1	3	1	2	1	1	16
	2	25JAN95	15 , .	3	2	2	3	2	2	1	3	1	19
329.005.00113	SC	20JAN95	-10 , .	4	1	5	4	4	4	1	4	5	32
	BL	30JAN95	1 , .	4	1	4	4	4	4	1	4	3	29
	2	16FEB95	18 , .	2	1	2	2	4	3	1	3	1	19
329.005.00117	SC	06MAR95	-12 , .	4	2	5	4	3	3	1	4	1	27
	BL	16MAR95	-2 , .	4	2	5	4	3	3	1	4	1	27
	2	03APR95	17 , .	3	1	3	3	1	1	1	1	1	15

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00117	4	17APR95	31 , .	3	1	4	1	1	1	1	4	1	17
	6	01MAY95	45 , .	3	1	1	1	1	1	1	1	1	11
	8	15MAY95	59 , .	2	1	1	1	1	1	1	1	1	10
329.005.00118	SC	09MAY95	-8 , .	4	3	2	2	1	1	6	5	4	28
	BL	17MAY95	1 , .	4	2	5	2	1	3	1	5	3	26
	2	30MAY95	14 , .	3	1	2	3	4	4	1	2	3	23
	4	14JUN95	29 , .	4	1	2	2	1	3	1	3	1	18
	6	27JUN95	42 , .	2	1	2	1	1	1	1	1	1	11
329.005.00153	SC	11JAN96	-14 ,-70	3	2	4	4	1	1	1	5	1	22
	BL	25JAN96	1 ,-56	3	3	4	4	2	2	1	4	1	24
	2	08FEB96	15 ,-42	3	1	4	4	3	3	1	4	1	24
	4	22FEB96	29 ,-28	3	1	2	3	3	1	1	4	1	19
	6	06MAR96	42 ,-15	2	1	2	2	2	1	1	2	1	14
	8	21MAR96	57 , 1	2	1	1	2	1	1	1	1	1	11
	12	17APR96	84 , 28	3	2	1	1	1	1	1	1	2	13
	16	15MAY96	112 , 56	2	1	1	1	2	1	1	1	1	11
	20	12JUN96	140 , 84	1	1	1	1	2	1	1	1	1	10
	24	10JUL96	168 ,112	1	1	1	1	2	1	1	1	1	10
	28	05AUG96	194 ,138	2	1	1	1	1	1	1	1	1	10
	32	04SEP96	224 ,168	2	1	1	1	1	1	2	1	1	11
329.005.00255	SC	26FEB96	-7 , .	4	3	4	1	2	1	1	4	2	22
	BL	04MAR96	1 , .	4	3	4	3	2	1	1	3	1	22
	2	18MAR96	15 , .	5	3	5	1	1	1	1	4	1	22
	4	01APR96	29 , .	4	3	3	2	1	1	1	1	1	17
	6	15APR96	43 , .	4	3	3	1	1	1	1	5	1	20
	8	29APR96	57 , .	3	3	4	1	1	1	1	3	1	18

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00256	SC	20FEB96	-14 ,-70	4	1	1	4	4	1	1	5	2	23
	BL	05MAR96	1 ,-56	4	1	1	5	2	1	1	3	1	19
	2	21MAR96	17 ,-40	4	1	1	4	2	1	1	3	1	18
	4	02APR96	29 ,-28	2	1	1	3	2	1	1	3	1	15
	6	16APR96	43 ,-14	2	1	3	2	1	1	1	3	1	15
	8	30APR96	57 , 1	3	1	2	2	1	1	1	1	1	13
	12	28MAY96	85 , 29	2	1	1	3	1	1	1	3	1	14
	16	02JUL96	120 , 64	2	1	1	1	1	1	1	1	1	10
329.005.00295	SC	21MAR96	-7 , .	4	2	4	5	4	4	1	2	3	29
	BL	28MAR96	1 , .	4	2	4	3	4	3	1	2	1	24
	2	11APR96	15 , .	4	1	1	2	3	1	1	3	1	17
	4	24APR96	28 , .	4	1	1	2	4	1	1	3	3	20
	6	09MAY96	43 , .	4	1	1	1	3	1	1	3	1	16
	8	22MAY96	56 , .	2	1	1	2	1	1	1	3	1	13
329.005.00297	SC	28MAR96	-22 , .	4	1	3	4	4	1	1	4	1	23
	BL	19APR96	1 , .	4	1	3	5	4	1	1	5	1	25
	2	02MAY96	14 , .	1	1	3	4	4	1	1	2	1	18
329.005.00332	SC	05DEC96	-7 , .	4	2	4	4	2	4	1	1	1	23
	BL	12DEC96	1 , .	.	1	2	4	2	4	1	2	2	20
	2	26DEC96	15 , .	4	1	1	4	3	3	1	1	1	19
	4	09JAN97	29 , .	4	1	2	4	3	3	1	1	1	20
	6	23JAN97	43 , .	3	1	1	3	3	1	1	1	1	15
	8	06FEB97	57 , .	4	1	3	4	3	3	1	2	1	22
329.005.00335	SC	20FEB97	-8 , .	5	1	4	4	3	3	1	4	2	27
	BL	28FEB97	1 , .	4	1	4	4	3	2	1	4	1	24

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00335	2	14MAR97	15 , .	3	1	2	2	2	3	1	3	1	18
	4	27MAR97	28 , .	3	1	4	2	2	2	1	2	1	18
	6	10APR97	42 , .	3	2	1	2	2	3	1	3	1	18
	8	24APR97	56 , .	3	1	1	4	3	3	1	3	1	20
329.006.00040	SC	10FEB95	-6 , .	4	5	5	1	4	4	1	3	2	29
	BL	15FEB95	-1 , .	4	4	5	1	4	1	4	5	2	30
	2	01MAR95	14 , .	3	1	4	2	1	3	6	1	1	22
329.006.00041	SC	22MAR95	-14 ,-78	4	1	3	6	5	5	1	4	1	30
	BL	05APR95	1 ,-64	4	1	4	4	3	4	4	1	1	26
	2	19APR95	15 ,-50	4	1	4	6	3	4	2	3	1	28
	4	01MAY95	27 ,-38	4	1	5	5	1	5	1	4	1	27
	6	15MAY95	41 ,-24	4	1	4	5	4	4	4	4	1	31
	8	31MAY95	57 , -8	4	1	2	4	1	3	1	4	1	21
	12	05JUL95	92 , 28	4	1	1	2	1	2	4	1	1	17
	16	31JUL95	118 , 54	2	1	1	1	1	1	2	1	1	11
	20	24AUG95	142 , 78	2	1	1	1	1	1	1	4	1	13
	24	21SEP95	170 ,106	2	1	1	1	1	1	1	1	1	10
	28	24OCT95	203 ,139	4	1	1	3	1	2	1	3	1	17
	32	21NOV95	231 ,167	1	1	1	1	1	2	1	1	1	10
329.007.00139	SC	04MAY95	-4 , .	4	1	4	5	5	3	1	1	1	25
	BL	05MAY95	-3 , .	4	3	.	4	4	4	4	1	2	29
	2	25MAY95	18 , .	4	1	2	3	1	2	3	1	1	18
329.007.00143	SC	26OCT95	-14 , .	4	2	4	4	3	4	1	4	1	27
	BL	09NOV95	1 , .	5	1	5	4	3	3	1	4	1	27
	2	22NOV95	14 , .	5	1	4	3	1	4	1	3	1	23

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.007.00146	SC	18JAN96	-7 ,-60	5	3	5	4	1	5	1	2	2	28
	BL	25JAN96	1 ,-53	4	4	4	4	4	4	1	1	1	27
	2	05FEB96	12 ,-42	4	4	4	1	1	1	1	2	1	19
	4	19FEB96	26 ,-28	3	1	3	1	1	1	1	1	1	13
	6	04MAR96	40 ,-14	2	2	3	1	1	1	1	1	1	13
	8	18MAR96	54 , 1	1	1	1	1	1	1	1	1	1	9
	12	15APR96	82 , 29	4	4	1	3	1	1	3	1	1	19
	16	13MAY96	110 , 57	3	1	1	1	1	1	1	1	1	11
	20	06JUN96	134 , 81	4	3	3	1	1	1	1	1	1	16
	24	08JUL96	166 ,113	1	1	1	1	1	1	1	1	1	9
	28	05AUG96	194 ,141	2	1	2	1	1	1	1	1	1	11
	32	09SEP96	229 ,176	1	1	2	1	1	1	1	2	1	11
329.007.00269	SC	04APR96	-7 , .	5	5	4	5	4	4	1	5	3	36
	BL	11APR96	1 , .	5	4	5	3	4	1	1	5	2	30
	2	25APR96	15 , .	3	1	3	3	4	1	1	5	1	22
329.007.00270	SC	02MAY96	-7 , .	4	4	4	4	1	4	1	4	3	29
	BL	09MAY96	1 , .	4	3	4	3	1	1	1	4	1	22
	2	23MAY96	15 , .	2	1	3	1	1	1	1	2	1	13
	4	06JUN96	29 , .	1	1	1	1	1	1	1	2	1	10
	6	20JUN96	43 , .	1	1	1	1	1	3	1	4	1	14
329.007.00307	SC	09MAY96	-7 , .	4	5	5	5	4	5	4	5	2	39
	BL	16MAY96	1 , .	5	4	4	5	4	1	4	4	1	32
	2	30MAY96	15 , .	4	4	4	1	1	1	1	5	1	22
	4	13JUN96	29 , .	3	4	1	3	3	1	1	4	1	21
	8	25JUL96	71 , .	3	3	5	4	5	5	1	5	1	32

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.007.00308	SC	27JUN96	-5 , .	4	1	5	5	4	5	4	1	3	32
	BL	02JUL96	1 , .	4	4	4	4	3	4	4	1	1	29
329.008.00159	SC	06SEP95	-7 ,-69	4	4	4	5	4	1	6	4	2	34
	BL	13SEP95	1 ,-62	4	4	4	4	2	4	4	5	1	32
	2	27SEP95	15 ,-48	3	1	1	4	2	2	1	2	1	17
	4	10OCT95	28 ,-35	3	1	1	2	3	2	1	4	1	18
	6	24OCT95	42 ,-21	2	2	1	1	1	1	1	2	1	12
	8	14NOV95	63 , 1	3	2	1	2	3	1	1	3	1	17
	16	26DEC95	105 , 43	3	3	1	4	3	1	1	4	1	21
	20	23JAN96	133 , 71	3	2	1	3	2	2	1	4	2	20
329.008.00161	SC	31OCT95	-16 ,-71	4	4	4	5	2	4	4	4	3	34
	BL	31OCT95	-16 ,-71	.	.	.	.	.	1	.	.	.	9
	BL	16NOV95	1 ,-55	5	4	2	3	4	.	4	1	1	27
	2	29NOV95	14 ,-42	2	1	1	1	1	1	1	1	1	10
	4	15DEC95	30 ,-26	1	1	1	1	1	1	1	1	1	9
	8	10JAN96	56 , 1	1	1	1	1	1	1	1	1	1	9
329.008.00187	SC	15NOV95	-14 , .	4	1	4	4	1	4	4	4	1	27
	BL	29NOV95	1 , .	4	1	4	4	1	4	1	4	3	26
	2	14DEC95	16 , .	4	1	3	4	2	4	1	1	1	21
	4	28DEC95	30 , .	5	1	4	4	1	5	1	3	3	27
	6	11JAN96	44 , .	4	1	4	4	1	4	1	4	3	26
	8	26JAN96	59 , .	4	1	3	4	1	4	1	1	1	20
329.008.00192	SC	14FEB96	-20 , .	4	3	4	5	4	3	1	3	1	28
	BL	05MAR96	1 , .	3	4	4	4	5	1	1	2	1	25
	2	18MAR96	14 , .	2	1	3	1	1	1	1	1	1	12

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.008.00192	4	03APR96	30 , .	2	1	2	2	1	1	5	2	1	17
329.008.00272	SC	19MAR96	-15 ,-71	4	4	4	4	1	5	2	1	1	26
	BL	03APR96	1 ,-56	2	4	4	4	1	4	2	1	1	23
	2	17APR96	15 ,-42	3	3	3	2	1	4	1	1	1	19
	4	01MAY96	29 ,-28	2	4	2	1	2	1	1	1	1	15
	8	29MAY96	57 , 1	1	1	1	1	1	1	3	1	1	11
	12	26JUN96	85 , 29	1	1	1	1	1	3	1	5	1	15
	16	24JUL96	113 , 57	1	2	1	1	1	1	1	1	1	10
	20	21AUG96	141 , 85	1	1	1	1	1	1	1	1	1	9
	24	18SEP96	169 ,113	1	1	1	4	5	1	1	1	1	16
329.008.00273	SC	19APR96	-28 ,-91	5	2	4	4	1	4	1	4	1	26
	BL	17MAY96	1 ,-63	4	1	3	4	1	1	1	4	1	20
	2	31MAY96	15 ,-49	2	1	1	3	1	1	1	1	1	12
	4	17JUN96	32 ,-32	1	1	1	2	2	1	1	1	1	11
	6	01JUL96	46 ,-18	2	1	1	1	1	1	1	1	1	10
	8	19JUL96	64 , 1	2	1	1	1	1	1	1	1	1	10
	16	04SEP96	111 , 48	1	1	1	1	1	1	1	1	1	9
329.009.00127	SC	03APR95	-7 , .	6	4	.	5	2	4	1	5	4	35
	BL	10APR95	1 , .	5	3	5	5	1	4	1	5	4	33
	2	24APR95	15 , .	4	3	3	4	1	3	1	3	1	23
	4	08MAY95	29 , .	3	1	3	3	1	2	1	4	1	19
329.009.00132	SC	17MAY95	-6 ,-63	3	3	4	6	4	1	1	4	1	27
	BL	23MAY95	1 ,-57	5	3	4	5	4	4	1	5	1	32
	2	06JUN95	15 ,-43	3	2	3	2	2	3	1	4	1	21
	4	20JUN95	29 ,-29	1	1	1	1	1	2	1	5	1	14

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00132	6	05JUL95	44 ,-14	1	1	1	1	1	2	1	1	1	10
	8	19JUL95	58 , 1	1	1	1	1	1	2	1	1	1	10
	12	24AUG95	94 , 37	1	1	1	1	1	1	1	1	1	9
	16	15SEP95	116 , 59	1	1	1	2	1	1	1	3	1	12
	20	24OCT95	155 , 98	4	3	4	5	3	5	3	4	1	32
329.009.00134	SC	28JUN95	-8 , .	4	4	4	4	2	3	3	4	3	31
	BL	06JUL95	1 , .	5	4	5	3	3	3	1	5	3	32
	2	19JUL95	14 , .	5	4	4	4	2	3	3	4	2	31
	4	03AUG95	29 , .	4	2	4	3	3	3	4	2	2	27
	6	15AUG95	41 , .	2	1	2	2	2	2	2	3	1	17
	8	29AUG95	55 , .	4	3	3	2	3	3	1	4	3	26
329.009.00137	SC	03OCT95	-7 , .	4	2	4	5	4	1	1	3	4	28
	BL	10OCT95	1 , .	4	1	4	4	3	4	1	4	1	26
	2	24OCT95	15 , .	4	3	4	5	4	3	2	3	1	29
	4	07NOV95	29 , .	4	3	4	4	4	3	1	3	1	27
	6	21NOV95	43 , .	3	1	2	3	3	2	1	1	1	17
	8	05DEC95	57 , .	1	1	2	4	3	2	1	1	1	16
329.009.00171	SC	31OCT95	-7 , .	5	4	4	4	4	4	5	2	3	35
	BL	07NOV95	1 , .	5	4	4	5	5	4	5	3	3	38
329.009.00172	SC	06NOV95	-7 ,-64	5	2	5	5	3	3	1	4	2	30
	BL	13NOV95	1 ,-57	4	3	5	5	3	3	1	4	1	29
	2	27NOV95	15 ,-43	4	3	4	3	2	2	1	5	2	26
	4	11DEC95	29 ,-29	4	3	3	3	2	2	1	4	1	23
	6	27DEC95	45 ,-13	1	2	2	1	3	1	1	4	1	16
	8	09JAN96	58 , 1	3	4	3	3	2	3	1	1	1	21

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00172	12	07FEB96	87 , 30	1	2	1	2	1	1	1	1	1	11
	16	04MAR96	113 , 56	2	4	2	1	1	1	1	1	1	14
	20	01APR96	141 , 84	1	2	1	1	2	1	1	2	1	12
	24	29APR96	169 ,112	1	3	1	1	1	1	1	1	1	11
	28	10JUN96	211 ,154	2	3	1	1	1	1	1	3	1	14
	32	08JUL96	239 ,182	1	2	1	1	1	1	1	1	1	10
329.009.00194	SC	28NOV95	-7 ,-63	3	3	4	5	4	1	1	5	2	28
	BL	05DEC95	1 ,-56	4	3	5	5	5	4	1	4	1	32
	2	19DEC95	15 ,-42	4	3	4	5	5	4	1	4	1	31
	4	02JAN96	29 ,-28	4	3	4	4	4	3	1	4	1	28
	6	16JAN96	43 ,-14	3	3	3	3	3	3	1	3	1	23
	8	30JAN96	57 , 1	1	2	2	1	2	2	1	2	1	14
	12	27FEB96	85 , 29	1	1	1	1	2	2	1	3	1	13
	16	02APR96	120 , 64	2	1	1	1	1	2	1	2	2	13
	20	30APR96	148 , 92	1	1	1	1	2	2	1	1	1	11
	24	04JUN96	183 ,127	1	1	1	1	1	2	1	1	1	10
329.009.00195	SC	06DEC95	-9 , .	4	3	2	5	4	2	1	4	4	29
	BL	15DEC95	1 , .	6	4	5	4	4	4	1	4	2	34
	2	27DEC95	13 , .	3	3	2	2	2	2	1	1	1	17
	3	08JAN96	25 , .	3	3	2	2	2	2	1	1	1	17
329.009.00199	SC	10JAN96	-6 , .	5	5	5	4	3	3	1	4	4	34
	BL	16JAN96	1 , .	5	5	5	4	4	2	1	4	4	34
	2	29JAN96	14 , .	4	4	3	3	4	1	1	4	3	27
	4	14FEB96	30 , .	4	3	4	3	3	3	1	4	1	26
	6	28FEB96	44 , .	4	3	3	3	3	3	1	4	1	25
	8	13MAR96	58 , .	4	2	4	2	3	3	1	4	1	24

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00203	SC	28FEB96	-5 , .	4	3	4	5	1	4	1	4	1	27
	BL	04MAR96	1 , .	4	3	4	4	1	4	1	4	1	26
	2	19MAR96	16 , .	4	2	4	4	2	3	1	4	1	25
329.009.00236	SC	17DEC96	-13 , .	4	3	4	5	3	4	1	2	3	29
	BL	30DEC96	1 , .	5	2	4	5	3	4	1	3	2	29
	2	15JAN97	17 , .	5	2	4	5	2	4	1	3	1	27
	4	27JAN97	29 , .	5	3	4	5	2	4	1	4	1	29
329.009.00239	SC	11NOV96	-8 ,-65	4	3	4	4	3	4	1	4	3	30
	BL	18NOV96	-1 ,-58	5	2	4	5	2	4	3	4	1	30
	2	02DEC96	14 ,-44	3	2	3	3	1	3	1	3	1	20
	4	16DEC96	28 ,-30	1	1	2	1	1	1	1	1	1	10
	6	30DEC96	42 ,-16	1	1	3	2	1	1	2	4	1	16
	8	15JAN97	58 , 1	1	1	1	1	1	1	1	1	1	9
	12	18FEB97	92 , 35	1	1	1	1	2	1	1	1	1	10
	16	17MAR97	119 , 62	1	1	1	1	1	1	1	1	1	9
	20	14APR97	147 , 90	1	1	1	1	1	1	1	1	1	9
	24	12MAY97	175 ,118	4	4	3	4	4	4	1	4	3	31
329.009.00262	SC	07FEB97	-10 , .	4	3	4	3	3	4	3	3	3	30
	BL	17FEB97	1 , .	4	1	4	3	1	4	1	3	3	24
	2	03MAR97	15 , .	3	2	3	3	2	3	1	2	1	20
	4	17MAR97	29 , .	4	3	3	2	2	3	1	1	1	20
	6	31MAR97	43 , .	4	3	4	3	3	4	1	1	1	24
	8	14APR97	57 , .	4	3	4	3	3	4	1	1	2	25
329.009.00264	SC	25OCT96	-7 , .	4	3	4	4	1	4	1	4	3	28
	BL	01NOV96	1 , .	4	2	4	4	2	4	2	4	1	27

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00264	1	11NOV96	11 , .	4	3	4	4	5	4	1	1	1	27
	3	25NOV96	25 , .	3	3	4	3	3	4	3	1	1	25
	6	11DEC96	41 , .	4	3	4	4	3	4	3	4	1	30
	7	23DEC96	53 , .	4	3	4	4	3	4	4	1	1	28
329.009.00301	SC	06MAR96	-13 ,-69	4	3	4	5	3	4	2	4	3	32
	BL	19MAR96	1 ,-56	5	3	4	5	3	3	1	3	1	28
	2	05APR96	18 ,-39	5	3	4	4	3	4	1	3	1	28
	4	16APR96	29 ,-28	4	3	3	3	3	4	1	2	1	24
	6	30APR96	43 ,-14	3	2	2	2	1	3	2	1	1	17
	8	14MAY96	57 , 1	2	1	2	1	1	2	1	1	1	12
	12	11JUN96	85 , 29	1	1	1	1	1	1	1	1	1	9
329.009.00305	SC	01MAY96	-6 ,-63	4	2	5	5	2	4	2	4	2	30
	BL	07MAY96	1 ,-57	5	2	4	5	2	4	1	4	1	28
	2	21MAY96	15 ,-43	4	2	4	4	2	4	1	4	1	26
	4	04JUN96	29 ,-29	4	2	4	4	2	3	1	4	1	25
	6	19JUN96	44 ,-14	3	2	3	3	1	3	1	3	1	20
	8	03JUL96	58 , 1	3	2	3	3	3	3	1	2	1	21
	12	06AUG96	92 , 35	1	1	2	2	1	1	1	1	1	11
	16	27AUG96	113 , 56	1	1	1	1	1	2	1	1	1	10
	20	24SEP96	141 , 84	1	1	1	1	1	1	1	1	1	9
	24	29OCT96	176 ,119	2	1	1	2	1	2	1	1	1	12
	28	03DEC96	211 ,154	1	1	1	1	1	1	1	1	1	9
	32	10JAN97	249 ,192	1	1	1	1	1	1	1	1	1	9
329.009.00325	SC	21AUG96	-6 ,-61	4	3	4	4	3	4	1	4	3	30
	BL	27AUG96	1 ,-55	4	4	4	4	5	3	1	4	2	31
	2	09SEP96	14 ,-42	4	4	4	4	3	3	2	4	1	29

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00325	4	23SEP96	28 ,-28	3	3	3	1	1	2	2	4	1	20
	6	10OCT96	45 ,-11	2	1	3	1	2	2	2	3	1	17
	8	21OCT96	56 , 1	1	1	1	2	2	2	2	3	1	15
	12	18NOV96	84 , 29	1	2	2	1	2	2	3	4	1	18
	16	16DEC96	112 , 57	5	3	5	5	4	4	1	4	2	33
329.009.00326	SC	26AUG96	-10 ,-63	5	4	5	5	3	4	1	5	3	35
	BL	05SEP96	1 ,-53	4	4	4	4	4	4	1	5	3	33
	2	16SEP96	12 ,-42	3	2	4	3	3	2	1	2	1	21
	4	30SEP96	26 ,-28	1	1	1	1	2	2	1	1	1	11
	6	17OCT96	43 ,-11	1	1	1	2	2	2	1	2	1	13
	8	28OCT96	54 , 1	1	1	1	2	2	2	1	1	1	12
	12	25NOV96	82 , 29	4	2	3	3	2	4	3	3	1	25
	16	16DEC96	103 , 50	5	4	4	4	1	4	4	4	1	31
329.010.00279	SC	08MAR96	-14 ,-70	4	1	5	3	1	3	4	4	1	26
	BL	22MAR96	1 ,-56	4	1	5	3	1	3	4	4	1	26
	2	05APR96	15 ,-42	4	1	4	4	3	3	2	1	1	23
	4	19APR96	29 ,-28	4	4	4	4	3	3	3	4	2	31
	6	03MAY96	43 ,-14	2	2	4	1	1	1	1	3	1	16
	8	17MAY96	57 , 1	3	1	4	4	1	1	1	4	1	20
	12	14JUN96	85 , 29	4	1	3	3	1	1	1	1	1	16
	16	11JUL96	112 , 56	2	1	1	1	3	1	1	3	1	14
	20	08AUG96	140 , 84	3	2	2	1	3	2	4	3	1	21
	24	05SEP96	168 ,112	2	1	2	1	2	2	1	1	1	13
	28	02OCT96	195 ,139	2	1	3	1	3	1	2	1	1	15
	32	06NOV96	230 ,174	1	1	1	1	1	1	1	1	1	9
329.010.00281	SC	19JUL96	-7 ,-68	4	2	4	4	4	3	1	4	2	28

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.010.00281	BL	26JUL96	1 ,-61	4	2	4	4	4	3	1	4	1	27
	2	09AUG96	15 ,-47	4	1	3	4	4	3	4	4	1	28
	4	26AUG96	32 ,-30	2	1	2	3	2	3	3	1	1	18
	6	09SEP96	46 ,-16	1	1	2	3	2	2	1	1	1	14
	8	25SEP96	62 , 1	1	1	1	4	1	1	1	1	1	12
	12	25OCT96	92 , 31	1	1	2	3	1	3	1	1	1	14
	16	20NOV96	118 , 57	1	1	2	2	2	1	1	1	1	12
	20	20DEC96	148 , 87	1	1	3	4	1	3	3	1	1	18
	24	03JAN97	162 ,101	1	1	4	6	3	4	6	1	1	27
329.011.00163	SC	18NOV95	-7 , .	4	1	3	1	2	1	4	1	3	20
	BL	24NOV95	-1 , .	4	2	4	4	3	1	4	2	2	26
	2	11DEC95	17 , .	4	1	4	4	4	1	5	2	3	28
	5	27DEC95	33 , .	3	1	3	1	3	1	4	2	1	19
329.011.00208	SC	22AUG96	-15 ,-74	4	4	3	1	1	2	1	4	4	24
	BL	05SEP96	-1 ,-60	4	3	3	1	1	1	1	3	2	19
	2	17SEP96	12 ,-48	4	1	3	2	1	1	1	3	1	17
	4	03OCT96	28 ,-32	3	1	4	2	1	1	1	1	2	16
	6	17OCT96	42 ,-18	2	1	1	1	1	1	0	1	1	9
	8	03NOV96	59 , -1	1	1	1	1	1	1	1	1	1	9
329.011.00209	SC	23AUG96	-19 ,-81	4	1	4	4	3	1	5	1	2	25
	BL	10SEP96	-1 ,-63	4	1	1	1	3	1	1	1	1	14
	2	26SEP96	16 ,-47	3	1	1	1	1	1	1	1	1	11
	4	11OCT96	31 ,-32	1	1	2	1	1	1	1	1	1	10
	6	24OCT96	44 ,-19	1	1	1	1	1	1	1	1	1	9
	8	11NOV96	62 , -1	1	1	1	1	1	1	1	1	1	9
	12	18DEC96	99 , 37	3	1	2	1	1	1	2	2	1	14

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.011.00284	SC	13MAR96	-9 ,-65	5	1	5	4	2	4	6	4	4	35
	BL	21MAR96	-1 ,-57	5	1	5	5	2	4	1	5	1	29
	2	05APR96	15 ,-42	3	1	1	1	2	1	2	1	1	13
	4	19APR96	29 ,-28	2	1	1	1	1	1	1	2	1	11
	6	02MAY96	42 ,-15	3	2	2	1	1	1	1	1	3	15
	8	16MAY96	56 , -1	1	1	1	1	1	1	1	2	1	10
	12	10JUN96	81 , 25	1	1	1	1	2	1	1	1	1	10
	16	08JUL96	109 , 53	2	1	1	1	1	1	1	1	1	10
	20	05AUG96	137 , 81	1	1	1	1	1	1	1	1	1	9
329.011.00286	SC	15MAY96	-22 ,-90	4	2	4	5	1	1	1	4	2	24
	BL	05JUN96	-1 ,-69	4	1	4	1	1	2	1	4	1	19
	2	21JUN96	16 ,-53	1	4	3	1	1	1	1	1	1	14
	5	08JUL96	33 ,-36	2	1	1	1	1	1	1	1	1	10
	7	24JUL96	49 ,-20	1	1	1	1	1	1	1	1	1	9
	8	09AUG96	65 , -4	1	1	1	1	1	1	1	1	1	9
	16	17SEP96	104 , 36	1	1	1	1	2	1	1	2	1	11
	20	24OCT96	141 , 73	3	1	1	1	1	1	1	1	1	11
	24	25NOV96	173 ,105	2	1	1	1	1	1	1	1	1	10
	28	30DEC96	208 ,140	2	1	1	1	1	1	1	1	1	10
329.012.00026	SC	09NOV95	-19 , .	5	3	5	5	1	1	1	3	2	26
	BL	28NOV95	1 , .	5	3	4	5	1	1	1	2	1	23
329.012.00219	SC	24MAY96	-7 ,-67	5	3	5	5	3	2	1	3	3	30
	BL	31MAY96	1 ,-60	5	4	5	5	3	2	1	3	3	31
	2	14JUN96	15 ,-46	4	3	4	4	1	4	2	4	1	27
	5	02JUL96	33 ,-28	2	1	2	1	1	1	1	2	1	12
	7	16JUL96	47 ,-14	1	3	1	1	1	1	1	3	1	13

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.012.00219	8	30JUL96	61 , 1	1	3	1	1	1	1	1	1	1	11
	12	30AUG96	92 , 32	1	2	1	1	1	1	1	1	1	10
	16	26SEP96	119 , 59	1	1	1	1	2	1	1	1	1	10
	20	25OCT96	148 , 88	1	1	1	1	1	1	1	2	1	10
	24	22NOV96	176 ,116	1	2	1	1	1	1	1	3	1	12
	28	20DEC96	204 ,144	1	2	1	1	1	1	1	2	1	11
	32	24JAN97	239 ,179	1	1	1	1	1	1	1	1	1	9
329.012.00221	SC	18JUN96	-7 ,-70	6	2	5	4	5	1	1	5	5	34
	BL	25JUN96	1 ,-63	7	4	4	5	5	1	1	5	4	36
	2	09JUL96	15 ,-49	4	2	5	4	4	1	1	3	3	27
	4	23JUL96	29 ,-35	4	4	2	2	4	1	1	3	1	22
	6	09AUG96	46 ,-18	1	3	1	1	2	1	1	1	1	12
	8	27AUG96	64 , 1	1	2	1	1	4	1	1	3	1	15
	12	23SEP96	91 , 28	1	1	1	2	2	1	1	1	1	11
	16	21OCT96	119 , 56	1	2	1	2	3	1	1	1	1	13
	20	04NOV96	133 , 70	4	2	2	3	3	1	1	3	7	26
329.012.00223	SC	23AUG96	-7 , .	5	4	5	3	1	1	4	6	1	30
	BL	30AUG96	1 , .	5	4	5	2	1	1	5	5	1	29
	2	16SEP96	18 , .	4	3	4	3	1	2	1	4	3	25
	5	01OCT96	33 , .	5	2	3	3	2	1	3	4	5	28
329.012.00227	SC	12DEC96	-6 ,-75	4	4	4	4	3	4	1	1	4	29
	BL	18DEC96	1 ,-69	4	4	3	4	3	4	1	3	4	30
	3	06JAN97	20 ,-50	3	1	3	2	1	4	1	3	1	19
	5	24JAN97	38 ,-32	3	1	4	4	1	1	1	3	1	19
	8	14FEB97	59 ,-11	2	4	2	4	3	3	1	4	1	24
	8	25FEB97	70 , 1	3	1	2	3	1	2	3	4	3	22

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.012.00227	16	27MAR97	100 , 31	3	1	3	3	1	3	3	4	3	24
	20	25APR97	129 , 60	3	1	2	4	3	1	1	4	1	20
	24	26MAY97	160 , 91	5	3	2	3	3	1	1	1	1	20
	28	25JUN97	190 ,121	1	1	1	1	3	1	1	3	1	13
	32	21JUL97	216 ,147	2	1	1	1	1	1	1	2	1	11
	32	19AUG97	245 ,176	1	1	1	1	1	1	2	3	1	12
329.012.00230	SC	20FEB97	-8 ,-77	4	3	3	4	1	3	1	4	3	26
	BL	28FEB97	1 ,-69	4	3	4	2	1	3	1	4	2	24
	2	14MAR97	15 ,-55	4	2	4	4	4	2	2	3	1	26
	5	03APR97	35 ,-35	4	1	3	4	4	2	2	3	1	24
	8	23APR97	55 ,-15	2	4	3	3	2	1	2	1	1	19
	8	08MAY97	70 , 1	4	1	2	3	3	3	1	2	1	20
	12	16MAY97	78 , 9	4	1	3	5	1	4	1	1	1	21

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.001.00062	SC	06OCT94	-14 , .	6	5	6	5	5	5	5	5	2	44
	BL	20OCT94	1 , .	5	4	6	4	5	5	3	4	1	37
	2	03NOV94	15 , .	3	1	4	4	5	4	1	4	1	27
329.001.00064	SC	04NOV94	-6 ,-60	6	1	5	5	3	5	3	4	1	33
	BL	10NOV94	1 ,-54	4	1	5	4	3	5	3	4	1	30
	2	22NOV94	13 ,-42	3	1	3	4	2	4	1	4	1	23
	4	06DEC94	27 ,-28	2	1	2	1	1	3	1	4	1	16
	6	20DEC94	41 ,-14	3	1	3	1	2	4	1	3	1	19
	8	03JAN95	55 , 1	3	1	4	1	1	4	3	3	1	21
	12	31JAN95	83 , 29	2	1	2	1	1	3	3	4	1	18
	16	28FEB95	111 , 57	2	1	2	4	2	4	1	4	1	21
	20	28MAR95	139 , 85	3	1	4	4	2	4	2	4	1	25
329.001.00069	SC	07FEB95	-9 , .	6	6	6	5	4	5	3	5	3	43
	BL	16FEB95	1 , .	5	1	5	5	5	5	5	4	1	36
	2	02MAR95	15 , .	4	1	4	4	3	4	3	4	1	28
	4	16MAR95	29 , .	2	1	2	2	4	3	2	3	1	20
	6	30MAR95	43 , .	5	3	3	3	3	4	1	4	3	29
	8	13APR95	57 , .	3	1	3	4	4	4	3	4	3	29
329.001.00071	SC	02FEB95	-21 , .	5	2	5	5	4	5	3	5	2	36
	BL	23FEB95	1 , .	7	4	5	4	3	5	3	5	3	39
	2	09MAR95	15 , .	5	1	5	3	3	5	3	5	3	33
	4	23MAR95	29 , .	4	1	2	3	2	4	3	5	1	25
	6	06APR95	43 , .	5	1	5	2	2	5	2	4	3	29
	8	20APR95	57 , .	4	2	5	3	3	5	3	5	1	31
329.001.00123	SC	14DEC95	-21 , .	6	4	5	5	2	4	4	5	4	39

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.001.00123	BL	04JAN96	1 , .	5	1	5	4	3	5	5	4	2	34
	2	18JAN96	15 , .	2	1	2	4	3	3	3	3	1	22
	4	01FEB96	29 , .	2	1	2	4	4	2	2	4	1	22
	6	15FEB96	43 , .	1	1	2	3	2	2	2	3	1	17
329.001.00207	SC	19FEB96	-9 , .	4	4	4	5	4	4	1	3	3	32
	BL	28FEB96	1 , .	5	3	4	4	5	4	2	3	4	34
	2	13MAR96	15 , .	1	2	2	3	3	2	1	4	1	19
	4	26MAR96	28 , .	1	1	3	2	2	1	3	2	1	16
	6	10APR96	43 , .	4	1	5	3	3	3	1	3	1	24
	8	24APR96	57 , .	5	3	3	4	3	4	1	4	1	28
329.002.00049	SC	03MAR95	-6 , .	4	1	5	4	1	4	1	2	1	23
	BL	08MAR95	-1 , .	4	1	5	4	1	4	1	4	1	25
	2	22MAR95	14 , .	5	1	5	4	1	4	1	2	1	24
	4	05APR95	28 , .	5	1	5	4	1	4	1	3	1	25
	6	19APR95	42 , .	5	1	5	4	1	1	4	1	1	23
	8	05MAY95	58 , .	4	1	5	4	1	4	1	3	1	24
329.002.00059	SC	03NOV94	-7 , .	5	1	5	5	1	4	4	3	1	29
	BL	10NOV94	1 , .	3	1	4	4	1	2	2	2	1	20
	2	23NOV94	14 , .	4	1	5	4	1	1	1	1	1	19
	4	08DEC94	29 , .	3	1	5	4	1	1	1	1	1	18
	6	22DEC94	43 , .	2	1	4	4	1	3	4	2	1	22
	8	05JAN95	57 , .	4	1	4	4	1	3	3	3	1	24
329.002.00060	SC	24JAN95	-7 ,-63	4	4	5	5	1	3	1	3	1	27
	BL	31JAN95	1 ,-56	4	4	5	5	1	3	1	3	1	27
	2	14FEB95	15 ,-42	4	1	4	4	1	2	1	3	1	21

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.002.00060	4	28FEB95	29 ,-28	4	4	4	4	1	3	1	4	1	26
	6	14MAR95	43 ,-14	2	2	3	4	1	2	1	1	1	17
	8	28MAR95	57 , 1	3	1	4	4	1	2	1	3	1	20
	12	25APR95	85 , 29	4	3	4	4	1	4	1	4	1	26
329.002.00097	SC	20DEC94	-14 ,-72	6	5	5	5	4	3	1	3	2	34
	BL	03JAN95	1 ,-58	6	5	5	5	4	3	1	3	1	33
	2	18JAN95	16 ,-43	4	2	3	4	3	3	1	3	1	24
	4	31JAN95	29 ,-30	4	3	3	1	2	2	1	4	1	21
	6	14FEB95	43 ,-16	4	4	3	4	2	2	1	3	1	24
	8	02MAR95	59 , 1	3	3	2	4	1	2	1	2	1	19
	12	30MAR95	87 , 29	4	4	2	4	1	1	1	4	1	22
	16	27APR95	115 , 57	1	1	1	1	2	2	2	1	1	12
	20	23MAY95	141 , 83	4	1	3	4	3	2	1	3	1	22
	24	29JUN95	178 ,120	4	1	3	3	2	1	1	2	1	18
	28	01AUG95	211 ,153	3	1	3	1	3	3	3	5	1	23
	32	05SEP95	246 ,188	3	1	2	3	2	1	1	2	1	16
329.002.00101	SC	20MAR95	-8 ,-66	5	3	4	4	3	2	4	3	2	30
	2	13APR95	17 ,-42	4	4	3	1	2	1	1	3	1	20
	4	27APR95	31 ,-28	2	2	3	4	3	2	2	3	1	22
	6	11MAY95	45 ,-14	4	2	3	4	2	3	1	1	0	20
	8	25MAY95	59 , 1	2	2	3	4	1	2	1	2	1	18
	12	22JUN95	87 , 29	1	2	3	3	2	2	1	1	1	16
329.002.00107	SC	18JAN96	-7 ,-63	4	3	4	4	3	3	4	4	2	31
	2	08FEB96	15 ,-42	3	2	2	2	1	3	3	3	1	20
	4	20FEB96	27 ,-30	2	1	2	3	2	1	2	2	1	16
	6	05MAR96	41 ,-16	3	2	1	2	2	2	2	2	1	17

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.002.00107	8	21MAR96	57 , 1	3	1	2	1	1	2	1	1	1	13
	12	23APR96	90 , 34	3	2	2	1	2	2	1	2	1	16
	16	21MAY96	118 , 62	2	2	1	2	2	1	1	2	2	15
	20	20JUN96	148 , 92	2	2	1	1	1	1	1	1	1	11
	24	18JUL96	176 ,120	3	1	2	1	1	1	1	1	1	12
	32	29AUG96	218 ,162	2	1	2	1	1	1	1	2	1	12
	32	26SEP96	246 ,190	2	1	2	2	1	1	1	1	1	12
329.002.00241	SC	25JAN96	-12 ,-68	4	1	3	4	3	5	1	4	1	26
	BL	06FEB96	1 ,-56	4	1	3	4	3	5	1	4	1	26
	2	22FEB96	17 ,-40	2	1	1	2	2	1	1	1	1	12
	4	05MAR96	29 ,-28	1	1	1	3	2	1	1	1	1	12
	6	19MAR96	43 ,-14	1	1	1	3	1	1	1	1	1	11
	8	02APR96	57 , 1	1	1	1	1	2	1	1	1	1	10
	12	30APR96	85 , 29	2	1	1	3	2	1	1	2	1	14
329.002.00246	SC	01APR96	-17 , .	5	4	5	5	4	2	2	3	3	33
	2	02MAY96	15 , .	3	1	3	4	4	2	1	2	1	21
	4	16MAY96	29 , .	4	3	4	4	3	1	1	2	3	25
	6	30MAY96	43 , .	4	3	3	3	2	2	2	3	2	24
	8	18JUN96	62 , .	4	3	4	4	3	3	1	1	2	25
329.002.00320	SC	09MAY96	-7 ,-68	3	2	3	1	3	1	1	5	1	20
	BL	16MAY96	1 ,-61	4	3	3	1	3	1	1	6	2	24
	2	30MAY96	15 ,-47	7	2	5	5	2	4	1	6	2	34
	5	18JUN96	34 ,-28	4	4	4	4	3	2	1	5	2	29
	7	02JUL96	48 ,-14	4	4	4	1	2	2	1	4	4	26
	8	16JUL96	62 , 1	3	2	3	1	1	2	1	2	1	16
	12	13AUG96	90 , 29	4	4	2	1	2	1	1	4	3	22

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.002.00320	16	17SEP96	125 , 64	4	3	3	1	1	1	1	4	1	19
329.002.00323	SC	04NOV96	-8 ,-66	5	3	4	4	1	3	3	3	3	29
	2	26NOV96	15 ,-44	3	3	4	4	2	3	1	3	1	24
	4	10DEC96	29 ,-30	4	1	4	3	1	2	1	4	1	21
	6	26DEC96	45 ,-14	2	1	3	2	1	2	1	2	1	15
	8	09JAN97	59 , 1	2	1	3	2	1	2	1	3	1	16
	12	04FEB97	85 , 27	2	1	3	2	1	2	1	2	1	15
	16	04MAR97	113 , 55	2	2	2	2	1	2	1	2	1	15
	20	03APR97	143 , 85	2	1	2	1	1	2	1	2	1	13
	24	30APR97	170 ,112	1	1	1	1	1	2	1	2	1	11
	28	27MAY97	197 ,139	1	1	2	2	1	2	1	1	1	12
	32	12JUN97	213 ,155	1	1	1	1	1	2	1	1	0	9
329.003.00074	SC	18JAN95	-7 ,-63	5	2	6	5	5	4	0	1	2	30
	BL	25JAN95	1 ,-56	4	1	4	4	5	1	1	1	3	24
	2	08FEB95	15 ,-42	4	1	5	5	5	3	1	1	2	27
	4	21FEB95	28 ,-29	4	1	4	5	3	2	0	1	1	21
	12	19APR95	85 , 29	4	1	2	4	1	2	1	1	1	17
	16	17MAY95	113 , 57	1	1	3	2	1	1	1	1	1	12
	20	19JUN95	146 , 90	1	1	1	1	1	1	1	1	1	9
	24	24JUL95	181 ,125	2	1	3	1	1	1	1	1	1	12
	32	30AUG95	218 ,162	1	1	1	1	1	1	1	1	1	9
	32	11OCT95	260 ,204	2	1	1	1	1	1	1	1	1	10
329.003.00078	SC	11APR95	-15 , .	4	1	3	4	1	2	0	1	1	17
	BL	26APR95	1 , .	4	2	3	4	1	1	1	1	1	18
	4	24MAY95	29 , .	5	1	3	4	1	2	1	1	1	19
	6	07JUN95	43 , .	5	1	3	4	1	2	1	1	1	19

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00078	8	21JUN95	57 , .	4	1	2	4	1	1	1	1	1	16
329.003.00080	BL	27NOV95	1 , .	5	2	2	5	1	3	1	4	2	25
	5	29DEC95	33 , .	3	1	5	4	1	4	1	4	2	25
	6	10JAN96	45 , .	3	1	3	4	1	3	1	4	2	22
	8	24JAN96	59 , .	4	1	4	4	1	5	1	4	2	26
329.003.00085	SC	26OCT94	-13 , .	5	1	5	4	3	1	.	1	3	26
	BL	07NOV94	-1 , .	6	1	.	6	5	2	1	5	5	35
	2	21NOV94	14 , .	4	0	4	2	4	2	1	5	1	23
	4	05DEC94	28 , .	4	0	4	2	4	1	1	5	1	22
	6	19DEC94	42 , .	4	1	3	1	2	1	1	5	1	19
	8	03JAN95	57 , .	4	1	4	1	5	1	1	5	1	23
329.003.00086	SC	09NOV94	-19 ,-76	4	2	4	5	3	1	3	3	3	28
	BL	21NOV94	-7 ,-64	6	2	5	3	1	4	3	1	0	25
	2	12DEC94	15 ,-43	3	2	4	3	4	4	1	1	1	23
	4	27DEC94	30 ,-28	4	4	3	3	2	3	1	1	1	22
	6	09JAN95	43 ,-15	5	3	3	5	4	4	1	1	1	27
	8	23JAN95	57 , -1	3	1	1	4	3	3	1	2	1	19
	12	13FEB95	78 , 21	3	2	1	3	2	1	1	2	1	16
	16	28MAR95	121 , 64	1	1	1	1	1	1	0	1	1	8
	20	25APR95	149 , 92	1	1	1	1	1	1	1	1	1	9
	28	30MAY95	184 ,127	1	1	1	1	1	1	1	1	1	9
	32	17AUG95	263 ,206	1	1	1	1	1	1	1	2	1	10
329.003.00094	SC	20OCT95	-4 , .	7	4	6	6	1	4	1	1	5	35
	BL	24OCT95	1 , .	5	0	5	5	1	3	1	1	3	24
	2	07NOV95	15 , .	7	4	6	1	1	1	1	1	5	27

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00094	4	21NOV95	29 , .	7	5	5	3	5	3	1	3	3	35
	6	05DEC95	43 , .	6	4	6	4	3	1	1	1	2	28
	8	19DEC95	57 , .	7	5	5	4	3	4	2	4	4	38
329.003.00251	SC	19MAR96	-9 , .	7	5	6	5	4	4	1	5	4	41
	BL	27MAR96	-1 , .	5	3	4	5	2	1	1	4	3	28
	2	09APR96	13 , .	1	1	1	1	1	1	1	4	1	12
329.003.00252	SC	19MAR96	-22 , .	5	2	5	5	3	3	1	1	2	27
	BL	09APR96	-1 , .	6	1	5	4	1	4	1	4	4	30
	2	23APR96	14 , .	1	1	1	1	1	1	1	1	1	9
	4	09MAY96	30 , .	4	1	1	1	1	3	1	1	1	14
	8	04JUN96	56 , .	4	1	5	4	1	4	1	1	2	23
329.003.00291	SC	01JUL96	-2 ,-67	7	6	5	5	4	5	1	5	2	40
	5	07AUG96	36 ,-30	3	4	2	4	4	3	1	4	1	26
	8	04SEP96	64 , -2	2	1	1	1	1	1	1	1	1	10
	12	02OCT96	92 , 27	1	0	1	1	1	1	0	1	1	7
	16	30OCT96	120 , 55	2	2	1	1	1	1	1	1	1	11
329.003.00315	SC	29OCT96	-14 , .	5	5	6	1	4	4	6	5	3	39
	2	26NOV96	15 , .	4	2	1	1	3	1	3	5	1	21
	4	12DEC96	31 , .	4	1	2	1	1	4	1	1	1	16
	6	23DEC96	42 , .	1	1	1	1	1	1	1	1	1	9
	8	07JAN97	57 , .	1	1	1	1	1	1	1	1	1	9
329.003.00316	SC	05DEC96	-12 , .	6	5	4	5	5	1	6	4	2	38
	4	14JAN97	29 , .	5	5	1	5	4	1	1	1	2	25
	6	28JAN97	43 , .	7	5	3	4	5	1	1	3	3	32

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.003.00316	8	11FEB97	57 , .	7	5	3	4	4	1	1	4	1	30
329.004.00016	SC	01MAR95	-12 , .	5	1	4	4	3	3	1	4	1	26
	BL	13MAR95	1 , .	5	1	4	4	2	3	1	4	1	25
	2	29MAR95	17 , .	4	1	4	4	3	1	1	5	1	24
	4	12APR95	31 , .	4	1	5	4	3	4	1	5	1	28
	5	19APR95	38 , .	5	1	5	4	2	4	1	4	1	27
329.004.00018	SC	19APR95	-14 , .	5	4	4	5	4	4	1	5	3	35
	BL	03MAY95	1 , .	5	3	4	5	4	2	1	4	3	31
	2	18MAY95	16 , .	3	1	1	3	3	1	1	5	1	19
	4	01JUN95	30 , .	5	3	4	6	4	2	1	4	1	30
	7	19JUN95	48 , .	5	2	4	5	3	1	1	4	2	27
	8	29JUN95	58 , .	2	1	1	4	3	1	1	4	1	18
329.004.00020	SC	02NOV95	-7 , .	5	5	4	6	3	1	1	4	4	33
	BL	09NOV95	1 , .	5	4	4	5	3	1	1	5	3	31
	2	24NOV95	16 , .	4	3	4	5	4	1	1	4	3	29
329.004.00213	SC	18JUL96	-15 ,-69	5	2	4	4	1	1	1	1	4	23
	BL	01AUG96	-1 ,-55	5	1	4	4	3	1	1	1	3	23
	2	15AUG96	14 ,-41	5	1	4	4	1	1	4	4	0	24
	4	29AUG96	28 ,-27	2	1	2	3	1	1	4	2	1	17
	8	24SEP96	54 , -1	4	1	1	2	1	1	1	1	4	16
	12	22OCT96	82 , 28	1	1	1	1	2	1	1	1	1	10
	16	19NOV96	110 , 56	2	1	1	1	3	1	1	1	1	12
	20	20DEC96	141 , 87	3	1	1	2	3	1	1	1	3	16
	24	21JAN97	173 ,119	2	1	1	1	1	1	1	1	3	12
	28	18FEB97	201 ,147	3	1	1	2	1	1	1	1	4	15

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.004.00213	32	19MAR97	230 ,176	1	1	2	2	1	1	1	1	1	11
329.005.00001	SC	11APR94	-9 , .	4	1	4	1	1	1	1	5	3	21
	BL	20APR94	1 , .	6	1	5	4	1	4	1	5	2	29
	1	27APR94	8 , .	4	1	5	4	1	3	1	3	3	25
	3	11MAY94	22 , .	5	1	5	4	1	3	1	2	3	25
	6	01JUN94	43 , .	4	1	4	5	1	1	1	3	2	22
	8	15JUN94	57 , .	4	1	6	4	1	3	2	3	2	26
329.005.00005	SC	24OCT94	-8 , .	5	1	3	1	1	3	1	3	4	22
	BL	01NOV94	1 , .	4	1	3	1	1	1	1	4	3	19
329.005.00010	SC	07DEC94	-6 ,-63	4	4	5	3	4	3	1	4	2	30
	BL	13DEC94	1 ,-57	4	2	5	3	4	3	1	4	2	28
	2	27DEC94	15 ,-43	1	3	2	3	2	1	1	1	1	15
	4	11JAN95	30 ,-28	1	1	1	1	2	1	1	5	1	14
	6	25JAN95	44 ,-14	2	1	1	2	2	1	1	2	1	13
	8	08FEB95	58 , 1	1	1	1	2	2	1	1	2	1	12
	12	10MAR95	88 , 31	2	2	1	2	2	1	1	1	1	13
	16	13APR95	122 , 65	1	1	1	1	2	1	1	1	1	10
	20	10MAY95	149 , 92	2	1	1	1	2	1	1	1	1	11
	24	06JUN95	176 ,119	1	1	1	1	1	1	1	1	1	9
	32	12JUL95	212 ,155	1	1	1	1	1	1	1	1	1	9
	32	09AUG95	240 ,183	1	1	1	1	1	1	1	1	1	9
329.005.00012	SC	12DEC94	-7 ,-66	5	2	4	5	4	4	1	2	1	28
	BL	19DEC94	1 ,-59	5	2	4	4	4	4	1	2	1	27
	2	05JAN95	18 ,-42	4	1	4	4	4	4	1	3	2	27
	4	18JAN95	31 ,-29	3	1	3	3	3	4	1	1	1	20

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00012	6	31JAN95	44 ,-16	3	1	2	2	2	2	1	1	1	15
	8	16FEB95	60 , 1	3	1	1	2	1	1	1	1	1	12
	12	27MAR95	99 , 40	3	1	2	3	1	1	1	1	1	14
	20	04MAY95	137 , 78	3	1	1	2	1	1	1	1	1	12
	24	31MAY95	164 ,105	3	1	1	2	1	1	1	3	1	14
329.005.00111	SC	05JAN95	-6 ,-62	4	1	4	2	1	2	1	5	2	22
	BL	11JAN95	1 ,-56	4	1	4	3	3	3	1	4	1	24
	2	25JAN95	15 ,-42	4	1	2	3	4	1	1	2	1	19
	4	08FEB95	29 ,-28	1	1	1	2	4	1	1	2	1	14
	6	22FEB95	43 ,-14	1	1	1	2	2	1	1	2	1	12
	8	08MAR95	57 , 1	1	1	1	1	2	1	1	2	1	11
	12	05APR95	85 , 29	2	1	1	1	2	1	1	2	1	12
	12	19APR95	99 , 43	1	1	2	1	1	1	2	3	1	13
329.005.00114	SC	23JAN95	-8 ,-65	4	1	3	5	1	1	4	1	3	23
	BL	31JAN95	1 ,-57	4	1	3	4	1	1	4	1	2	21
	2	14FEB95	15 ,-43	4	1	2	2	1	1	1	2	1	15
	4	28FEB95	29 ,-29	3	1	2	1	1	1	1	2	1	13
	6	15MAR95	44 ,-14	1	1	1	1	1	1	1	2	1	10
	8	29MAR95	58 , 1	3	2	2	2	1	1	1	3	2	17
	12	26APR95	86 , 29	4	1	1	3	1	1	1	1	2	15
	16	17MAY95	107 , 50	4	1	4	1	1	1	1	2	1	16
329.005.00115	SC	27JAN95	-10 ,-81	4	1	4	4	4	4	1	5	3	30
	BL	06FEB95	1 ,-71	4	1	3	4	4	4	1	5	1	27
	2	20FEB95	15 ,-57	1	1	1	2	3	1	1	2	1	13
	5	10MAR95	33 ,-39	1	1	1	2	3	1	1	2	1	13
	7	28MAR95	51 ,-21	1	1	1	3	2	1	1	1	1	12

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00115	8	18APR95	72 , 1	1	1	1	1	1	1	1	1	1	9
329.005.00120	SC	22AUG95	-8 , .	6	4	4	1	1	4	5	1	2	28
	BL	30AUG95	1 , .	4	1	4	4	1	2	4	2	1	23
	2	14SEP95	16 , .	2	1	3	2	1	1	3	1	1	15
	4	28SEP95	30 , .	2	2	3	2	1	1	1	3	1	16
	6	12OCT95	44 , .	4	2	2	2	1	1	1	3	3	19
	8	26OCT95	58 , .	2	1	2	2	1	1	1	3	1	14
329.005.00253	SC	31JAN96	-8 , .	3	3	2	4	4	2	1	3	2	24
	BL	08FEB96	1 , .	4	3	4	4	4	2	1	4	2	28
	2	21FEB96	14 , .	4	1	4	4	3	1	1	3	2	23
	4	06MAR96	28 , .	4	2	4	4	3	1	1	4	2	25
	6	20MAR96	42 , .	4	1	4	4	3	1	1	4	1	23
	8	03APR96	56 , .	4	1	4	4	4	1	1	4	2	25
329.005.00254	SC	08FEB96	-7 ,-62	5	3	4	4	1	4	4	1	3	29
	BL	14FEB96	-1 ,-56	4	3	2	4	1	4	1	2	2	23
	2	28FEB96	14 ,-42	4	3	2	4	1	4	1	3	3	25
	4	13MAR96	28 ,-28	3	2	1	3	1	2	1	3	1	17
	6	27MAR96	42 ,-14	2	1	1	3	1	1	1	3	1	14
	8	10APR96	56 , 1	2	1	1	2	1	1	1	2	1	12
	12	22MAY96	98 , 43	1	1	1	2	1	1	1	1	1	10
	16	12JUN96	119 , 64	1	1	1	1	1	1	1	1	1	9
	20	10JUL96	147 , 92	1	1	1	1	1	1	1	1	1	9
	24	07AUG96	175 ,120	1	1	1	1	1	1	1	1	1	9
	28	12SEP96	211 ,156	1	1	1	1	1	1	1	1	1	9
	32	16OCT96	245 ,190	1	1	1	2	1	1	1	1	1	10

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00293	SC	06MAR97	-6 , .	4	1	5	3	2	4	1	1	1	22
	BL	12MAR97	1 , .	4	3	5	4	1	3	1	1	2	24
	2	25MAR97	14 , .	2	2	3	2	1	3	1	2	1	17
	4	09APR97	29 , .	3	1	2	1	1	2	1	1	1	13
	6	23APR97	43 , .	2	1	2	1	1	2	1	1	1	12
	8	07MAY97	57 , .	2	1	1	1	1	1	1	1	1	10
329.005.00298	SC	15MAY96	-7 ,-63	6	2	4	5	1	5	1	4	3	31
	BL	22MAY96	1 ,-56	6	1	3	5	3	5	1	4	1	29
	2	06JUN96	16 ,-41	3	1	4	3	3	4	1	2	1	22
	4	19JUN96	29 ,-28	2	1	1	3	3	4	1	2	1	18
	6	03JUL96	43 ,-14	3	1	1	3	1	4	1	2	1	17
	8	17JUL96	57 , 1	2	1	1	1	1	2	1	1	1	11
	12	07AUG96	78 , 22	1	1	1	1	1	0	1	1	1	8
	16	19SEP96	121 , 65	1	1	1	2	2	2	1	1	1	12
	20	17OCT96	149 , 93	2	1	1	1	1	1	1	1	1	10
	24	14NOV96	177 ,121	2	1	1	2	1	1	1	1	1	11
	28	12DEC96	205 ,149	2	2	1	2	1	1	1	1	1	12
	32	13JAN97	237 ,181	1	1	1	1	2	2	1	1	1	11
329.005.00331	SC	14NOV96	-7 , .	5	4	5	3	4	5	1	5	3	35
	BL	21NOV96	1 , .	5	4	4	3	4	5	1	4	1	31
	2	04DEC96	14 , .	4	4	3	4	3	2	1	4	4	29
	4	19DEC96	29 , .	3	2	1	3	3	2	1	3	1	19
	6	02JAN97	43 , .	3	2	1	3	2	1	1	2	2	17
	8	16JAN97	57 , .	3	1	1	3	3	1	1	3	1	17
329.005.00334	SC	24JAN97	-7 , .	5	2	4	5	1	3	1	5	4	30
	BL	29JAN97	-2 , .	5	1	3	5	1	3	1	4	2	25

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.005.00334	2	13FEB97	14 , .	3	1	1	3	1	1	1	1	3	15
	4	26FEB97	27 , .	3	1	1	1	2	1	1	2	3	15
	6	13MAR97	42 , .	2	1	1	1	2	1	1	1	1	11
	8	27MAR97	56 , .	1	1	1	1	1	1	1	2	1	10
329.006.00037	SC	20JAN95	-8 , .	2	1	2	3	1	3	1	1	1	15
	BL	27JAN95	-1 , .	4	1	2	5	2	1	.	1	1	19
	2	13FEB95	17 , .	2	3	2	3	1	0	1	4	1	17
329.006.00042	SC	01DEC95	-6 ,-63	5	3	4	3	1	3	4	4	2	29
	BL	06DEC95	-1 ,-58	5	4	4	3	1	3	4	4	2	30
	2	20DEC95	14 ,-44	3	3	3	2	1	3	1	2	1	19
	4	03JAN96	28 ,-30	4	4	4	2	1	2	1	4	1	23
	6	17JAN96	42 ,-16	3	3	3	1	1	2	1	3	1	18
	8	02FEB96	58 , 1	2	3	1	2	3	2	1	1	2	17
	12	29FEB96	85 , 28	3	3	1	1	2	1	1	1	2	15
	16	26MAR96	111 , 54	4	1	1	1	2	1	1	1	1	13
	20	23APR96	139 , 82	3	1	1	1	1	1	1	1	2	12
	24	21MAY96	167 ,110	2	3	2	2	3	2	1	1	1	17
	28	18JUN96	195 ,138	2	2	2	2	1	1	1	4	1	16
	32	16JUL96	223 ,166	4	3	1	2	2	2	1	1	2	18
329.006.00259	SC	22APR96	-32 , .	3	2	1	3	3	2	1	3	3	21
	BL	22MAY96	-2 , .	4	1	2	4	3	3	1	3	2	23
	2	06JUN96	14 , .	2	1	1	4	2	3	1	4	1	19
	4	20JUN96	28 , .	3	1	1	3	3	1	1	1	2	16
	6	03JUL96	41 , .	2	1	1	1	3	2	1	1	2	14
	8	17JUL96	55 , .	1	1	1	3	2	2	1	4	1	16

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.007.00141	SC	14SEP95	-7 , .	4	5	4	4	1	4	1	4	1	28
	BL	21SEP95	1 , .	3	4	3	3	3	3	1	4	1	25
	2	05OCT95	15 , .	4	3	3	3	2	3	1	1	1	21
329.007.00144	SC	30NOV95	-7 ,-63	4	4	4	5	2	6	4	3	4	36
	BL	07DEC95	1 ,-56	5	5	4	5	2	4	3	2	3	33
	2	21DEC95	15 ,-42	4	4	4	3	2	4	2	2	3	28
	4	04JAN96	29 ,-28	5	4	4	3	1	4	1	3	3	28
	6	18JAN96	43 ,-14	2	1	1	2	1	1	1	1	1	11
	8	01FEB96	57 , 1	4	2	1	4	1	3	1	3	1	20
329.007.00266	SC	29FEB96	-7 , .	4	4	5	4	4	5	1	5	2	34
	BL	07MAR96	1 , .	4	4	4	4	3	3	1	4	1	28
	3	25MAR96	19 , .	2	1	3	1	1	1	3	1	1	14
	4	04APR96	29 , .	4	4	4	4	1	1	1	4	1	24
	6	18APR96	43 , .	4	1	5	1	1	4	1	4	1	22
	8	02MAY96	57 , .	3	1	1	1	1	4	1	1	1	14
329.007.00267	SC	29FEB96	-7 , .	5	3	5	4	4	5	1	1	1	29
	BL	07MAR96	1 , .	5	5	5	4	1	5	1	4	1	31
	2	21MAR96	15 , .	1	1	1	1	1	3	3	1	1	13
	4	04APR96	29 , .	1	1	2	1	1	1	1	1	1	10
	6	18APR96	43 , .	1	1	1	1	1	3	1	1	1	11
	8	02MAY96	57 , .	1	1	1	1	1	1	1	1	1	9
329.007.00311	SC	26SEP96	-7 ,-67	4	4	4	4	4	4	1	3	4	32
	BL	03OCT96	1 ,-60	4	4	4	5	2	2	1	5	1	28
	2	17OCT96	15 ,-46	3	1	2	1	3	1	1	3	2	17
	4	31OCT96	29 ,-32	3	1	3	1	1	1	1	3	1	15

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.007.00311	6	14NOV96	43 ,-18	3	1	1	1	1	1	1	3	1	13
	8	02DEC96	61 , 1	2	1	3	1	1	1	1	4	1	15
	12	02JAN97	92 , 32	4	1	3	1	1	4	1	1	2	18
	16	30JAN97	120 , 60	2	1	2	1	1	1	1	3	1	13
	24	13MAR97	162 ,102	3	4	1	3	3	1	1	4	1	21
	28	11APR97	191 ,131	4	4	4	1	1	1	1	5	1	22
329.008.00158	SC	06SEP95	-7 ,-69	4	2	4	5	2	4	1	5	2	29
	BL	13SEP95	1 ,-62	4	1	5	4	1	5	1	5	2	28
	2	27SEP95	15 ,-48	3	1	3	3	2	4	1	4	1	22
	4	10OCT95	28 ,-35	3	1	3	1	1	3	3	1	1	17
	6	24OCT95	42 ,-21	3	1	1	1	1	4	1	1	1	14
	8	14NOV95	63 , 1	1	1	1	1	1	1	1	1	1	9
	16	26DEC95	105 , 43	3	1	4	1	1	4	1	4	1	20
	20	23JAN96	133 , 71	4	1	3	4	1	4	1	4	2	24
329.008.00162	SC	26OCT95	-6 ,-71	5	4	5	5	1	4	2	4	4	34
	BL	01NOV95	1 ,-65	5	4	5	4	3	4	1	4	2	32
	3	20NOV95	20 ,-46	3	4	4	3	3	3	4	4	3	31
	5	07DEC95	37 ,-29	3	3	4	4	1	3	4	4	1	27
	7	20DEC95	50 ,-16	1	3	4	4	1	1	2	3	1	20
	8	05JAN96	66 , 1	2	3	4	4	1	1	1	3	2	21
	16	09FEB96	101 , 36	2	1	3	2	1	1	1	2	1	14
	20	08MAR96	129 , 64	2	1	1	2	2	1	1	4	1	15
	24	10APR96	162 , 97	1	1	3	1	3	1	1	3	1	15
	24	01MAY96	183 ,118	1	1	1	1	1	1	1	2	1	10
	32	05JUN96	218 ,153	1	1	3	1	1	1	1	4	1	14
	32	02JUL96	245 ,180	2	1	4	1	2	2	1	4	1	18

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.008.00191	SC	12JAN96	-20 ,-81	4	4	4	4	1	4	5	4	1	31
	BL	01FEB96	1 ,-61	4	4	4	1	1	4	4	4	2	28
	3	20FEB96	20 ,-42	3	4	3	1	1	1	6	3	1	23
	5	05MAR96	34 ,-28	2	1	1	1	1	1	1	1	1	10
	7	18MAR96	47 ,-15	2	1	1	1	1	1	1	1	1	10
	8	02APR96	62 , 1	2	1	1	1	1	1	1	2	1	11
	12	01MAY96	91 , 30	1	1	1	1	1	1	1	1	1	9
	16	05JUN96	126 , 65	1	1	1	1	1	1	1	1	1	9
329.009.00128	SC	05APR95	-6 , .	4	4	3	3	3	3	1	4	3	28
	BL	11APR95	1 , .	4	4	4	4	4	3	1	4	3	31
	2	25APR95	15 , .	4	4	3	3	3	4	1	4	3	29
329.009.00129	SC	22MAR95	-20 , .	5	4	5	4	3	3	1	4	3	32
	BL	11APR95	1 , .	6	4	5	5	4	4	1	4	1	34
	2	25APR95	15 , .	5	4	5	4	3	4	1	4	1	31
	4	09MAY95	29 , .	5	4	5	4	3	5	1	4	3	34
329.009.00135	SC	25SEP95	-7 , .	7	4	6	6	1	5	5	3	1	38
	BL	02OCT95	1 , .	6	5	6	5	2	5	4	3	1	37
	2	16OCT95	15 , .	6	5	6	5	2	5	4	3	1	37
	4	30OCT95	29 , .	5	5	6	5	2	5	4	3	1	36
329.009.00136	SC	26SEP95	-7 , .	5	1	5	5	1	3	2	5	3	30
	BL	03OCT95	1 , .	5	2	5	5	2	4	3	5	3	34
	2	17OCT95	15 , .	5	4	4	4	4	4	3	4	1	33
	4	03NOV95	32 , .	4	3	4	4	3	3	1	4	1	27
	6	14NOV95	43 , .	5	3	4	5	3	4	2	4	1	31
	8	28NOV95	57 , .	5	4	5	5	3	4	2	4	1	33

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00169	SC	25OCT95	-6 ,-71	5	4	4	5	4	1	1	4	3	31
	BL	31OCT95	1 ,-65	5	4	4	5	5	4	2	4	3	36
	2	14NOV95	15 ,-51	1	2	3	3	2	1	2	1	1	16
	4	28NOV95	29 ,-37	1	2	1	3	3	2	2	1	1	16
	6	12DEC95	43 ,-23	2	2	3	4	3	3	1	1	1	20
	8	27DEC95	58 , -8	1	1	1	4	3	1	1	1	1	14
	12	23JAN96	85 , 20	1	1	1	4	4	1	1	1	1	15
329.009.00174	SC	14NOV95	-7 ,-64	3	2	4	5	4	1	1	4	2	26
	BL	21NOV95	1 ,-57	3	2	3	5	4	1	1	5	2	26
	2	05DEC95	15 ,-43	3	2	3	4	3	2	1	3	1	22
	4	19DEC95	29 ,-29	2	2	2	3	2	1	1	1	1	15
	6	02JAN96	43 ,-15	1	1	2	2	1	1	1	1	1	11
	8	17JAN96	58 , 1	3	2	2	2	2	1	1	1	1	15
	12	31JAN96	72 , 15	3	1	3	4	2	3	1	1	1	19
329.009.00197	SC	20DEC95	-9 ,-63	5	2	4	5	4	3	3	2	1	29
	BL	29DEC95	1 ,-54	5	3	5	5	4	4	1	4	2	33
	1	08JAN96	11 ,-44	4	3	5	5	4	4	1	3	2	31
	4	23JAN96	26 ,-29	3	3	3	4	3	3	1	2	1	23
	6	06FEB96	40 ,-15	1	2	2	2	1	2	1	1	1	13
	8	20FEB96	54 , -1	1	1	1	2	1	2	1	1	1	11
	12	19MAR96	82 , 28	1	1	1	1	1	1	1	1	1	9
	16	23APR96	117 , 63	1	1	1	1	1	1	1	1	1	9
	20	21MAY96	145 , 91	1	1	1	1	1	1	1	1	1	9
	24	25JUN96	180 ,126	1	1	1	1	1	1	1	1	1	9
	28	16JUL96	201 ,147	1	1	1	1	1	2	1	1	1	10
	32	20AUG96	236 ,182	1	1	1	1	1	1	1	1	1	9

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00198	SC	19DEC95	-14 , .	5	4	5	5	4	2	1	5	4	35
	BL	02JAN96	1 , .	5	4	5	5	4	4	1	5	3	36
	2	16JAN96	15 , .	4	4	5	5	4	4	1	5	3	35
	4	30JAN96	29 , .	5	4	5	5	4	4	2	5	3	37
	6	13FEB96	43 , .	5	4	5	5	4	4	2	5	3	37
	8	27FEB96	57 , .	5	4	5	5	4	4	2	5	1	35
329.009.00200	SC	17JAN96	-6 , .	5	4	5	5	4	4	1	4	3	35
	BL	23JAN96	1 , .	5	4	5	5	4	4	1	5	3	36
	2	06FEB96	15 , .	5	3	5	5	4	4	1	5	2	34
	4	20FEB96	29 , .	5	3	5	5	4	4	1	5	2	34
	6	08MAR96	46 , .	6	4	5	5	4	5	2	5	2	38
329.009.00202	SC	14FEB96	-6 , .	4	4	4	5	4	3	1	6	2	33
	BL	20FEB96	1 , .	5	4	5	5	5	5	4	5	3	41
	2	08MAR96	18 , .	5	4	5	5	4	4	3	4	1	35
	5	26MAR96	36 , .	3	2	3	4	3	2	1	3	1	22
329.009.00237	SC	04NOV96	-7 , .	4	1	4	4	3	4	1	4	2	27
	BL	11NOV96	1 , .	5	3	4	4	2	4	2	4	1	29
329.009.00238	SC	28OCT96	-15 , .	4	4	4	4	3	3	1	5	1	29
	BL	12NOV96	1 , .	4	4	3	4	2	3	1	4	4	29
	2	26NOV96	15 , .	4	2	3	4	1	2	1	4	2	23
	4	10DEC96	29 , .	2	1	2	2	1	1	1	2	1	13
	6	23DEC96	42 , .	3	2	1	2	1	1	1	1	1	13
	8	07JAN97	57 , .	4	2	3	4	1	3	1	4	1	23
329.009.00276	SC	17JAN97	-4 , .	5	2	5	4	2	4	1	4	4	31

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00276	BL	21JAN97	1 , .	5	2	4	4	3	4	1	5	4	32
	2	04FEB97	15 , .	4	2	4	3	2	2	1	4	2	24
	4	18FEB97	29 , .	4	1	4	4	2	3	1	3	3	25
	6	04MAR97	43 , .	3	1	2	3	1	1	1	3	1	16
	8	18MAR97	57 , .	3	1	4	2	2	1	1	4	1	19
329.009.00302	SC	20MAR96	-7 , .	4	2	5	5	1	4	1	4	2	28
	BL	27MAR96	1 , .	4	2	4	3	2	1	1	4	1	22
	2	10APR96	15 , .	3	3	4	3	2	2	1	1	1	20
329.009.00306	SC	03JUN96	-8 , .	4	4	4	4	1	4	4	5	3	33
	BL	11JUN96	1 , .	5	4	5	4	3	5	4	5	3	38
	2	25JUN96	15 , .	5	4	5	5	4	5	4	5	3	40
	4	09JUL96	29 , .	4	4	4	4	3	4	3	3	2	31
	6	23JUL96	43 , .	4	2	4	4	1	3	1	1	1	21
	8	06AUG96	57 , .	3	2	4	3	1	3	4	1	1	22
329.009.00312	SC	30OCT96	-5 , .	4	4	4	4	2	4	5	4	1	32
	BL	04NOV96	1 , .	5	4	4	4	3	4	5	4	2	35
	2	18NOV96	15 , .	4	3	4	4	2	4	3	3	1	28
	5	09DEC96	36 , .	4	3	4	4	2	4	3	3	1	28
	8	27DEC96	54 , .	4	4	4	4	3	4	4	3	1	31
	8	06JAN97	64 , .	4	4	4	4	3	4	4	3	1	31
329.009.00327	SC	09SEP96	-7 , .	5	4	5	5	4	4	1	5	2	35
	BL	16SEP96	1 , .	5	4	5	5	4	4	1	5	3	36
	2	30SEP96	15 , .	5	3	3	5	4	3	1	5	1	30
	4	14OCT96	29 , .	5	4	5	5	4	4	1	5	2	35
	5	21OCT96	36 , .	5	4	5	5	4	5	1	5	2	36

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.009.00330	SC	15OCT96	-6 , .	4	1	4	4	4	4	1	5	5	32
	BL	21OCT96	1 , .	5	3	4	4	4	4	1	5	3	33
	2	04NOV96	15 , .	4	1	4	4	4	2	1	4	1	25
329.010.00183	SC	21NOV95	-12 , .	4	1	4	4	3	1	6	1	4	28
	BL	28NOV95	-5 , .	4	1	4	4	3	1	6	4	1	28
	2	19DEC95	17 , .	3	1	3	4	3	1	5	1	1	22
329.010.00263	SC	24JUL96	-16 , .	4	4	4	4	1	3	1	4	1	26
	BL	09AUG96	1 , .	4	4	4	4	1	3	4	3	1	28
	2	21AUG96	13 , .	3	2	4	3	1	3	3	2	1	22
	4	04SEP96	27 , .	1	1	1	3	1	1	1	1	1	11
	6	18SEP96	41 , .	1	1	2	2	1	2	1	1	1	12
	8	09OCT96	62 , .	1	1	2	2	1	2	1	2	1	13
329.010.00277	SC	23FEB96	-7 ,-63	4	1	4	6	4	4	5	1	1	30
	BL	01MAR96	1 ,-56	4	1	.	6	4	4	5	4	1	33
	2	18MAR96	18 ,-39	3	3	4	4	3	4	2	3	1	27
	4	29MAR96	29 ,-28	2	1	5	1	3	4	2	1	1	20
	6	15APR96	46 ,-11	3	1	2	1	2	1	1	1	1	13
	8	26APR96	57 , 1	2	1	2	1	1	1	1	1	1	11
	12	24MAY96	85 , 29	1	1	1	1	1	1	1	1	1	9
	16	21JUN96	113 , 57	1	1	1	1	1	1	1	1	1	9
	24	07AUG96	160 ,104	1	1	1	1	1	1	1	1	1	9
329.010.00282	SC	19JUL96	-7 , .	2	1	4	4	3	1	4	1	1	21
	BL	26JUL96	1 , .	4	1	3	4	3	1	4	1	1	22
	2	09AUG96	15 , .	3	1	2	1	2	1	3	1	1	15
	4	26AUG96	32 , .	2	1	2	1	1	1	2	1	1	12

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.010.00282	7	13SEP96	50 , .	1	1	2	1	2	1	1	1	1	11
	8	27SEP96	64 , .	1	1	1	1	1	1	1	1	1	9
329.011.00164	SC	15DEC95	-7 , .	4	1	4	4	4	3	6	3	1	30
	BL	21DEC95	-1 , .	5	2	4	5	3	4	6	3	1	33
	2	04JAN96	14 , .	4	1	4	3	4	3	5	4	1	29
	4	18JAN96	28 , .	3	1	4	4	4	4	5	4	1	30
329.011.00210	SC	13SEP96	-15 ,-81	4	2	4	4	1	3	1	4	3	26
	BL	27SEP96	-1 ,-67	4	1	4	5	1	2	1	4	2	24
	2	09OCT96	12 ,-55	5	3	6	1	3	2	2	1	3	26
	4	24OCT96	27 ,-40	1	1	1	4	1	1	1	5	1	16
	6	12NOV96	46 ,-21	1	3	1	1	1	1	1	1	1	11
	8	02DEC96	66 , -1	2	1	1	1	1	1	1	1	1	10
329.011.00285	SC	08MAY96	-10 , .	4	4	4	6	1	3	1	5	3	31
	BL	17MAY96	-1 , .	4	1	4	5	3	1	1	5	1	25
	2	03JUN96	17 , .	4	4	4	6	1	2	1	5	2	29
	5	21JUN96	35 , .	5	1	5	5	4	1	1	5	3	30
	7	08JUL96	52 , .	3	1	4	3	1	1	1	5	2	21
	8	24JUL96	68 , .	2	1	3	1	3	1	1	4	1	17
329.011.00287	SC	25JUN96	-8 , .	4	4	4	4	3	3	1	4	3	30
	BL	02JUL96	-1 , .	4	1	3	5	3	2	1	4	2	25
	2	17JUL96	15 , .	2	2	1	2	3	1	1	5	2	19
	4	30JUL96	28 , .	3	1	3	1	1	2	1	2	3	17
	6	13AUG96	42 , .	1	2	1	1	1	1	1	3	2	13
	8	27AUG96	56 , .	3	1	2	1	1	1	1	4	1	15

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.012.00027	SC	23NOV95	-13 , .	6	4	5	5	1	5	1	5	3	35
	BL	06DEC95	1 , .	6	4	5	5	1	5	1	5	1	33
	2	19DEC95	14 , .	5	4	5	4	1	3	1	5	3	31
	4	02JAN96	28 , .	5	3	4	4	1	1	1	5	2	26
329.012.00217	SC	14MAY96	-7 , .	5	3	5	6	1	3	2	4	5	34
	BL	21MAY96	1 , .	5	1	5	5	1	3	1	5	3	29
	2	07JUN96	18 , .	5	1	4	5	1	1	1	1	3	22
	4	19JUN96	30 , .	5	4	5	4	1	1	1	5	3	29
329.012.00218	SC	04JUN96	-12 ,-70	6	1	5	5	1	2	1	4	5	30
	BL	14JUN96	-2 ,-60	4	3	4	4	1	2	1	4	2	25
	2	28JUN96	13 ,-46	3	2	3	1	1	1	1	2	3	17
	4	12JUL96	27 ,-32	1	1	2	1	1	1	1	1	1	10
	6	29JUL96	44 ,-15	1	3	1	1	1	1	1	1	1	11
	8	13AUG96	59 , 1	1	1	1	1	1	1	1	1	1	9
	12	18SEP96	95 , 37	1	1	1	1	1	1	1	1	1	9
329.012.00224	SC	30AUG96	-17 ,-83	4	4	4	5	1	2	1	4	3	28
	BL	16SEP96	1 ,-66	4	4	4	3	1	2	1	4	3	26
	2	03OCT96	18 ,-49	3	2	3	2	3	1	1	4	1	20
	4	17OCT96	32 ,-35	1	4	1	1	1	1	1	1	1	12
	7	04NOV96	50 ,-17	1	3	1	1	1	1	1	1	1	11
	8	20NOV96	66 , -1	1	3	1	1	1	1	1	1	1	11
	12	19DEC96	95 , 29	3	3	2	1	1	1	1	1	1	14
	16	20JAN97	127 , 61	1	3	1	3	1	1	1	1	1	13
	24	18FEB97	156 , 90	1	3	1	1	1	1	1	1	1	11
329.012.00225	SC	19NOV96	-7 ,-71	5	1	3	3	1	3	1	4	1	22

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.3
Listing of K-SADS-L Scores by Treatment Group (Depression 9 Item Subscale, Last 2 Weeks)
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Worst Severity Q2	Q20	Q34	Q42	Q44	Q56	Q83	Q85	Q109	Total
329.012.00225	BL	26NOV96	1 ,-64	4	1	4	3	1	3	1	3	1	21
	2	10DEC96	15 ,-50	2	2	1	2	1	2	1	3	1	15
	4	27DEC96	32 ,-33	1	1	3	1	1	1	1	2	1	12
	7	13JAN97	49 ,-16	1	1	1	1	1	1	1	1	1	9
	8	29JAN97	65 , 1	1	1	1	1	1	1	1	1	1	9
	12	24FEB97	91 , 27	2	1	1	1	1	1	1	1	1	10
	16	20MAR97	115 , 51	2	1	3	3	1	1	3	1	1	16
	20	21APR97	147 , 83	3	1	2	1	2	1	1	1	1	13
	24	26MAY97	182 ,118	1	1	1	1	1	1	2	1	1	10
	32	30JUN97	217 ,153	1	1	1	3	1	1	1	1	1	11
	32	30JUL97	247 ,183	2	1	1	1	1	1	1	1	1	10

* days relative to start of acute phase, days relative to start of continuation phase
Q2=Depressed Mood, Q20=Excessive Inappropriate Guilt, Q34=Anhedonia-Lack of Interest, Q42=Difficulty Concentrating-Inattention, Q44=Psychomotor Agitation, Q56=Psychomotor Retardation, Q83=Hypersomnia, Q85=Insomnia, Q109=Suicidal Ideation

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.001.00063	1	15NOV94	8, .	Much Improved (2)
	2	22NOV94	15, .	Much Improved (2)
	3	29NOV94	22, .	Very Much Improved (1)
	4	06DEC94	29, .	Very Much Improved (1)
	5	13DEC94	36, .	Minimally Improved (3)
329.001.00065	1	21NOV94	5, .	No Change (4)
329.001.00068	1	15FEB95	8, .	No Change (4)
	2	22FEB95	15, .	No Change (4)
	3	01MAR95	22, .	No Change (4)
	4	08MAR95	29, .	Much Improved (2)
	5	15MAR95	36, .	Much Improved (2)
	6	22MAR95	43, .	Minimally Improved (3)
	7	29MAR95	50, .	Much Improved (2)
	8	05APR95	57, .	Minimally Improved (3)
329.001.00072	1	27MAR95	8, .	Much Improved (2)
	2	03APR95	15, .	Very Much Improved (1)
	3	10APR95	22, .	Very Much Improved (1)
329.001.00121	1	11APR95	8, -49	Minimally Improved (3)
	2	18APR95	15, -42	Minimally Improved (3)
	3	26APR95	23, -34	Minimally Improved (3)
	4	02MAY95	29, -28	Minimally Improved (3)
	5	09MAY95	36, -21	Very Much Improved (1)
	6	16MAY95	43, -14	Very Much Improved (1)
	7	23MAY95	50, -7	Very Much Improved (1)
	8	30MAY95	57, 1	Very Much Improved (1)
	12	27JUN95	85, 29	Very Much Improved (1)
	16	24JUL95	112, 56	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.001.00121	20	21AUG95	140, 84	Much Worse (6)
329.001.00205	1	14FEB96	8, .	Much Worse (6)
329.001.00206	1	28FEB96	8, .	Minimally Improved (3)
	2	06MAR96	15, .	No Change (4)
	3	13MAR96	22, .	Much Improved (2)
	4	20MAR96	29, .	Minimally Worse (5)
	5	26MAR96	35, .	No Change (4)
	6	03APR96	43, .	Minimally Improved (3)
	7	10APR96	50, .	Minimally Improved (3)
	8	17APR96	57, .	Minimally Improved (3)
329.002.00055	1	30JUN94	7, -49	No Change (4)
	2	07JUL94	14, -42	Minimally Improved (3)
	3	14JUL94	21, -35	Much Improved (2)
	4	21JUL94	28, -28	Much Improved (2)
	5	28JUL94	35, -21	Much Improved (2)
	6	04AUG94	42, -14	Much Improved (2)
	7	11AUG94	49, -7	Much Improved (2)
	8	18AUG94	56, 1	Much Improved (2)
	12	15SEP94	84, 29	Much Improved (2)
	16	13OCT94	112, 57	Much Improved (2)
	20	10NOV94	140, 85	Much Worse (6)
329.002.00058	1	29SEP94	10, -49	Minimally Improved (3)
	2	07OCT94	18, -41	Much Improved (2)
	3	13OCT94	24, -35	Much Improved (2)
	4	20OCT94	31, -28	Very Much Improved (1)
	5	27OCT94	38, -21	Very Much Improved (1)
	6	03NOV94	45, -14	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00058	7	10NOV94	52, -7	Minimally Improved (3)
	8	17NOV94	59, 1	Very Much Improved (1)
	12	15DEC94	87, 29	Much Improved (2)
	16	13JAN95	116, 58	Much Improved (2)
	20	27JAN95	130, 72	Much Worse (6)
329.002.00099	1	07MAR95	6, -50	No Change (4)
	2	14MAR95	13, -43	Minimally Improved (3)
	3	21MAR95	20, -36	Much Improved (2)
	4	28MAR95	27, -29	Very Much Improved (1)
	5	04APR95	34, -22	Very Much Improved (1)
	6	11APR95	41, -15	Much Improved (2)
	7	18APR95	48, -8	Very Much Improved (1)
	8	25APR95	55, -1	Very Much Improved (1)
	12	23MAY95	83, 28	Very Much Improved (1)
	16	27JUN95	118, 63	Very Much Improved (1)
	20	01AUG95	153, 98	Much Improved (2)
	24	31AUG95	183, 128	Very Much Improved (1)
	28	28SEP95	211, 156	Very Much Improved (1)
	32	26OCT95	239, 184	Very Much Worse (7)
329.002.00102	1	18APR95	6, -49	Minimally Improved (3)
	2	25APR95	13, -42	Minimally Improved (3)
	3	02MAY95	20, -35	Much Improved (2)
	4	09MAY95	27, -28	Much Improved (2)
	5	16MAY95	34, -21	Much Improved (2)
	6	23MAY95	41, -14	Very Much Improved (1)
	7	30MAY95	48, -7	Very Much Improved (1)
	8	06JUN95	55, 1	Very Much Improved (1)
	12	13JUL95	92, 38	Very Much Improved (1)
	16	10AUG95	120, 66	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00102	20	12SEP95	153, 99	Very Much Improved (1)
	24	10OCT95	181, 127	Very Much Improved (1)
	28	09NOV95	211, 157	Much Improved (2)
	32	05DEC95	237, 183	Very Much Improved (1)
329.002.00105	1	03AUG95	8, .	No Change (4)
	2	10AUG95	15, .	Minimally Improved (3)
	3	17AUG95	22, .	Much Improved (2)
329.002.00106	1	03AUG95	8, .	Minimally Improved (3)
	2	08AUG95	13, .	Minimally Worse (5)
	3	17AUG95	22, .	No Change (4)
	4	24AUG95	29, .	Much Improved (2)
	5	31AUG95	36, .	Minimally Improved (3)
	6	05SEP95	41, .	Much Improved (2)
	7	12SEP95	48, .	Very Much Improved (1)
329.002.00242	1	14FEB96	8, -51	Minimally Improved (3)
	2	21FEB96	15, -44	Much Improved (2)
	3	29FEB96	23, -36	Minimally Improved (3)
	4	06MAR96	29, -30	Minimally Improved (3)
	5	14MAR96	37, -22	Minimally Improved (3)
	6	20MAR96	43, -16	Much Improved (2)
	7	28MAR96	51, -8	Very Much Improved (1)
	8	05APR96	59, 1	Very Much Improved (1)
	12	08MAY96	92, 34	Much Improved (2)
	16	05JUN96	120, 62	Minimally Worse (5)
	20	10JUL96	155, 97	Much Improved (2)
329.002.00245	1	04APR96	8, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00319	1	07MAY96	8, -49	Minimally Improved (3)
	2	14MAY96	15, -42	Very Much Improved (1)
	3	21MAY96	22, -35	Much Improved (2)
	4	28MAY96	29, -28	Minimally Worse (5)
	5	04JUN96	36, -21	Very Much Improved (1)
	6	11JUN96	43, -14	Very Much Improved (1)
	7	18JUN96	50, -7	Very Much Improved (1)
	8	25JUN96	57, 1	Very Much Improved (1)
	12	23JUL96	85, 29	Very Much Improved (1)
	16	15AUG96	108, 52	Very Much Improved (1)
	20	24SEP96	148, 92	Very Much Improved (1)
	24	22OCT96	176, 120	Much Improved (2)
	28	19NOV96	204, 148	Very Much Improved (1)
	32	17DEC96	232, 176	Very Much Improved (1)
329.003.00075	1	01FEB95	8, -49	Minimally Improved (3)
	2	08FEB95	15, -42	Minimally Improved (3)
	3	15FEB95	22, -35	Minimally Improved (3)
	4	21FEB95	28, -29	Much Improved (2)
	5	01MAR95	36, -21	Much Improved (2)
	6	08MAR95	43, -14	Much Improved (2)
	7	15MAR95	50, -7	Minimally Worse (5)
	8	22MAR95	57, 1	Much Improved (2)
	12	19APR95	85, 29	Very Much Improved (1)
	16	17MAY95	113, 57	Very Much Improved (1)
	20	14JUN95	141, 85	Minimally Improved (3)
	24	12JUL95	169, 113	Much Improved (2)
	32	13SEP95	232, 176	Much Improved (2)
329.003.00077	1	13MAR95	8, -52	Minimally Improved (3)
	2	20MAR95	15, -45	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00077	3	27MAR95	22, -38	Very Much Improved (1)
	4	05APR95	31, -29	Much Improved (2)
	5	12APR95	38, -22	Very Much Improved (1)
	6	19APR95	45, -15	Very Much Improved (1)
	7	26APR95	52, -8	Much Improved (2)
	8	03MAY95	59, -1	Very Much Improved (1)
	12	07JUN95	94, 35	Very Much Improved (1)
329.003.00081	1	18DEC95	8, .	No Change (4)
	2	28DEC95	18, .	No Change (4)
	3	03JAN96	24, .	No Change (4)
	4	10JAN96	31, .	Minimally Improved (3)
	5	17JAN96	38, .	Minimally Improved (3)
	6	24JAN96	45, .	Minimally Improved (3)
	7	31JAN96	52, .	Minimally Improved (3)
	8	07FEB96	59, .	Minimally Improved (3)
329.003.00089	1	14MAR95	8, .	No Change (4)
	2	21MAR95	15, .	Minimally Improved (3)
	3	28MAR95	22, .	Much Improved (2)
	4	04APR95	29, .	Much Improved (2)
	5	11APR95	36, .	Much Improved (2)
	6	18APR95	43, .	Much Improved (2)
	7	25APR95	50, .	Much Improved (2)
	8	02MAY95	57, .	Much Improved (2)
329.003.00091	1	28MAR95	5, -50	No Change (4)
	2	04APR95	12, -43	Minimally Improved (3)
	3	11APR95	19, -36	Much Improved (2)
	4	18APR95	26, -29	Minimally Improved (3)
	5	25APR95	33, -22	Minimally Worse (5)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00091	6	02MAY95	40, -15	Much Improved (2)
	7	09MAY95	47, -8	Much Improved (2)
	8	16MAY95	54, -1	Much Improved (2)
	12	16JUN95	85, 31	Much Improved (2)
	16	14JUL95	113, 59	Much Improved (2)
	24	05SEP95	166, 112	Much Improved (2)
	28	03OCT95	194, 140	Much Improved (2)
	32	07NOV95	229, 175	Much Improved (2)
329.003.00248	1	05MAR96	5, .	No Change (4)
	2	12MAR96	12, .	Minimally Improved (3)
	3	19MAR96	19, .	Minimally Improved (3)
	4	26MAR96	26, .	Minimally Improved (3)
	5	02APR96	33, .	Minimally Improved (3)
	6	11APR96	42, .	No Change (4)
	7	16APR96	47, .	No Change (4)
	8	23APR96	54, .	No Change (4)
329.003.00250	1	19MAR96	6, -52	No Change (4)
	2	26MAR96	13, -45	Minimally Improved (3)
	3	02APR96	20, -38	Minimally Improved (3)
	4	12APR96	30, -28	Minimally Improved (3)
	5	16APR96	34, -24	Much Worse (6)
	6	23APR96	41, -17	Minimally Worse (5)
	7	30APR96	48, -10	Minimally Improved (3)
	8	09MAY96	57, -1	Much Improved (2)
	12	28MAY96	76, 19	Very Much Worse (7)
329.003.00292	1	16AUG96	10, -49	Minimally Improved (3)
	2	21AUG96	15, -44	Very Much Improved (1)
	3	30AUG96	24, -35	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00292	4	04SEP96	29, -30	Very Much Improved (1)
	6	18SEP96	43, -16	Minimally Improved (3)
	8	04OCT96	59, 1	Much Improved (2)
329.003.00313	1	21MAY96	5, .	No Change (4)
	2	28MAY96	12, .	Very Much Worse (7)
329.004.00015	1	14DEC94	7, -51	Minimally Worse (5)
	2	21DEC94	14, -44	No Change (4)
	3	28DEC94	21, -37	Minimally Improved (3)
	4	04JAN95	28, -30	Minimally Improved (3)
	5	11JAN95	35, -23	Minimally Improved (3)
	6	18JAN95	42, -16	Much Improved (2)
	7	25JAN95	49, -9	Much Improved (2)
	8	03FEB95	58, 1	Very Much Improved (1)
	12	27FEB95	82, 25	Much Improved (2)
	16	22MAR95	105, 48	Much Improved (2)
	20	19APR95	133, 76	Much Improved (2)
	24	17MAY95	161, 104	Much Improved (2)
	28	14JUN95	189, 132	Much Improved (2)
329.004.00017	1	30MAR95	9, -48	No Change (4)
	2	06APR95	16, -41	Minimally Improved (3)
	3	13APR95	23, -34	Minimally Improved (3)
	4	20APR95	30, -27	Minimally Improved (3)
	5	26APR95	36, -21	Minimally Improved (3)
	6	03MAY95	43, -14	Minimally Improved (3)
	7	10MAY95	50, -7	Minimally Improved (3)
	8	17MAY95	57, 1	Much Improved (2)
	12	14JUN95	85, 29	Much Improved (2)
	16	13JUL95	114, 58	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.004.00017	20	10AUG95	142, 86	Much Improved (2)
	24	06SEP95	169, 113	Very Much Improved (1)
	28	04OCT95	197, 141	Very Much Improved (1)
	32	01NOV95	225, 169	Very Much Improved (1)
329.004.00019	1	07JUN95	8, .	No Change (4)
	2	14JUN95	15, .	Minimally Improved (3)
329.004.00212	1	10JUN96	8, .	No Change (4)
	3	21JUN96	19, .	Very Much Worse (7)
	4	28JUN96	26, .	No Change (4)
329.004.00214	1	09OCT96	6, -55	No Change (4)
	2	15OCT96	12, -49	Minimally Improved (3)
	2	21OCT96	18, -43	Minimally Improved (3)
	4	01NOV96	29, -32	Minimally Improved (3)
	5	11NOV96	39, -22	Minimally Improved (3)
	6	18NOV96	46, -15	Much Improved (2)
	7	25NOV96	53, -8	Much Improved (2)
	8	03DEC96	61, 1	Much Improved (2)
	12	30DEC96	88, 28	Much Improved (2)
329.005.00002	1	01JUN94	8, -49	No Change (4)
	2	08JUN94	15, -42	No Change (4)
	3	15JUN94	22, -35	No Change (4)
	4	23JUN94	30, -27	No Change (4)
	5	30JUN94	37, -20	No Change (4)
	6	07JUL94	44, -13	No Change (4)
	7	14JUL94	51, -6	Minimally Improved (3)
	8	20JUL94	57, 1	Minimally Improved (3)
	12	17AUG94	85, 29	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00002	16	15SEP94	114, 58	Much Improved (2)
	20	18OCT94	147, 91	Much Improved (2)
329.005.00004	1	20OCT94	11, -49	Minimally Worse (5)
	2	27OCT94	18, -42	Minimally Improved (3)
	3	03NOV94	25, -35	Minimally Improved (3)
	4	10NOV94	32, -28	Much Improved (2)
	5	17NOV94	39, -21	Very Much Improved (1)
	6	23NOV94	45, -15	Much Improved (2)
	7	01DEC94	53, -7	Very Much Improved (1)
	8	08DEC94	60, 1	Very Much Improved (1)
	12	05JAN95	88, 29	Very Much Improved (1)
329.005.00008	1	23NOV94	8, -48	No Change (4)
	2	30NOV94	15, -41	Much Improved (2)
	3	07DEC94	22, -34	Much Improved (2)
	4	14DEC94	29, -27	Much Improved (2)
	5	21DEC94	36, -20	No Change (4)
	6	28DEC94	43, -13	Much Improved (2)
	7	03JAN95	49, -7	No Change (4)
	8	10JAN95	56, 1	Very Much Improved (1)
	12	06FEB95	83, 28	Very Much Worse (7)
	16	08MAR95	113, 58	Minimally Improved (3)
	24	10MAY95	176, 121	Very Much Improved (1)
329.005.00011	1	20DEC94	8, -49	No Change (4)
	2	27DEC94	15, -42	Minimally Improved (3)
	3	03JAN95	22, -35	Minimally Worse (5)
	4	09JAN95	28, -29	Minimally Improved (3)
	5	17JAN95	36, -21	Minimally Improved (3)
	6	23JAN95	42, -15	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00011	7	31JAN95	50, -7	Very Much Improved (1)
	8	07FEB95	57, 1	Very Much Improved (1)
	12	09MAR95	87, 31	Much Improved (2)
	16	06APR95	115, 59	Very Much Improved (1)
	20	03MAY95	142, 86	Very Much Improved (1)
329.005.00109	1	05JAN95	7, -47	Much Improved (2)
	2	12JAN95	14, -40	Much Improved (2)
	3	19JAN95	21, -33	Very Much Improved (1)
	4	26JAN95	28, -26	Very Much Improved (1)
	5	02FEB95	35, -19	Very Much Improved (1)
	6	08FEB95	41, -13	Very Much Improved (1)
	7	16FEB95	49, -5	Very Much Improved (1)
	8	21FEB95	54, 1	Very Much Improved (1)
	12	23MAR95	84, 31	Very Much Improved (1)
	16	24APR95	116, 63	Very Much Improved (1)
	20	25MAY95	147, 94	Very Much Improved (1)
329.005.00112	1	01FEB95	7, -49	Minimally Improved (3)
	2	08FEB95	14, -42	Minimally Improved (3)
	3	15FEB95	21, -35	Much Improved (2)
	4	23FEB95	29, -27	Much Improved (2)
	5	01MAR95	35, -21	No Change (4)
	6	08MAR95	42, -14	Minimally Improved (3)
	7	15MAR95	49, -7	Very Much Improved (1)
	8	22MAR95	56, 1	Very Much Improved (1)
	12	19APR95	84, 29	Very Much Improved (1)
	20	21JUN95	147, 92	Very Much Improved (1)
329.005.00116	1	13FEB95	7, -52	Minimally Improved (3)
	2	20FEB95	14, -45	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00116	3	27FEB95	21, -38	Very Much Improved (1)
	4	09MAR95	31, -28	Much Improved (2)
	5	16MAR95	38, -21	Minimally Improved (3)
	6	23MAR95	45, -14	Much Improved (2)
	7	30MAR95	52, -7	Much Improved (2)
	8	06APR95	59, 1	Much Improved (2)
	12	04MAY95	87, 29	Very Much Improved (1)
	16	31MAY95	114, 56	Minimally Improved (3)
	20	28JUN95	142, 84	Minimally Improved (3)
	24	26JUL95	170, 112	Much Improved (2)
329.005.00119	1	18JUL95	8, -52	No Change (4)
	2	26JUL95	16, -44	No Change (4)
	3	02AUG95	23, -37	No Change (4)
	4	08AUG95	29, -31	Minimally Improved (3)
	5	15AUG95	36, -24	Much Improved (2)
	6	23AUG95	44, -16	Much Improved (2)
	7	29AUG95	50, -10	Much Improved (2)
	8	08SEP95	60, 1	Much Improved (2)
	12	03OCT95	85, 26	Much Improved (2)
	16	30OCT95	112, 53	Much Improved (2)
	20	28NOV95	141, 82	Much Improved (2)
	24	02JAN96	176, 117	Much Improved (2)
329.005.00151	1	14SEP95	9, -49	No Change (4)
	2	20SEP95	15, -43	Minimally Improved (3)
	3	28SEP95	23, -35	Minimally Improved (3)
	4	03OCT95	28, -30	Minimally Improved (3)
	5	11OCT95	36, -22	Minimally Improved (3)
	6	19OCT95	44, -14	Much Improved (2)
	7	26OCT95	51, -7	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00151	8	02NOV95	58, 1	Much Improved (2)
	12	28NOV95	84, 27	Minimally Improved (3)
	16	02JAN96	119, 62	Minimally Improved (3)
	20	31JAN96	148, 91	Much Improved (2)
	24	27FEB96	175, 118	Much Improved (2)
	28	27MAR96	204, 147	Much Improved (2)
	32	01MAY96	239, 182	Much Improved (2)
329.005.00152	1	02NOV95	8, .	No Change (4)
329.005.00257	1	18MAR96	8, -49	Minimally Improved (3)
	2	25MAR96	15, -42	Minimally Improved (3)
	3	01APR96	22, -35	Minimally Improved (3)
	4	08APR96	29, -28	Much Improved (2)
	5	15APR96	36, -21	Minimally Improved (3)
	6	22APR96	43, -14	Much Improved (2)
	7	29APR96	50, -7	Much Improved (2)
	8	06MAY96	57, 1	Much Improved (2)
	12	03JUN96	85, 29	Much Improved (2)
	16	08JUL96	120, 64	Much Improved (2)
	20	07AUG96	150, 94	Much Improved (2)
	24	27AUG96	170, 114	Much Improved (2)
	28	01OCT96	205, 149	Much Improved (2)
	32	21OCT96	225, 169	Much Improved (2)
329.005.00258	1	19MAR96	8, .	No Change (4)
	2	26MAR96	15, .	Minimally Improved (3)
	3	02APR96	22, .	Minimally Improved (3)
	4	09APR96	29, .	Minimally Improved (3)
	5	18APR96	38, .	Much Improved (2)
	6	23APR96	43, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00258	7	30APR96	50, .	Minimally Improved (3)
	8	07MAY96	57, .	Minimally Improved (3)
329.005.00299	1	18JUN96	11, -50	Minimally Improved (3)
	2	25JUN96	18, -43	Minimally Improved (3)
	3	02JUL96	25, -36	Much Improved (2)
	5	10JUL96	33, -28	Minimally Improved (3)
	5	16JUL96	39, -22	Much Improved (2)
	6	22JUL96	45, -16	Very Much Improved (1)
	8	31JUL96	54, -7	Very Much Improved (1)
	8	07AUG96	61, 1	Much Improved (2)
	12	03SEP96	88, 28	Much Improved (2)
	16	01OCT96	116, 56	Much Improved (2)
	20	29OCT96	144, 84	Minimally Improved (3)
	20	05NOV96	151, 91	Minimally Worse (5)
329.005.00300	1	26SEP96	8, .	No Change (4)
	2	03OCT96	15, .	Minimally Improved (3)
	3	10OCT96	22, .	Minimally Improved (3)
	4	17OCT96	29, .	Minimally Improved (3)
	5	24OCT96	36, .	Minimally Improved (3)
	6	31OCT96	43, .	Minimally Improved (3)
	7	07NOV96	50, .	Minimally Improved (3)
	8	14NOV96	57, .	Much Worse (6)
329.005.00333	1	31JAN97	9, .	Minimally Improved (3)
	2	06FEB97	15, .	No Change (4)
	3	13FEB97	22, .	Minimally Improved (3)
	4	20FEB97	29, .	Minimally Improved (3)
	5	26FEB97	35, .	Minimally Worse (5)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00336	1	12MAR97	9, .	Much Improved (2)
	2	19MAR97	16, .	Much Improved (2)
	3	25MAR97	22, .	Much Improved (2)
	4	02APR97	30, .	Very Much Improved (1)
	5	09APR97	37, .	Much Improved (2)
	6	16APR97	44, .	Much Improved (2)
	7	23APR97	51, .	Very Much Improved (1)
	8	30APR97	58, .	Very Much Improved (1)
329.006.00038	1	22FEB95	8, .	No Change (4)
	2	03MAR95	17, .	Much Improved (2)
	3	08MAR95	22, .	Much Improved (2)
	4	15MAR95	29, .	Much Improved (2)
	5	22MAR95	36, .	Much Improved (2)
	6	29MAR95	43, .	Much Improved (2)
	7	05APR95	50, .	Minimally Improved (3)
	8	12APR95	57, .	Very Much Worse (7)
329.006.00039	1	13FEB95	6, -56	No Change (4)
	2	22FEB95	15, -47	No Change (4)
	3	01MAR95	22, -40	No Change (4)
	4	08MAR95	29, -33	No Change (4)
	5	17MAR95	38, -24	Minimally Improved (3)
	6	22MAR95	43, -19	Minimally Improved (3)
	7	29MAR95	50, -12	Minimally Worse (5)
	8	05APR95	57, -5	Minimally Improved (3)
	12	01MAY95	83, 22	Minimally Worse (5)
329.006.00260	1	26JUL96	9, -50	Minimally Improved (3)
	2	01AUG96	15, -44	Minimally Improved (3)
	3	07AUG96	21, -38	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.006.00260	4	14AUG96	28, -31	Much Improved (2)
	5	21AUG96	35, -24	Much Improved (2)
	6	28AUG96	42, -17	Much Improved (2)
	7	04SEP96	49, -10	Much Improved (2)
	8	18SEP96	63, 5	Very Much Improved (1)
	12	09OCT96	84, 26	Much Improved (2)
	16	06NOV96	112, 54	Very Much Improved (1)
	20	05DEC96	141, 83	Much Improved (2)
329.006.00261	1	03DEC96	8, -51	No Change (4)
	2	10DEC96	15, -44	Minimally Improved (3)
	3	17DEC96	22, -37	Minimally Improved (3)
	4	24DEC96	29, -30	Minimally Improved (3)
	5	02JAN97	38, -21	Minimally Improved (3)
	6	09JAN97	45, -14	Much Improved (2)
	7	15JAN97	51, -8	Very Much Improved (1)
	8	23JAN97	59, 1	Very Much Improved (1)
	12	20FEB97	87, 29	Very Much Improved (1)
	20	02APR97	128, 70	Very Much Improved (1)
329.007.00140	1	21SEP95	7, -49	Minimally Improved (3)
	2	28SEP95	14, -42	Much Improved (2)
	3	05OCT95	21, -35	Much Improved (2)
	4	12OCT95	28, -28	Much Improved (2)
	5	18OCT95	34, -22	Very Much Improved (1)
	6	26OCT95	42, -14	Very Much Improved (1)
	7	02NOV95	49, -7	Very Much Improved (1)
	8	09NOV95	56, 1	Much Improved (2)
	8	22NOV95	69, 14	Very Much Improved (1)
329.007.00142	1	26OCT95	9, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.007.00142	2	02NOV95	16, .	No Change (4)
	3	09NOV95	23, .	Minimally Improved (3)
	4	16NOV95	30, .	No Change (4)
	5	22NOV95	36, .	Minimally Improved (3)
	6	30NOV95	44, .	Minimally Worse (5)
	8	21DEC95	65, .	No Change (4)
329.007.00145	1	18JAN96	8, -49	Minimally Improved (3)
	2	25JAN96	15, -42	Minimally Improved (3)
	3	01FEB96	22, -35	Minimally Improved (3)
	4	08FEB96	29, -28	Minimally Improved (3)
	5	12FEB96	33, -24	Minimally Improved (3)
	6	21FEB96	42, -15	Minimally Improved (3)
	7	26FEB96	47, -10	Much Improved (2)
	8	07MAR96	57, 1	Much Improved (2)
	12	04APR96	85, 29	Much Improved (2)
	16	02MAY96	113, 57	Very Much Improved (1)
	20	30MAY96	141, 85	Very Much Improved (1)
	24	27JUN96	169, 113	Very Much Improved (1)
	28	25JUL96	197, 141	Very Much Improved (1)
	32	23AUG96	226, 170	Very Much Improved (1)
329.007.00265	2	15FEB96	15, .	No Change (4)
329.007.00268	1	11APR96	11, -49	Very Much Improved (1)
	2	18APR96	18, -42	Very Much Improved (1)
	3	25APR96	25, -35	Much Improved (2)
	4	02MAY96	32, -28	Much Improved (2)
	5	09MAY96	39, -21	Minimally Improved (3)
	6	16MAY96	46, -14	Minimally Improved (3)
	8	30MAY96	60, 1	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.007.00268	12	27JUN96	88, 29	Very Much Improved (1)
	16	01AUG96	123, 64	Much Improved (2)
	20	30AUG96	152, 93	Very Much Improved (1)
	24	30SEP96	183, 124	Very Much Improved (1)
	32	07NOV96	221, 162	Very Much Improved (1)
	32	05DEC96	249, 190	Very Much Improved (1)
329.007.00294	1	10MAR97	11, .	No Change (4)
	2	17MAR97	18, .	No Change (4)
	4	28MAR97	29, .	No Change (4)
	5	03APR97	35, .	No Change (4)
	6	10APR97	42, .	No Change (4)
329.007.00309	1	18JUL96	4, -49	Much Improved (2)
	1	25JUL96	11, -42	Very Much Improved (1)
	3	08AUG96	25, -28	Much Improved (2)
	4	15AUG96	32, -21	Much Improved (2)
	6	23AUG96	40, -13	Very Much Improved (1)
	7	30AUG96	47, -6	Much Improved (2)
	7	05SEP96	53, 1	Very Much Improved (1)
	12	03OCT96	81, 29	Much Improved (2)
	16	31OCT96	109, 57	Very Much Improved (1)
	20	13DEC96	152, 100	Much Improved (2)
	24	09JAN97	179, 127	Very Much Improved (1)
	28	10FEB97	211, 159	Much Improved (2)
	32	13MAR97	242, 190	Much Improved (2)
329.007.00310	1	03OCT96	8, -53	No Change (4)
	2	10OCT96	15, -46	Minimally Improved (3)
	3	17OCT96	22, -39	Much Improved (2)
	5	28OCT96	33, -28	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.007.00310	5	31OCT96	36, -25	Very Much Improved (1)
	6	08NOV96	44, -17	Much Improved (2)
	8	18NOV96	54, -7	Minimally Improved (3)
	8	25NOV96	61, 1	Much Improved (2)
	12	02JAN97	99, 39	Very Much Improved (1)
	20	14FEB97	142, 82	Very Much Improved (1)
	24	13MAR97	169, 109	Very Much Improved (1)
	28	17APR97	204, 144	Very Much Improved (1)
	32	15MAY97	232, 172	Very Much Improved (1)
	32	12JUN97	260, 200	Very Much Improved (1)
329.008.00157	1	05SEP95	7, -49	Minimally Improved (3)
	2	12SEP95	14, -42	Minimally Improved (3)
	3	20SEP95	22, -34	Much Improved (2)
	4	26SEP95	28, -28	Much Improved (2)
	5	04OCT95	36, -20	No Change (4)
	6	10OCT95	42, -14	No Change (4)
	7	16OCT95	48, -8	Minimally Worse (5)
	8	24OCT95	56, 1	Very Much Improved (1)
	12	23NOV95	86, 31	Very Much Improved (1)
	16	15DEC95	108, 53	Very Much Improved (1)
	20	23JAN96	147, 92	Very Much Improved (1)
	24	20FEB96	175, 120	Very Much Improved (1)
329.008.00160	1	10NOV95	10, -57	Minimally Improved (3)
	3	20NOV95	20, -47	Minimally Improved (3)
	4	27NOV95	27, -40	Much Improved (2)
	5	05DEC95	35, -32	Much Improved (2)
	6	13DEC95	43, -24	Minimally Improved (3)
	7	20DEC95	50, -17	Much Improved (2)
	8	27DEC95	57, -10	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.008.00160	8	05JAN96	66, -1	Very Much Improved (1)
	12	31JAN96	92, 26	Very Much Improved (1)
	16	05MAR96	126, 60	Minimally Improved (3)
	24	09APR96	161, 95	Very Much Improved (1)
	28	16MAY96	198, 132	Very Much Improved (1)
	32	18JUN96	231, 165	Very Much Improved (1)
	32	23JUL96	266, 200	Very Much Improved (1)
329.008.00188	1	10JAN96	7, .	No Change (4)
	2	17JAN96	14, .	No Change (4)
	3	24JAN96	21, .	Minimally Improved (3)
	4	31JAN96	28, .	No Change (4)
	5	07FEB96	35, .	No Change (4)
	6	14FEB96	42, .	Minimally Improved (3)
	7	21FEB96	49, .	Minimally Improved (3)
	8	27FEB96	55, .	Minimally Improved (3)
329.008.00271	1	18MAR96	8, -57	No Change (4)
	2	25MAR96	15, -50	Minimally Improved (3)
	3	01APR96	22, -43	Minimally Improved (3)
	4	08APR96	29, -36	Minimally Improved (3)
	5	15APR96	36, -29	Minimally Improved (3)
	6	22APR96	43, -22	Minimally Improved (3)
	7	02MAY96	53, -12	No Change (4)
	8	14MAY96	65, 1	Much Improved (2)
	12	10JUN96	92, 28	Minimally Improved (3)
	16	12JUL96	124, 60	Much Improved (2)
	20	09AUG96	152, 88	Minimally Improved (3)
	24	06SEP96	180, 116	Minimally Improved (3)
	28	07OCT96	211, 147	Minimally Improved (3)
	32	05NOV96	240, 176	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.008.00275	1	15MAY96	8, -48	Minimally Improved (3)
	2	21MAY96	14, -42	Minimally Improved (3)
	3	28MAY96	21, -35	Minimally Improved (3)
	4	04JUN96	28, -28	Minimally Improved (3)
	5	11JUN96	35, -21	Much Improved (2)
	7	25JUN96	49, -7	Much Improved (2)
	8	02JUL96	56, 1	Much Improved (2)
	12	23JUL96	77, 22	Very Much Improved (1)
	16	20AUG96	105, 50	Much Improved (2)
	20	16SEP96	132, 77	Much Worse (6)
	24	21OCT96	167, 112	Minimally Worse (5)
	28	25NOV96	202, 147	Much Improved (2)
	32	16DEC96	223, 168	Much Improved (2)
329.009.00130	1	25APR95	8, -49	No Change (4)
	2	02MAY95	15, -42	No Change (4)
	3	09MAY95	22, -35	Minimally Improved (3)
	4	16MAY95	29, -28	Much Improved (2)
	5	23MAY95	36, -21	No Change (4)
	6	30MAY95	43, -14	Minimally Improved (3)
	7	06JUN95	50, -7	Very Much Improved (1)
	8	13JUN95	57, 1	Very Much Improved (1)
	16	07AUG95	112, 56	Much Improved (2)
	20	19SEP95	155, 99	Very Much Improved (1)
	24	03OCT95	169, 113	No Change (4)
329.009.00131	1	09MAY95	8, -49	Minimally Improved (3)
	2	16MAY95	15, -42	Minimally Improved (3)
	3	23MAY95	22, -35	Minimally Improved (3)
	4	30MAY95	29, -28	Much Improved (2)
	5	06JUN95	36, -21	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00131	6	13JUN95	43, -14	Very Much Improved (1)
	7	20JUN95	50, -7	Much Improved (2)
	8	27JUN95	57, 1	Very Much Improved (1)
	12	25JUL95	85, 29	Minimally Improved (3)
	16	24AUG95	115, 59	Minimally Improved (3)
	20	26SEP95	148, 92	Minimally Improved (3)
329.009.00133	1	20JUN95	8, .	No Change (4)
	2	27JUN95	15, .	No Change (4)
	3	05JUL95	23, .	No Change (4)
	4	11JUL95	29, .	No Change (4)
	5	18JUL95	36, .	No Change (4)
	6	27JUL95	45, .	No Change (4)
329.009.00138	1	17OCT95	8, .	No Change (4)
329.009.00170	1	14NOV95	8, -50	Minimally Improved (3)
	2	21NOV95	15, -43	Minimally Improved (3)
	3	28NOV95	22, -36	Minimally Improved (3)
	4	05DEC95	29, -29	No Change (4)
	5	12DEC95	36, -22	Much Improved (2)
	6	21DEC95	45, -13	Much Improved (2)
	7	29DEC95	53, -5	Much Improved (2)
	8	03JAN96	58, 1	Much Improved (2)
	12	29JAN96	84, 27	Much Improved (2)
	16	26FEB96	112, 55	Very Much Improved (1)
	20	01APR96	147, 90	Much Improved (2)
	24	22APR96	168, 111	Much Improved (2)
	28	23MAY96	199, 142	Very Much Improved (1)
	32	24JUN96	231, 174	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00173	1	27NOV95	8, -56	No Change (4)
	2	04DEC95	15, -49	No Change (4)
	3	11DEC95	22, -42	No Change (4)
	4	18DEC95	29, -35	Minimally Improved (3)
	6	29DEC95	40, -24	Minimally Improved (3)
	7	08JAN96	50, -14	Minimally Improved (3)
	8	15JAN96	57, -7	Minimally Improved (3)
	8	22JAN96	64, 1	Much Improved (2)
	12	26FEB96	99, 36	Minimally Improved (3)
329.009.00193	1	05DEC95	8, .	No Change (4)
	2	12DEC95	15, .	No Change (4)
	3	19DEC95	22, .	No Change (4)
	4	27DEC95	30, .	Minimally Improved (3)
	5	05JAN96	39, .	No Change (4)
	6	09JAN96	43, .	No Change (4)
	7	16JAN96	50, .	No Change (4)
	8	24JAN96	58, .	No Change (4)
329.009.00196	1	27DEC95	10, .	No Change (4)
	2	02JAN96	16, .	Minimally Improved (3)
	3	08JAN96	22, .	Minimally Improved (3)
	4	15JAN96	29, .	Minimally Improved (3)
	5	22JAN96	36, .	Minimally Improved (3)
	6	29JAN96	43, .	Much Improved (2)
	7	05FEB96	50, .	Much Improved (2)
	8	12FEB96	57, .	Much Improved (2)
329.009.00201	1	13FEB96	8, .	No Change (4)
	2	20FEB96	15, .	Much Improved (2)
	3	28FEB96	23, .	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00201	4	05MAR96	29, .	Very Much Improved (1)
	5	12MAR96	36, .	Very Much Improved (1)
	6	19MAR96	43, .	Very Much Improved (1)
	7	26MAR96	50, .	Minimally Improved (3)
	8	02APR96	57, .	Very Much Improved (1)
329.009.00204	1	26MAR96	8, -49	No Change (4)
	2	02APR96	15, -42	Minimally Improved (3)
	3	09APR96	22, -35	Minimally Improved (3)
	4	16APR96	29, -28	Much Improved (2)
	5	23APR96	36, -21	Very Much Improved (1)
	6	30APR96	43, -14	Very Much Improved (1)
	7	07MAY96	50, -7	Very Much Improved (1)
	8	14MAY96	57, 1	Very Much Improved (1)
	12	11JUN96	85, 29	Very Much Improved (1)
	16	09JUL96	113, 57	Very Much Improved (1)
	20	13AUG96	148, 92	Very Much Improved (1)
	24	10SEP96	176, 120	Very Much Improved (1)
	28	14OCT96	210, 154	Very Much Improved (1)
329.009.00235	1	23DEC96	6, -49	No Change (4)
	2	30DEC96	13, -42	Much Improved (2)
	3	06JAN97	20, -35	Much Improved (2)
	4	15JAN97	29, -26	Very Much Improved (1)
	5	20JAN97	34, -21	Very Much Improved (1)
	6	27JAN97	41, -14	Very Much Improved (1)
	7	03FEB97	48, -7	Very Much Improved (1)
	8	10FEB97	55, 1	Very Much Improved (1)
	12	17MAR97	90, 36	Much Improved (2)
	16	14APR97	118, 64	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00240	1	21JAN97	8, .	No Change (4)
	2	28JAN97	15, .	Minimally Improved (3)
	3	04FEB97	22, .	Minimally Improved (3)
	4	11FEB97	29, .	Much Improved (2)
	5	18FEB97	36, .	Minimally Improved (3)
	6	25FEB97	43, .	Minimally Improved (3)
	7	04MAR97	50, .	Minimally Improved (3)
329.009.00303	1	09APR96	8, -49	No Change (4)
	2	16APR96	15, -42	Minimally Improved (3)
	3	23APR96	22, -35	Much Improved (2)
	4	30APR96	29, -28	Much Improved (2)
	5	07MAY96	36, -21	Very Much Improved (1)
	6	14MAY96	43, -14	Very Much Improved (1)
	7	22MAY96	51, -6	Very Much Improved (1)
	8	28MAY96	57, 1	Very Much Improved (1)
	12	25JUN96	85, 29	Very Much Improved (1)
	16	30JUL96	120, 64	Very Much Improved (1)
	20	27AUG96	148, 92	Very Much Improved (1)
	24	25SEP96	177, 121	Very Much Improved (1)
	32	30OCT96	212, 156	Very Much Improved (1)
	32	10DEC96	253, 197	Very Much Improved (1)
329.009.00304	1	16APR96	8, -49	No Change (4)
	2	23APR96	15, -42	No Change (4)
	3	30APR96	22, -35	Minimally Improved (3)
	4	07MAY96	29, -28	Minimally Improved (3)
	5	14MAY96	36, -21	Much Improved (2)
	6	21MAY96	43, -14	Much Improved (2)
	7	28MAY96	50, -7	Much Improved (2)
	8	04JUN96	57, 1	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00304	12	02JUL96	85, 29	Very Much Improved (1)
	16	30JUL96	113, 57	Much Improved (2)
	20	27AUG96	141, 85	Very Much Improved (1)
	24	23SEP96	168, 112	Minimally Improved (3)
	28	21OCT96	196, 140	Much Improved (2)
329.009.00324	1	04NOV96	8, .	No Change (4)
	2	11NOV96	15, .	Much Improved (2)
	3	18NOV96	22, .	Very Much Improved (1)
	4	25NOV96	29, .	Very Much Improved (1)
	5	02DEC96	36, .	Very Much Improved (1)
	6	09DEC96	43, .	Very Much Improved (1)
	7	16DEC96	50, .	Very Much Improved (1)
	8	27DEC96	61, .	Very Much Improved (1)
329.009.00329	1	16OCT96	8, .	No Change (4)
	2	23OCT96	15, .	No Change (4)
	3	29OCT96	21, .	Minimally Improved (3)
	4	05NOV96	28, .	No Change (4)
	5	12NOV96	35, .	Minimally Improved (3)
	6	19NOV96	42, .	Minimally Improved (3)
	7	26NOV96	49, .	Minimally Improved (3)
	8	03DEC96	56, .	Minimally Improved (3)
329.010.00182	3	12JAN96	25, .	Much Improved (2)
	4	19JAN96	32, .	Much Improved (2)
329.010.00278	1	16FEB96	8, -49	Minimally Improved (3)
	2	23FEB96	15, -42	Minimally Improved (3)
	3	01MAR96	22, -35	Minimally Improved (3)
	4	08MAR96	29, -28	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.010.00278	5	15MAR96	36, -21	Much Improved (2)
	6	22MAR96	43, -14	Much Improved (2)
	7	29MAR96	50, -7	Much Improved (2)
	8	05APR96	57, 1	Much Improved (2)
	12	03MAY96	85, 29	Much Improved (2)
	16	31MAY96	113, 57	Much Improved (2)
	20	27JUN96	140, 84	Much Improved (2)
	24	25JUL96	168, 112	Minimally Improved (3)
	28	22AUG96	196, 140	Very Much Improved (1)
	32	19SEP96	224, 168	Much Improved (2)
329.010.00280	1	24MAY96	8, -48	Minimally Improved (3)
	2	31MAY96	15, -41	No Change (4)
	3	07JUN96	22, -34	Minimally Improved (3)
	4	14JUN96	29, -27	Minimally Improved (3)
	5	21JUN96	36, -20	Minimally Improved (3)
	6	27JUN96	42, -14	Minimally Improved (3)
	7	03JUL96	48, -8	Minimally Improved (3)
	8	11JUL96	56, 1	Much Improved (2)
	12	21AUG96	97, 42	No Change (4)
329.011.00283	1	14FEB96	7, -51	Minimally Improved (3)
	2	21FEB96	14, -44	Much Improved (2)
	3	29FEB96	22, -36	Much Improved (2)
	4	07MAR96	29, -29	Much Improved (2)
	5	15MAR96	37, -21	Much Improved (2)
	6	22MAR96	44, -14	Much Improved (2)
	7	28MAR96	50, -8	Very Much Improved (1)
	8	04APR96	57, -1	Much Improved (2)
329.011.00288	1	01AUG96	8, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.011.00288	2	09AUG96	16, .	Minimally Improved (3)
	4	19AUG96	26, .	Minimally Improved (3)
	5	29AUG96	36, .	Minimally Improved (3)
	6	04SEP96	42, .	Much Worse (6)
329.012.00025	1	31OCT95	8, .	Minimally Improved (3)
	2	07NOV95	15, .	Minimally Improved (3)
	3	14NOV95	22, .	Minimally Improved (3)
	4	21NOV95	29, .	Much Improved (2)
	5	28NOV95	36, .	Minimally Improved (3)
	6	05DEC95	43, .	No Change (4)
	7	12DEC95	50, .	Minimally Improved (3)
	8	19DEC95	57, .	Minimally Improved (3)
329.012.00220	1	22JUN96	6, -55	No Change (4)
	2	28JUN96	12, -49	Much Improved (2)
	3	05JUL96	19, -42	Much Improved (2)
	4	12JUL96	26, -35	Much Improved (2)
	5	19JUL96	33, -28	Very Much Improved (1)
	6	29JUL96	43, -18	Very Much Improved (1)
	7	06AUG96	51, -10	Very Much Improved (1)
	8	16AUG96	61, 1	Very Much Improved (1)
	12	13SEP96	89, 29	Very Much Improved (1)
	16	11OCT96	117, 57	Much Improved (2)
	20	08NOV96	145, 85	Much Improved (2)
	24	06DEC96	173, 113	Minimally Worse (5)
329.012.00222	1	05JUL96	8, -56	No Change (4)
	2	12JUL96	15, -49	Minimally Improved (3)
	3	19JUL96	22, -42	Much Improved (2)
	4	29JUL96	32, -32	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.012.00222	6	06AUG96	40, -24	Much Improved (2)
	7	13AUG96	47, -17	Much Improved (2)
	8	20AUG96	54, -10	Very Much Improved (1)
	8	30AUG96	64, 1	Very Much Improved (1)
	12	27SEP96	92, 29	Very Much Improved (1)
329.012.00226	1	10DEC96	8, .	No Change (4)
	2	20DEC96	18, .	No Change (4)
329.012.00228	1	27MAR97	9, .	No Change (4)
329.012.00231	1	17MAR97	11, -51	Minimally Improved (3)
	2	24MAR97	18, -44	Minimally Improved (3)
	4	02APR97	27, -35	Much Improved (2)
	5	09APR97	34, -28	Minimally Improved (3)
	6	17APR97	42, -20	Much Improved (2)
	7	25APR97	50, -12	Much Improved (2)
	8	01MAY97	56, -6	Much Improved (2)
	8	07MAY97	62, 1	Much Improved (2)
	12	04JUN97	90, 29	Much Improved (2)
	16	30JUN97	116, 55	Much Improved (2)
	20	05AUG97	152, 91	Minimally Improved (3)
	24	19AUG97	166, 105	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.001.00061	1	04AUG94	7, .	No Change (4)
	2	11AUG94	14, .	No Change (4)
	3	18AUG94	21, .	Much Improved (2)
	4	25AUG94	28, .	Very Much Improved (1)
	5	01SEP94	35, .	Much Improved (2)
329.001.00066	1	28NOV94	7, .	No Change (4)
	2	05DEC94	14, .	Much Improved (2)
329.001.00067	1	29NOV94	8, .	No Change (4)
	2	06DEC94	15, .	Minimally Improved (3)
329.001.00070	1	28FEB95	7, .	No Change (4)
	2	08MAR95	15, .	Minimally Improved (3)
	3	15MAR95	22, .	Much Improved (2)
329.001.00122	1	27JUN95	8, -50	No Change (4)
	2	05JUL95	16, -42	Minimally Improved (3)
	3	11JUL95	22, -36	Minimally Improved (3)
	4	18JUL95	29, -29	Much Improved (2)
	5	25JUL95	36, -22	Much Improved (2)
	6	01AUG95	43, -15	Much Improved (2)
	7	08AUG95	50, -8	Much Improved (2)
	8	16AUG95	58, 1	Much Improved (2)
	12	12SEP95	85, 28	Much Improved (2)
	16	10OCT95	113, 56	Very Much Improved (1)
	20	07NOV95	141, 84	Minimally Worse (5)
	24	05DEC95	169, 112	Much Worse (6)
329.002.00050	1	29MAR95	7, .	No Change (4)
	2	05APR95	14, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00050	3	12APR95	21, .	No Change (4)
	5	28APR95	37, .	No Change (4)
329.002.00056	1	26JUL94	8, .	No Change (4)
	2	02AUG94	15, .	Minimally Improved (3)
	3	09AUG94	22, .	Much Improved (2)
	4	16AUG94	29, .	Minimally Improved (3)
329.002.00057	1	15SEP94	8, -50	Minimally Improved (3)
	2	22SEP94	15, -43	Minimally Improved (3)
	3	29SEP94	22, -36	Much Improved (2)
	4	06OCT94	29, -29	Much Improved (2)
	5	13OCT94	36, -22	Very Much Improved (1)
	6	20OCT94	43, -15	Very Much Improved (1)
	7	27OCT94	50, -8	Very Much Improved (1)
	8	03NOV94	57, -1	Very Much Improved (1)
	12	01DEC94	85, 28	Very Much Improved (1)
	16	29DEC94	113, 56	Very Much Improved (1)
329.002.00098	1	10JAN95	8, .	No Change (4)
	2	18JAN95	16, .	Minimally Improved (3)
	3	24JAN95	22, .	Minimally Improved (3)
	4	31JAN95	29, .	Minimally Worse (5)
	5	07FEB95	36, .	Minimally Improved (3)
	6	14FEB95	43, .	Minimally Worse (5)
	7	21FEB95	50, .	Much Worse (6)
	8	02MAR95	59, .	Minimally Worse (5)
329.002.00100	1	14MAR95	8, -51	Minimally Improved (3)
	2	21MAR95	15, -44	No Change (4)
	3	28MAR95	22, -37	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00100	4	04APR95	29, -30	Minimally Improved (3)
	5	11APR95	36, -23	Much Improved (2)
	6	18APR95	43, -16	Much Improved (2)
	7	25APR95	50, -9	Much Improved (2)
	8	04MAY95	59, 1	Much Improved (2)
	12	30MAY95	85, 27	Much Improved (2)
	16	27JUN95	113, 55	Much Improved (2)
	16	06JUL95	122, 64	Minimally Improved (3)
329.002.00103	1	27APR95	8, -49	No Change (4)
	2	02MAY95	13, -44	Minimally Improved (3)
	3	09MAY95	20, -37	Much Improved (2)
	4	16MAY95	27, -30	Very Much Improved (1)
	5	25MAY95	36, -21	Very Much Improved (1)
	6	30MAY95	41, -16	Very Much Improved (1)
	7	06JUN95	48, -9	Very Much Improved (1)
	8	15JUN95	57, 1	Very Much Improved (1)
	12	13JUL95	85, 29	Very Much Improved (1)
	16	10AUG95	113, 57	Very Much Worse (7)
329.002.00104	1	11MAY95	8, -49	Minimally Improved (3)
	2	18MAY95	15, -42	Minimally Improved (3)
	3	25MAY95	22, -35	Minimally Improved (3)
	4	01JUN95	29, -28	Much Improved (2)
	5	09JUN95	37, -20	Much Improved (2)
	6	16JUN95	44, -13	Much Improved (2)
	7	22JUN95	50, -7	Much Improved (2)
	8	29JUN95	57, 1	Very Much Improved (1)
	12	25JUL95	83, 27	Very Much Improved (1)
	16	29AUG95	118, 62	Very Much Improved (1)
	20	03OCT95	153, 97	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00104	28	06NOV95	187, 131	Very Much Improved (1)
	32	06DEC95	217, 161	Very Much Improved (1)
	32	02JAN96	244, 188	Very Much Improved (1)
329.002.00243	1	21MAR96	8, .	Minimally Improved (3)
	2	28MAR96	15, .	Minimally Worse (5)
	3	04APR96	22, .	Minimally Worse (5)
329.002.00244	1	28MAR96	8, -50	No Change (4)
	2	04APR96	15, -43	No Change (4)
	3	11APR96	22, -36	Minimally Improved (3)
	4	18APR96	29, -29	Minimally Improved (3)
	5	25APR96	36, -22	Much Improved (2)
	6	02MAY96	43, -15	Minimally Worse (5)
	7	09MAY96	50, -8	Minimally Improved (3)
	8	16MAY96	57, -1	Minimally Improved (3)
329.002.00321	1	30MAY96	8, .	Minimally Improved (3)
329.002.00322	1	16JAN97	8, .	No Change (4)
	2	23JAN97	15, .	Minimally Improved (3)
	3	30JAN97	22, .	Minimally Improved (3)
	4	04FEB97	27, .	Minimally Improved (3)
	5	13FEB97	36, .	Minimally Improved (3)
329.003.00073	1	25JAN95	7, .	No Change (4)
	2	03FEB95	16, .	Minimally Improved (3)
	3	07FEB95	20, .	Minimally Improved (3)
	4	14FEB95	27, .	Minimally Improved (3)
	5	22FEB95	35, .	Minimally Improved (3)
	6	01MAR95	42, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00073	7	08MAR95	49, .	Minimally Worse (5)
329.003.00076	1	07FEB95	8, -48	Minimally Improved (3)
	2	14FEB95	15, -41	Much Improved (2)
	3	21FEB95	22, -34	Very Much Improved (1)
	4	27FEB95	28, -28	Much Improved (2)
	5	06MAR95	35, -21	Very Much Improved (1)
	6	13MAR95	42, -14	Very Much Improved (1)
	7	20MAR95	49, -7	Very Much Improved (1)
	8	27MAR95	56, 1	Very Much Improved (1)
	12	03MAY95	93, 38	Very Much Improved (1)
	16	31MAY95	121, 66	Very Much Improved (1)
	20	28JUN95	149, 94	Much Improved (2)
	28	02AUG95	184, 129	Much Improved (2)
	32	06SEP95	219, 164	Much Improved (2)
	32	11OCT95	254, 199	Much Improved (2)
329.003.00079	1	10MAY95	8, .	No Change (4)
	2	19MAY95	17, .	No Change (4)
329.003.00082	2	28DEC95	18, .	No Change (4)
	3	03JAN96	24, .	No Change (4)
	4	11JAN96	32, .	Minimally Improved (3)
	5	17JAN96	38, .	Minimally Improved (3)
329.003.00088	1	09MAR95	10, .	No Change (4)
	2	14MAR95	15, .	No Change (4)
	3	21MAR95	22, .	Minimally Improved (3)
	4	30MAR95	31, .	Minimally Improved (3)
	5	04APR95	36, .	No Change (4)
	6	11APR95	43, .	Minimally Worse (5)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00090	2	28MAR95	15, .	No Change (4)
	3	04APR95	22, .	No Change (4)
	4	11APR95	29, .	No Change (4)
	5	18APR95	36, .	No Change (4)
	6	25APR95	43, .	Minimally Improved (3)
	7	02MAY95	50, .	No Change (4)
	8	09MAY95	57, .	Minimally Improved (3)
	8	16MAY95	64, .	Minimally Improved (3)
329.003.00092	1	11MAY95	9, -50	Minimally Improved (3)
	2	16MAY95	14, -45	Much Improved (2)
	3	26MAY95	24, -35	Much Improved (2)
	4	02JUN95	31, -28	Much Improved (2)
	5	06JUN95	35, -24	Much Improved (2)
	6	13JUN95	42, -17	Much Improved (2)
	7	20JUN95	49, -10	Much Improved (2)
	8	30JUN95	59, 1	Much Improved (2)
	12	08AUG95	98, 40	Much Improved (2)
	16	05SEP95	126, 68	Minimally Improved (3)
	20	26SEP95	147, 89	Much Improved (2)
	28	07NOV95	189, 131	Much Improved (2)
	32	05DEC95	217, 159	Much Improved (2)
	32	02JAN96	245, 187	Much Improved (2)
329.003.00093	1	27JUN95	7, -57	No Change (4)
	2	06JUL95	16, -48	No Change (4)
	4	21JUL95	31, -33	No Change (4)
	5	25JUL95	35, -29	Minimally Improved (3)
	8	22AUG95	63, -1	Much Improved (2)
	16	03OCT95	105, 42	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00247	1	06FEB96	6, -49	No Change (4)
	2	13FEB96	13, -42	Minimally Improved (3)
	3	20FEB96	20, -35	Minimally Improved (3)
	4	27FEB96	27, -28	Much Improved (2)
	5	07MAR96	36, -19	Much Improved (2)
	6	12MAR96	41, -14	Much Improved (2)
	7	21MAR96	50, -5	Much Improved (2)
	8	26MAR96	55, 1	Much Improved (2)
	12	30APR96	90, 36	Much Improved (2)
	16	21MAY96	111, 57	Much Improved (2)
329.003.00249	1	12MAR96	6, .	No Change (4)
	2	19MAR96	13, .	No Change (4)
	3	26MAR96	20, .	No Change (4)
	4	02APR96	27, .	Minimally Improved (3)
	5	09APR96	34, .	No Change (4)
	6	16APR96	41, .	Minimally Worse (5)
	7	23APR96	48, .	Minimally Worse (5)
	8	30APR96	55, .	No Change (4)
329.003.00289	1	06MAR96	8, -49	No Change (4)
	2	13MAR96	15, -42	Minimally Improved (3)
	3	20MAR96	22, -35	Much Improved (2)
	4	27MAR96	29, -28	Minimally Improved (3)
	5	03APR96	36, -21	Much Improved (2)
	6	10APR96	43, -14	Much Improved (2)
	7	17APR96	50, -7	Very Much Improved (1)
	8	24APR96	57, 1	Very Much Improved (1)
	12	22MAY96	85, 29	Very Much Improved (1)
	16	20JUN96	114, 58	Very Much Improved (1)
	20	19JUL96	143, 87	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00289	24	16AUG96	171, 115	Very Much Improved (1)
	28	13SEP96	199, 143	Very Much Improved (1)
	32	11OCT96	227, 171	Much Improved (2)
329.003.00290	1	20MAR96	10, .	No Change (4)
	2	22MAR96	12, .	Minimally Worse (5)
329.003.00314	1	29OCT96	8, .	Minimally Improved (3)
	2	05NOV96	15, .	Minimally Worse (5)
	3	14NOV96	24, .	Minimally Improved (3)
	5	26NOV96	36, .	Much Improved (2)
	6	03DEC96	43, .	Much Improved (2)
	7	10DEC96	50, .	Much Improved (2)
	8	17DEC96	57, .	Minimally Improved (3)
	8	23DEC96	63, .	Much Improved (2)
329.003.00317	1	23DEC96	5, .	No Change (4)
	3	07JAN97	20, .	Minimally Improved (3)
	4	14JAN97	27, .	Minimally Improved (3)
	5	21JAN97	34, .	Minimally Improved (3)
	6	28JAN97	41, .	No Change (4)
	7	04FEB97	48, .	No Change (4)
	8	11FEB97	55, .	No Change (4)
329.004.00013	1	26JUL94	8, -52	Minimally Improved (3)
	2	02AUG94	15, -45	Minimally Improved (3)
	3	09AUG94	22, -38	Minimally Improved (3)
	4	15AUG94	28, -32	No Change (4)
	5	23AUG94	36, -24	Much Improved (2)
	6	31AUG94	44, -16	Much Improved (2)
	7	08SEP94	52, -8	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.004.00013	8	16SEP94	60, 1	Very Much Improved (1)
	12	11OCT94	85, 26	Very Much Improved (1)
	16	08NOV94	113, 54	Much Improved (2)
	20	06DEC94	141, 82	Very Much Improved (1)
	24	10JAN95	176, 117	Very Much Improved (1)
	28	07FEB95	204, 145	Very Much Improved (1)
	32	10MAR95	235, 176	Very Much Improved (1)
329.004.00014	1	05DEC94	7, .	No Change (4)
	2	13DEC94	15, .	No Change (4)
329.004.00211	1	08FEB96	7, .	No Change (4)
	2	16FEB96	15, .	Much Improved (2)
	3	23FEB96	22, .	Minimally Improved (3)
	4	29FEB96	28, .	Much Improved (2)
	5	07MAR96	35, .	Very Much Improved (1)
	6	14MAR96	42, .	Very Much Improved (1)
	7	25MAR96	53, .	Very Much Improved (1)
329.004.00215	1	27MAR97	8, .	No Change (4)
	2	03APR97	15, .	Much Improved (2)
	3	10APR97	22, .	Much Improved (2)
	4	15APR97	27, .	Much Improved (2)
	5	24APR97	36, .	Much Improved (2)
	6	29APR97	41, .	Very Much Worse (7)
329.005.00003	1	27SEP94	8, .	Minimally Improved (3)
	2	04OCT94	15, .	Minimally Improved (3)
329.005.00006	1	14NOV94	11, -50	Minimally Worse (5)
	2	21NOV94	18, -43	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00006	3	28NOV94	25, -36	Minimally Improved (3)
	4	05DEC94	32, -29	Much Improved (2)
	5	12DEC94	39, -22	Much Improved (2)
	6	19DEC94	46, -15	Very Much Improved (1)
	8	27DEC94	54, -7	Very Much Improved (1)
	8	03JAN95	61, 1	Very Much Improved (1)
	12	02FEB95	91, 31	Much Improved (2)
	16	27FEB95	116, 56	Minimally Improved (3)
	20	05APR95	153, 93	Very Much Improved (1)
329.005.00007	2	23NOV94	15, -49	Minimally Worse (5)
	3	30NOV94	22, -42	No Change (4)
	4	07DEC94	29, -35	Minimally Worse (5)
	5	14DEC94	36, -28	Minimally Improved (3)
	6	21DEC94	43, -21	Much Improved (2)
	7	28DEC94	50, -14	Much Improved (2)
	8	04JAN95	57, -7	Much Improved (2)
	8	11JAN95	64, 1	Much Improved (2)
	12	15FEB95	99, 36	No Change (4)
	20	22MAR95	134, 71	Very Much Improved (1)
	24	19APR95	162, 99	Much Improved (2)
	28	17MAY95	190, 127	Very Much Improved (1)
	32	09AUG95	274, 211	Very Much Improved (1)
329.005.00009	1	19DEC94	8, .	No Change (4)
	2	27DEC94	16, .	Minimally Improved (3)
	3	03JAN95	23, .	Much Worse (6)
	4	11JAN95	31, .	Minimally Improved (3)
	5	18JAN95	38, .	Minimally Improved (3)
	6	25JAN95	45, .	Minimally Worse (5)
	7	31JAN95	51, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00009	8	07FEB95	58, .	Minimally Improved (3)
329.005.00110	1	18JAN95	8, .	Minimally Improved (3)
	2	25JAN95	15, .	Much Improved (2)
329.005.00113	1	08FEB95	10, .	No Change (4)
	2	16FEB95	18, .	Minimally Improved (3)
	3	23FEB95	25, .	Much Improved (2)
	4	02MAR95	32, .	Much Worse (6)
329.005.00117	1	27MAR95	10, .	Minimally Improved (3)
	2	03APR95	17, .	Much Improved (2)
	3	10APR95	24, .	Much Improved (2)
	4	17APR95	31, .	Minimally Improved (3)
	5	24APR95	38, .	Minimally Improved (3)
	6	01MAY95	45, .	Minimally Improved (3)
	7	08MAY95	52, .	Minimally Improved (3)
	8	15MAY95	59, .	Minimally Improved (3)
329.005.00118	1	24MAY95	8, .	No Change (4)
	2	30MAY95	14, .	Minimally Improved (3)
	3	06JUN95	21, .	Minimally Improved (3)
	4	14JUN95	29, .	Minimally Improved (3)
	5	20JUN95	35, .	Much Improved (2)
	6	27JUN95	42, .	Much Improved (2)
329.005.00153	1	01FEB96	8, -49	No Change (4)
	2	08FEB96	15, -42	No Change (4)
	3	15FEB96	22, -35	Minimally Improved (3)
	4	22FEB96	29, -28	Minimally Improved (3)
	5	29FEB96	36, -21	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00153	6	06MAR96	42, -15	Much Improved (2)
	7	14MAR96	50, -7	Very Much Improved (1)
	8	21MAR96	57, 1	Very Much Improved (1)
	12	17APR96	84, 28	Much Improved (2)
	16	15MAY96	112, 56	Very Much Improved (1)
	20	12JUN96	140, 84	Very Much Improved (1)
	24	10JUL96	168, 112	Very Much Improved (1)
	28	05AUG96	194, 138	Very Much Improved (1)
	32	04SEP96	224, 168	Very Much Improved (1)
329.005.00255	1	11MAR96	8, .	Minimally Improved (3)
	2	18MAR96	15, .	Minimally Worse (5)
	3	25MAR96	22, .	No Change (4)
	4	01APR96	29, .	Minimally Improved (3)
	5	08APR96	36, .	Minimally Improved (3)
	6	15APR96	43, .	Minimally Improved (3)
	7	23APR96	51, .	Minimally Improved (3)
	8	29APR96	57, .	Minimally Improved (3)
329.005.00256	1	12MAR96	8, -49	Minimally Improved (3)
	2	21MAR96	17, -40	Minimally Improved (3)
	3	26MAR96	22, -35	Minimally Improved (3)
	4	02APR96	29, -28	Minimally Improved (3)
	5	11APR96	38, -19	Very Much Improved (1)
	6	16APR96	43, -14	Much Improved (2)
	7	23APR96	50, -7	Minimally Improved (3)
	8	30APR96	57, 1	Minimally Improved (3)
	12	28MAY96	85, 29	Much Improved (2)
	16	02JUL96	120, 64	Much Improved (2)
329.005.00295	1	04APR96	8, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00295	2	11APR96	15, .	Much Improved (2)
	3	18APR96	22, .	Much Improved (2)
	4	24APR96	28, .	Much Improved (2)
	6	06MAY96	40, .	Minimally Improved (3)
	6	09MAY96	43, .	Much Improved (2)
	7	16MAY96	50, .	Very Much Improved (1)
	8	22MAY96	56, .	Much Improved (2)
329.005.00297	1	26APR96	8, .	Minimally Improved (3)
	2	02MAY96	14, .	Much Improved (2)
	4	14MAY96	26, .	Minimally Improved (3)
329.005.00332	1	19DEC96	8, .	Minimally Improved (3)
	2	26DEC96	15, .	Minimally Improved (3)
	3	02JAN97	22, .	No Change (4)
	4	09JAN97	29, .	No Change (4)
	5	16JAN97	36, .	No Change (4)
	6	23JAN97	43, .	Much Improved (2)
	7	30JAN97	50, .	Minimally Worse (5)
	8	06FEB97	57, .	No Change (4)
329.005.00335	1	07MAR97	8, .	Minimally Worse (5)
	2	14MAR97	15, .	Minimally Improved (3)
	3	21MAR97	22, .	Minimally Improved (3)
	4	27MAR97	28, .	No Change (4)
	5	03APR97	35, .	Minimally Improved (3)
	6	10APR97	42, .	Minimally Improved (3)
	7	17APR97	49, .	No Change (4)
	8	24APR97	56, .	No Change (4)
329.006.00040	1	22FEB95	7, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.006.00040	2	01MAR95	14, .	Minimally Worse (5)
329.006.00041	1	10APR95	6, -59	Minimally Improved (3)
	2	19APR95	15, -50	No Change (4)
	3	24APR95	20, -45	Minimally Improved (3)
	4	01MAY95	27, -38	Minimally Improved (3)
	5	08MAY95	34, -31	Much Improved (2)
	6	15MAY95	41, -24	Minimally Worse (5)
	7	24MAY95	50, -15	Minimally Improved (3)
	8	31MAY95	57, -8	Minimally Improved (3)
	12	05JUL95	92, 28	Much Improved (2)
	16	31JUL95	118, 54	Very Much Improved (1)
	20	24AUG95	142, 78	Very Much Improved (1)
	24	21SEP95	170, 106	Very Much Improved (1)
	28	24OCT95	203, 139	Much Improved (2)
	32	21NOV95	231, 167	Very Much Improved (1)
329.007.00139	1	18MAY95	11, .	Minimally Improved (3)
	2	25MAY95	18, .	Minimally Improved (3)
	6	19JUN95	43, .	Much Improved (2)
329.007.00143	1	16NOV95	8, .	No Change (4)
	2	22NOV95	14, .	No Change (4)
329.007.00146	1	01FEB96	8, -46	No Change (4)
	2	05FEB96	12, -42	No Change (4)
	3	12FEB96	19, -35	Minimally Improved (3)
	4	19FEB96	26, -28	Minimally Improved (3)
	5	26FEB96	33, -21	Much Improved (2)
	6	04MAR96	40, -14	Much Improved (2)
	7	11MAR96	47, -7	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.007.00146	8	18MAR96	54, 1	Very Much Improved (1)
	12	15APR96	82, 29	Minimally Improved (3)
	16	13MAY96	110, 57	Much Improved (2)
	20	06JUN96	134, 81	Much Improved (2)
	24	08JUL96	166, 113	Very Much Improved (1)
	28	05AUG96	194, 141	Much Improved (2)
	32	09SEP96	229, 176	Much Improved (2)
329.007.00269	1	18APR96	8, .	No Change (4)
	2	25APR96	15, .	Minimally Improved (3)
329.007.00270	1	16MAY96	8, .	Minimally Improved (3)
	2	23MAY96	15, .	Minimally Improved (3)
	3	30MAY96	22, .	Minimally Worse (5)
	4	06JUN96	29, .	Much Improved (2)
	5	13JUN96	36, .	Much Improved (2)
	6	20JUN96	43, .	Much Improved (2)
329.007.00307	1	23MAY96	8, .	Minimally Improved (3)
	2	30MAY96	15, .	Minimally Improved (3)
	3	06JUN96	22, .	Minimally Improved (3)
	4	13JUN96	29, .	Much Improved (2)
	5	20JUN96	36, .	Much Improved (2)
329.008.00159	1	19SEP95	7, -56	No Change (4)
	2	27SEP95	15, -48	No Change (4)
	3	03OCT95	21, -42	No Change (4)
	4	10OCT95	28, -35	No Change (4)
	5	16OCT95	34, -29	Minimally Improved (3)
	6	24OCT95	42, -21	No Change (4)
	7	31OCT95	49, -14	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.008.00159	8	14NOV95	63, 1	Much Improved (2)
	16	26DEC95	105, 43	Minimally Improved (3)
	20	23JAN96	133, 71	No Change (4)
329.008.00161	2	29NOV95	14, -42	Minimally Improved (3)
	3	07DEC95	22, -34	Much Improved (2)
	4	15DEC95	30, -26	Much Improved (2)
	6	27DEC95	42, -14	Much Improved (2)
	7	03JAN96	49, -7	Much Improved (2)
	8	10JAN96	56, 1	No Change (4)
329.008.00187	1	07DEC95	9, .	No Change (4)
	2	14DEC95	16, .	Much Improved (2)
	3	21DEC95	23, .	No Change (4)
	4	28DEC95	30, .	No Change (4)
	5	04JAN96	37, .	Much Worse (6)
	6	11JAN96	44, .	Minimally Worse (5)
	7	18JAN96	51, .	Minimally Improved (3)
	8	26JAN96	59, .	Minimally Improved (3)
329.008.00192	1	11MAR96	7, .	Minimally Improved (3)
	2	18MAR96	14, .	Minimally Improved (3)
	3	25MAR96	21, .	Minimally Improved (3)
	4	03APR96	30, .	No Change (4)
	5	12APR96	39, .	No Change (4)
329.008.00272	1	10APR96	8, -49	Minimally Improved (3)
	2	17APR96	15, -42	Minimally Improved (3)
	3	26APR96	24, -33	Minimally Improved (3)
	4	01MAY96	29, -28	Much Improved (2)
	5	07MAY96	35, -22	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.008.00272	7	22MAY96	50, -7	Very Much Improved (1)
	8	29MAY96	57, 1	Very Much Improved (1)
	12	26JUN96	85, 29	Very Much Improved (1)
	16	24JUL96	113, 57	Very Much Improved (1)
	20	21AUG96	141, 85	Much Improved (2)
	24	18SEP96	169, 113	Minimally Worse (5)
329.008.00273	1	24MAY96	8, -56	Much Improved (2)
	2	31MAY96	15, -49	Very Much Improved (1)
	3	10JUN96	25, -39	Very Much Improved (1)
	4	17JUN96	32, -32	Very Much Improved (1)
	5	24JUN96	39, -25	Very Much Improved (1)
	6	01JUL96	46, -18	Very Much Improved (1)
	8	11JUL96	56, -8	Very Much Improved (1)
	8	19JUL96	64, 1	Very Much Improved (1)
	16	04SEP96	111, 48	Very Much Improved (1)
329.009.00127	1	17APR95	8, .	No Change (4)
	2	24APR95	15, .	Minimally Improved (3)
	3	01MAY95	22, .	Minimally Improved (3)
	4	08MAY95	29, .	Minimally Improved (3)
	5	15MAY95	36, .	Minimally Improved (3)
329.009.00132	1	30MAY95	8, -50	Minimally Improved (3)
	2	06JUN95	15, -43	Much Improved (2)
	3	13JUN95	22, -36	Very Much Improved (1)
	4	20JUN95	29, -29	Very Much Improved (1)
	5	27JUN95	36, -22	Very Much Improved (1)
	6	05JUL95	44, -14	Very Much Improved (1)
	7	11JUL95	50, -8	Very Much Improved (1)
	8	19JUL95	58, 1	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00132	12	24AUG95	94, 37	Very Much Improved (1)
	16	15SEP95	116, 59	Much Improved (2)
	20	24OCT95	155, 98	No Change (4)
329.009.00134	1	14JUL95	9, .	No Change (4)
	2	19JUL95	14, .	No Change (4)
	3	26JUL95	21, .	Minimally Improved (3)
	4	03AUG95	29, .	Minimally Improved (3)
	5	08AUG95	34, .	Much Improved (2)
	6	15AUG95	41, .	Much Improved (2)
	7	24AUG95	50, .	Much Improved (2)
	8	29AUG95	55, .	Minimally Improved (3)
329.009.00137	1	17OCT95	8, .	No Change (4)
	2	24OCT95	15, .	Minimally Improved (3)
	3	31OCT95	22, .	Minimally Improved (3)
	4	07NOV95	29, .	Minimally Improved (3)
	5	14NOV95	36, .	Minimally Improved (3)
	6	21NOV95	43, .	Much Improved (2)
	7	28NOV95	50, .	Much Improved (2)
	8	05DEC95	57, .	Much Improved (2)
329.009.00171	1	14NOV95	8, .	No Change (4)
329.009.00172	1	20NOV95	8, -50	Minimally Improved (3)
	2	27NOV95	15, -43	Minimally Improved (3)
	3	04DEC95	22, -36	Minimally Improved (3)
	4	11DEC95	29, -29	Minimally Improved (3)
	5	21DEC95	39, -19	Much Improved (2)
	6	27DEC95	45, -13	Much Improved (2)
	7	03JAN96	52, -6	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00172	8	09JAN96	58, 1	Much Improved (2)
	12	07FEB96	87, 30	Very Much Improved (1)
	16	04MAR96	113, 56	Much Improved (2)
	20	01APR96	141, 84	Much Improved (2)
	24	29APR96	169, 112	Very Much Improved (1)
	28	10JUN96	211, 154	Very Much Improved (1)
	32	08JUL96	239, 182	Very Much Improved (1)
329.009.00194	1	12DEC95	8, -49	No Change (4)
	2	19DEC95	15, -42	No Change (4)
	3	27DEC95	23, -34	Minimally Improved (3)
	4	02JAN96	29, -28	Minimally Improved (3)
	5	09JAN96	36, -21	Minimally Improved (3)
	6	16JAN96	43, -14	Minimally Improved (3)
	7	23JAN96	50, -7	Much Improved (2)
	8	30JAN96	57, 1	Very Much Improved (1)
	12	27FEB96	85, 29	Very Much Improved (1)
	16	02APR96	120, 64	Very Much Improved (1)
	20	30APR96	148, 92	Very Much Improved (1)
	24	04JUN96	183, 127	Very Much Improved (1)
329.009.00195	1	19DEC95	5, .	Minimally Improved (3)
	2	27DEC95	13, .	Much Improved (2)
	3	02JAN96	19, .	Much Improved (2)
	3	08JAN96	25, .	Much Improved (2)
329.009.00199	1	23JAN96	8, .	No Change (4)
	2	29JAN96	14, .	Minimally Improved (3)
	3	07FEB96	23, .	Minimally Improved (3)
	4	14FEB96	30, .	Minimally Worse (5)
	5	21FEB96	37, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00199	6	28FEB96	44, .	No Change (4)
	7	06MAR96	51, .	Minimally Improved (3)
	8	13MAR96	58, .	No Change (4)
329.009.00203	1	11MAR96	8, .	No Change (4)
	2	19MAR96	16, .	Minimally Improved (3)
	3	26MAR96	23, .	Much Improved (2)
329.009.00236	1	06JAN97	8, .	No Change (4)
	2	15JAN97	17, .	No Change (4)
	3	20JAN97	22, .	No Change (4)
	4	27JAN97	29, .	No Change (4)
329.009.00239	1	25NOV96	7, -51	No Change (4)
	2	02DEC96	14, -44	Minimally Improved (3)
	3	09DEC96	21, -37	Very Much Improved (1)
	4	16DEC96	28, -30	Very Much Improved (1)
	5	23DEC96	35, -23	Very Much Improved (1)
	6	30DEC96	42, -16	Very Much Improved (1)
	7	06JAN97	49, -9	Much Improved (2)
	8	15JAN97	58, 1	Very Much Improved (1)
	12	18FEB97	92, 35	Very Much Improved (1)
	16	17MAR97	119, 62	Very Much Improved (1)
	20	14APR97	147, 90	Very Much Improved (1)
	24	12MAY97	175, 118	No Change (4)
329.009.00262	1	24FEB97	8, .	Minimally Worse (5)
	2	03MAR97	15, .	Much Improved (2)
	3	07MAR97	19, .	Much Improved (2)
	4	17MAR97	29, .	Much Improved (2)
	5	24MAR97	36, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00262	6	31MAR97	43, .	Minimally Improved (3)
	7	07APR97	50, .	Minimally Improved (3)
	8	14APR97	57, .	No Change (4)
329.009.00264	1	08NOV96	8, .	No Change (4)
	1	11NOV96	11, .	Minimally Worse (5)
	2	18NOV96	18, .	Minimally Improved (3)
	3	25NOV96	25, .	Minimally Improved (3)
	4	02DEC96	32, .	Minimally Improved (3)
	6	11DEC96	41, .	No Change (4)
	6	16DEC96	46, .	Minimally Improved (3)
	7	23DEC96	53, .	No Change (4)
329.009.00301	1	26MAR96	8, -49	No Change (4)
	2	05APR96	18, -39	No Change (4)
	3	12APR96	25, -32	No Change (4)
	4	16APR96	29, -28	Minimally Improved (3)
	5	23APR96	36, -21	Much Improved (2)
	6	30APR96	43, -14	Much Improved (2)
	7	07MAY96	50, -7	Very Much Improved (1)
	8	14MAY96	57, 1	Very Much Improved (1)
	12	11JUN96	85, 29	Very Much Improved (1)
329.009.00305	1	14MAY96	8, -50	No Change (4)
	2	21MAY96	15, -43	No Change (4)
	3	28MAY96	22, -36	No Change (4)
	4	04JUN96	29, -29	Minimally Improved (3)
	5	11JUN96	36, -22	Minimally Improved (3)
	6	19JUN96	44, -14	Minimally Improved (3)
	7	25JUN96	50, -8	Much Improved (2)
	8	03JUL96	58, 1	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00305	12	06AUG96	92, 35	Very Much Improved (1)
	16	27AUG96	113, 56	Very Much Improved (1)
	20	24SEP96	141, 84	Very Much Improved (1)
	24	29OCT96	176, 119	Much Improved (2)
	28	03DEC96	211, 154	Very Much Improved (1)
	32	10JAN97	249, 192	Very Much Improved (1)
329.009.00325	1	03SEP96	8, -48	No Change (4)
	2	09SEP96	14, -42	No Change (4)
	3	16SEP96	21, -35	Minimally Improved (3)
	4	23SEP96	28, -28	Much Improved (2)
	5	30SEP96	35, -21	Much Improved (2)
	6	10OCT96	45, -11	Much Improved (2)
	7	14OCT96	49, -7	Much Improved (2)
	8	21OCT96	56, 1	Much Improved (2)
	12	18NOV96	84, 29	Much Improved (2)
	16	16DEC96	112, 57	No Change (4)
329.009.00326	1	09SEP96	5, -49	No Change (4)
	2	16SEP96	12, -42	Much Improved (2)
	3	23SEP96	19, -35	Much Improved (2)
	4	30SEP96	26, -28	Much Improved (2)
	5	07OCT96	33, -21	Very Much Improved (1)
	6	17OCT96	43, -11	Much Improved (2)
	7	24OCT96	50, -4	Very Much Improved (1)
	8	28OCT96	54, 1	Very Much Improved (1)
	12	25NOV96	82, 29	Minimally Improved (3)
	16	16DEC96	103, 50	No Change (4)
329.010.00279	1	29MAR96	8, -49	No Change (4)
	2	05APR96	15, -42	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.010.00279	3	12APR96	22, -35	Minimally Improved (3)
	4	19APR96	29, -28	Minimally Improved (3)
	5	25APR96	35, -22	Much Improved (2)
	6	03MAY96	43, -14	Minimally Improved (3)
	7	10MAY96	50, -7	Much Improved (2)
	8	17MAY96	57, 1	Much Improved (2)
	12	14JUN96	85, 29	Minimally Improved (3)
	16	11JUL96	112, 56	Much Improved (2)
	20	08AUG96	140, 84	Much Improved (2)
	24	05SEP96	168, 112	Much Improved (2)
	28	02OCT96	195, 139	Much Improved (2)
	32	06NOV96	230, 174	Minimally Improved (3)
329.010.00281	1	02AUG96	8, -54	Minimally Improved (3)
	2	09AUG96	15, -47	Much Improved (2)
	3	19AUG96	25, -37	Much Improved (2)
	4	26AUG96	32, -30	Much Improved (2)
	6	04SEP96	41, -21	Minimally Improved (3)
	6	09SEP96	46, -16	Minimally Improved (3)
	8	18SEP96	55, -7	Much Improved (2)
	8	25SEP96	62, 1	Minimally Improved (3)
	12	25OCT96	92, 31	Much Improved (2)
	16	20NOV96	118, 57	Much Improved (2)
	20	20DEC96	148, 87	Minimally Worse (5)
	24	03JAN97	162, 101	Much Worse (6)
329.011.00163	1	01DEC95	7, .	No Change (4)
	2	11DEC95	17, .	No Change (4)
	3	18DEC95	24, .	Minimally Improved (3)
	5	27DEC95	33, .	Minimally Worse (5)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.011.00208	1	11SEP96	6, -54	No Change (4)
	2	17SEP96	12, -48	Minimally Improved (3)
	3	26SEP96	21, -39	Minimally Improved (3)
	4	03OCT96	28, -32	Minimally Improved (3)
	5	10OCT96	35, -25	Much Improved (2)
	6	17OCT96	42, -18	Much Improved (2)
	7	24OCT96	49, -11	Much Improved (2)
	8	03NOV96	59, -1	Very Much Improved (1)
329.011.00209	1	19SEP96	9, -54	No Change (4)
	2	26SEP96	16, -47	Minimally Improved (3)
	3	03OCT96	23, -40	Minimally Improved (3)
	4	11OCT96	31, -32	Much Improved (2)
	5	17OCT96	37, -26	Much Improved (2)
	6	24OCT96	44, -19	Very Much Improved (1)
	7	01NOV96	52, -11	Very Much Improved (1)
	8	11NOV96	62, -1	Very Much Improved (1)
	12	18DEC96	99, 37	Much Improved (2)
329.011.00284	1	28MAR96	7, -50	Minimally Improved (3)
	2	05APR96	15, -42	Minimally Improved (3)
	3	11APR96	21, -36	Minimally Improved (3)
	4	19APR96	29, -28	Much Improved (2)
	5	25APR96	35, -22	Minimally Improved (3)
	6	02MAY96	42, -15	Much Improved (2)
	7	09MAY96	49, -8	Much Improved (2)
	8	16MAY96	56, -1	Very Much Improved (1)
	12	10JUN96	81, 25	Very Much Improved (1)
	16	08JUL96	109, 53	Very Much Improved (1)
	20	05AUG96	137, 81	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.011.00286	1	14JUN96	9, -60	No Change (4)
	2	21JUN96	16, -53	Minimally Improved (3)
	3	28JUN96	23, -46	Minimally Improved (3)
	5	08JUL96	33, -36	Minimally Improved (3)
	6	17JUL96	42, -27	Minimally Improved (3)
	7	24JUL96	49, -20	Minimally Improved (3)
	8	02AUG96	58, -11	Much Improved (2)
	8	09AUG96	65, -4	Much Improved (2)
	16	17SEP96	104, 36	Much Improved (2)
	20	24OCT96	141, 73	Much Improved (2)
	24	25NOV96	173, 105	Much Improved (2)
	28	30DEC96	208, 140	Much Improved (2)
329.012.00026	1	05DEC95	8, .	Minimally Improved (3)
329.012.00219	1	07JUN96	8, -53	Much Improved (2)
	2	14JUN96	15, -46	Minimally Improved (3)
	3	24JUN96	25, -36	Much Improved (2)
	5	02JUL96	33, -28	Much Improved (2)
	6	09JUL96	40, -21	Much Improved (2)
	7	16JUL96	47, -14	Very Much Improved (1)
	8	23JUL96	54, -7	Very Much Improved (1)
	8	30JUL96	61, 1	Very Much Improved (1)
	12	30AUG96	92, 32	Very Much Improved (1)
	16	26SEP96	119, 59	Very Much Improved (1)
	20	25OCT96	148, 88	Very Much Improved (1)
	24	22NOV96	176, 116	Very Much Improved (1)
	28	20DEC96	204, 144	Much Improved (2)
	32	24JAN97	239, 179	Very Much Improved (1)
329.012.00221	1	02JUL96	8, -56	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.012.00221	2	09JUL96	15, -49	Minimally Improved (3)
	3	16JUL96	22, -42	Minimally Improved (3)
	4	23JUL96	29, -35	Minimally Improved (3)
	5	30JUL96	36, -28	Very Much Improved (1)
	6	09AUG96	46, -18	Very Much Improved (1)
	8	19AUG96	56, -8	Much Improved (2)
	8	27AUG96	64, 1	Much Improved (2)
	12	23SEP96	91, 28	Very Much Improved (1)
	16	21OCT96	119, 56	Very Much Improved (1)
	20	04NOV96	133, 70	Much Worse (6)
329.012.00223	1	06SEP96	8, .	No Change (4)
	2	16SEP96	18, .	No Change (4)
	3	23SEP96	25, .	No Change (4)
	5	01OCT96	33, .	Minimally Worse (5)
329.012.00227	1	27DEC96	10, -60	Much Improved (2)
	3	06JAN97	20, -50	Minimally Improved (3)
	4	15JAN97	29, -41	Minimally Improved (3)
	5	24JAN97	38, -32	Minimally Improved (3)
	7	04FEB97	49, -21	Much Improved (2)
	8	14FEB97	59, -11	Minimally Improved (3)
	8	20FEB97	65, -5	Much Improved (2)
	8	25FEB97	70, 1	Much Improved (2)
	16	27MAR97	100, 31	Minimally Improved (3)
	20	25APR97	129, 60	Minimally Improved (3)
	24	26MAY97	160, 91	Much Improved (2)
	28	25JUN97	190, 121	Much Improved (2)
	32	21JUL97	216, 147	Very Much Improved (1)
	32	19AUG97	245, 176	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.012.00230	1	07MAR97	8, -62	No Change (4)
	2	14MAR97	15, -55	No Change (4)
	3	24MAR97	25, -45	No Change (4)
	5	03APR97	35, -35	No Change (4)
	6	11APR97	43, -27	Minimally Improved (3)
	8	23APR97	55, -15	Much Improved (2)
	8	02MAY97	64, -6	Much Improved (2)
	8	08MAY97	70, 1	Much Improved (2)
	12	16MAY97	78, 9	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.001.00062	1	27OCT94	8, .	Minimally Improved (3)
	2	03NOV94	15, .	Minimally Improved (3)
	3	10NOV94	22, .	Much Improved (2)
329.001.00064	1	16NOV94	7, -48	Minimally Improved (3)
	2	22NOV94	13, -42	Much Improved (2)
	3	29NOV94	20, -35	Much Improved (2)
	4	06DEC94	27, -28	Much Improved (2)
	5	13DEC94	34, -21	Very Much Improved (1)
	6	20DEC94	41, -14	Much Improved (2)
	7	27DEC94	48, -7	Much Improved (2)
	8	03JAN95	55, 1	Much Improved (2)
	12	31JAN95	83, 29	Very Much Improved (1)
	16	28FEB95	111, 57	Much Improved (2)
	20	28MAR95	139, 85	Minimally Improved (3)
329.001.00069	1	23FEB95	8, .	Minimally Improved (3)
	2	02MAR95	15, .	Minimally Improved (3)
	3	09MAR95	22, .	Minimally Improved (3)
	4	16MAR95	29, .	Much Improved (2)
	5	23MAR95	36, .	Much Improved (2)
	6	30MAR95	43, .	Minimally Improved (3)
	7	06APR95	50, .	Minimally Improved (3)
	8	13APR95	57, .	Much Improved (2)
329.001.00071	1	02MAR95	8, .	Minimally Improved (3)
	2	09MAR95	15, .	No Change (4)
	3	16MAR95	22, .	Minimally Improved (3)
	4	23MAR95	29, .	Much Improved (2)
	5	30MAR95	36, .	Much Improved (2)
	6	06APR95	43, .	Minimally Worse (5)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.001.00071	7	13APR95	50, .	No Change (4)
	8	20APR95	57, .	No Change (4)
329.001.00123	1	12JAN96	9, .	Minimally Improved (3)
	2	18JAN96	15, .	Much Improved (2)
	3	25JAN96	22, .	Minimally Improved (3)
	4	01FEB96	29, .	Minimally Improved (3)
	5	08FEB96	36, .	Much Improved (2)
	6	15FEB96	43, .	Very Much Improved (1)
	7	22FEB96	50, .	Much Worse (6)
329.001.00207	1	06MAR96	8, .	Much Improved (2)
	2	13MAR96	15, .	Very Much Improved (1)
	3	20MAR96	22, .	Very Much Improved (1)
	4	26MAR96	28, .	Very Much Improved (1)
	5	03APR96	36, .	Much Improved (2)
	6	10APR96	43, .	Minimally Improved (3)
	7	17APR96	50, .	Minimally Improved (3)
	8	24APR96	57, .	Minimally Improved (3)
329.002.00049	1	15MAR95	7, .	No Change (4)
	2	22MAR95	14, .	No Change (4)
	3	29MAR95	21, .	No Change (4)
	4	05APR95	28, .	No Change (4)
	5	12APR95	35, .	No Change (4)
	6	19APR95	42, .	No Change (4)
	7	27APR95	50, .	No Change (4)
	8	05MAY95	58, .	No Change (4)
329.002.00059	1	17NOV94	8, .	No Change (4)
	2	23NOV94	14, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00059	3	01DEC94	22, .	Minimally Improved (3)
	4	08DEC94	29, .	Minimally Improved (3)
	5	15DEC94	36, .	Minimally Improved (3)
	6	22DEC94	43, .	Much Improved (2)
	7	29DEC94	50, .	Minimally Improved (3)
	8	05JAN95	57, .	Much Worse (6)
329.002.00060	1	07FEB95	8, -49	Minimally Improved (3)
	2	14FEB95	15, -42	Minimally Improved (3)
	3	21FEB95	22, -35	Minimally Improved (3)
	4	28FEB95	29, -28	Minimally Worse (5)
	5	07MAR95	36, -21	Much Improved (2)
	6	14MAR95	43, -14	Very Much Improved (1)
	7	21MAR95	50, -7	Very Much Improved (1)
	8	28MAR95	57, 1	Much Improved (2)
	12	25APR95	85, 29	No Change (4)
329.002.00097	1	10JAN95	8, -51	Minimally Improved (3)
	2	18JAN95	16, -43	Minimally Improved (3)
	3	24JAN95	22, -37	Minimally Improved (3)
	4	31JAN95	29, -30	Minimally Worse (5)
	5	07FEB95	36, -23	No Change (4)
	6	14FEB95	43, -16	Minimally Improved (3)
	7	21FEB95	50, -9	Much Improved (2)
	8	02MAR95	59, 1	Minimally Improved (3)
	12	30MAR95	87, 29	Minimally Improved (3)
	16	27APR95	115, 57	Much Improved (2)
	20	23MAY95	141, 83	Minimally Improved (3)
	24	29JUN95	178, 120	Minimally Improved (3)
	28	01AUG95	211, 153	Minimally Improved (3)
	32	05SEP95	246, 188	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00101	1	04APR95	8, -51	Minimally Improved (3)
	2	13APR95	17, -42	Much Improved (2)
	3	20APR95	24, -35	Minimally Improved (3)
	4	27APR95	31, -28	Very Much Improved (1)
	5	04MAY95	38, -21	Very Much Improved (1)
	6	11MAY95	45, -14	Much Improved (2)
	7	18MAY95	52, -7	Very Much Improved (1)
	8	25MAY95	59, 1	Very Much Improved (1)
	12	22JUN95	87, 29	Much Improved (2)
	12	27JUN95	92, 34	Very Much Improved (1)
329.002.00107	1	01FEB96	8, -49	Minimally Improved (3)
	2	08FEB96	15, -42	Minimally Improved (3)
	3	13FEB96	20, -37	Much Improved (2)
	4	20FEB96	27, -30	Much Improved (2)
	5	27FEB96	34, -23	Very Much Improved (1)
	6	05MAR96	41, -16	Very Much Improved (1)
	7	15MAR96	51, -6	Very Much Improved (1)
	8	21MAR96	57, 1	Very Much Improved (1)
	12	23APR96	90, 34	Very Much Improved (1)
	16	21MAY96	118, 62	Minimally Worse (5)
	20	20JUN96	148, 92	Much Improved (2)
	24	18JUL96	176, 120	Very Much Improved (1)
	32	29AUG96	218, 162	Very Much Improved (1)
	32	26SEP96	246, 190	Very Much Improved (1)
329.002.00241	1	13FEB96	8, -49	Very Much Improved (1)
	2	22FEB96	17, -40	Very Much Improved (1)
	3	27FEB96	22, -35	Very Much Improved (1)
	4	05MAR96	29, -28	Very Much Improved (1)
	5	12MAR96	36, -21	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00241	6	19MAR96	43, -14	Very Much Improved (1)
	7	26MAR96	50, -7	Very Much Improved (1)
	8	02APR96	57, 1	Very Much Improved (1)
	12	30APR96	85, 29	Much Improved (2)
329.002.00246	1	25APR96	8, .	No Change (4)
	2	02MAY96	15, .	Much Improved (2)
	3	09MAY96	22, .	Minimally Worse (5)
	4	16MAY96	29, .	Minimally Improved (3)
	5	23MAY96	36, .	Minimally Improved (3)
	6	30MAY96	43, .	No Change (4)
	7	04JUN96	48, .	No Change (4)
	8	18JUN96	62, .	No Change (4)
329.002.00320	1	23MAY96	8, -54	No Change (4)
	2	30MAY96	15, -47	No Change (4)
	3	04JUN96	20, -42	Minimally Improved (3)
	5	18JUN96	34, -28	Minimally Worse (5)
	6	25JUN96	41, -21	Much Improved (2)
	7	02JUL96	48, -14	No Change (4)
	8	09JUL96	55, -7	Minimally Improved (3)
	8	16JUL96	62, 1	Minimally Improved (3)
	12	13AUG96	90, 29	Much Improved (2)
	16	17SEP96	125, 64	Much Improved (2)
329.002.00323	1	19NOV96	8, -51	Minimally Improved (3)
	2	26NOV96	15, -44	No Change (4)
	3	05DEC96	24, -35	Minimally Improved (3)
	4	10DEC96	29, -30	Minimally Improved (3)
	5	17DEC96	36, -23	Minimally Improved (3)
	6	26DEC96	45, -14	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.002.00323	7	02JAN97	52, -7	Very Much Improved (1)
	8	09JAN97	59, 1	Very Much Improved (1)
	12	04FEB97	85, 27	Very Much Improved (1)
	16	04MAR97	113, 55	Very Much Improved (1)
	20	03APR97	143, 85	Very Much Improved (1)
	24	30APR97	170, 112	Very Much Improved (1)
	28	27MAY97	197, 139	Very Much Improved (1)
	32	12JUN97	213, 155	Very Much Improved (1)
329.003.00074	1	01FEB95	8, -49	Minimally Improved (3)
	2	08FEB95	15, -42	Minimally Improved (3)
	3	15FEB95	22, -35	Minimally Improved (3)
	4	21FEB95	28, -29	Minimally Improved (3)
	5	01MAR95	36, -21	Minimally Improved (3)
	7	15MAR95	50, -7	Much Improved (2)
	8	22MAR95	57, 1	Much Improved (2)
	12	19APR95	85, 29	Much Improved (2)
	16	17MAY95	113, 57	Much Improved (2)
	20	19JUN95	146, 90	Much Improved (2)
	24	24JUL95	181, 125	Much Improved (2)
	32	11OCT95	260, 204	Much Improved (2)
329.003.00078	1	02MAY95	7, .	Minimally Improved (3)
	2	10MAY95	15, .	No Change (4)
	3	17MAY95	22, .	No Change (4)
	4	24MAY95	29, .	No Change (4)
	5	30MAY95	35, .	No Change (4)
	6	07JUN95	43, .	No Change (4)
	7	15JUN95	51, .	No Change (4)
	8	21JUN95	57, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00080	1	04DEC95	8, .	No Change (4)
	1	07DEC95	11, .	No Change (4)
	3	18DEC95	22, .	Minimally Improved (3)
	5	04JAN96	39, .	Minimally Improved (3)
	6	10JAN96	45, .	Minimally Improved (3)
	7	17JAN96	52, .	Minimally Improved (3)
	8	24JAN96	59, .	Minimally Improved (3)
329.003.00085	1	14NOV94	7, .	No Change (4)
	2	21NOV94	14, .	Minimally Improved (3)
	3	28NOV94	21, .	Minimally Improved (3)
	4	05DEC94	28, .	No Change (4)
	5	12DEC94	35, .	Minimally Improved (3)
	6	19DEC94	42, .	No Change (4)
	7	27DEC94	50, .	Minimally Improved (3)
	8	03JAN95	57, .	Minimally Improved (3)
329.003.00086	1	05DEC94	8, -50	No Change (4)
	2	12DEC94	15, -43	Minimally Improved (3)
	3	19DEC94	22, -36	Minimally Improved (3)
	4	27DEC94	30, -28	Minimally Improved (3)
	5	03JAN95	37, -21	Minimally Improved (3)
	6	09JAN95	43, -15	Much Improved (2)
	7	17JAN95	51, -7	Much Improved (2)
	8	23JAN95	57, -1	Much Improved (2)
	12	13FEB95	78, 21	Much Improved (2)
	16	28MAR95	121, 64	Much Improved (2)
	20	25APR95	149, 92	Much Improved (2)
	28	30MAY95	184, 127	Much Improved (2)
	32	11JUL95	226, 169	Much Improved (2)
	32	17AUG95	263, 206	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00094	1	31OCT95	8, .	No Change (4)
	2	07NOV95	15, .	No Change (4)
	3	14NOV95	22, .	Minimally Improved (3)
	4	21NOV95	29, .	Minimally Improved (3)
	5	28NOV95	36, .	Minimally Worse (5)
	6	05DEC95	43, .	Minimally Worse (5)
	7	12DEC95	50, .	Much Worse (6)
	8	19DEC95	57, .	No Change (4)
329.003.00251	1	04APR96	8, .	No Change (4)
	2	09APR96	13, .	Minimally Improved (3)
329.003.00252	1	16APR96	7, .	No Change (4)
	2	23APR96	14, .	Minimally Improved (3)
	3	30APR96	21, .	Minimally Improved (3)
	4	09MAY96	30, .	Much Improved (2)
	5	14MAY96	35, .	Minimally Improved (3)
	6	21MAY96	42, .	Minimally Worse (5)
	7	28MAY96	49, .	Much Improved (2)
	8	04JUN96	56, .	Minimally Improved (3)
329.003.00291	2	15JUL96	13, -53	Minimally Improved (3)
	3	24JUL96	22, -44	Much Improved (2)
	4	31JUL96	29, -37	Much Improved (2)
	5	07AUG96	36, -30	Much Improved (2)
	6	14AUG96	43, -23	Much Improved (2)
	7	21AUG96	50, -16	Very Much Improved (1)
	8	28AUG96	57, -9	Very Much Improved (1)
	8	04SEP96	64, -2	Very Much Improved (1)
329.003.00315	1	21NOV96	10, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.003.00315	2	26NOV96	15, .	Minimally Improved (3)
	3	03DEC96	22, .	Minimally Improved (3)
	4	12DEC96	31, .	Much Improved (2)
	5	17DEC96	36, .	Much Improved (2)
	6	23DEC96	42, .	Much Improved (2)
	8	07JAN97	57, .	Much Improved (2)
329.003.00316	1	23DEC96	7, .	No Change (4)
	3	07JAN97	22, .	Minimally Improved (3)
	4	14JAN97	29, .	No Change (4)
	5	21JAN97	36, .	No Change (4)
	6	28JAN97	43, .	No Change (4)
	7	04FEB97	50, .	No Change (4)
	8	11FEB97	57, .	No Change (4)
329.004.00016	1	20MAR95	8, .	No Change (4)
	2	29MAR95	17, .	No Change (4)
	3	05APR95	24, .	No Change (4)
	4	12APR95	31, .	No Change (4)
	5	19APR95	38, .	No Change (4)
329.004.00018	1	11MAY95	9, .	Much Worse (6)
	2	18MAY95	16, .	Much Improved (2)
	3	25MAY95	23, .	No Change (4)
	4	01JUN95	30, .	Minimally Improved (3)
	5	08JUN95	37, .	Minimally Improved (3)
	7	19JUN95	48, .	No Change (4)
	7	22JUN95	51, .	Minimally Improved (3)
	8	29JUN95	58, .	Much Improved (2)
329.004.00020	1	16NOV95	8, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.004.00020	2	24NOV95	16, .	No Change (4)
329.004.00213	1	08AUG96	7, -48	Minimally Worse (5)
	2	15AUG96	14, -41	Much Worse (6)
	3	21AUG96	20, -35	Much Improved (2)
	4	29AUG96	28, -27	Much Improved (2)
	5	03SEP96	33, -22	Much Improved (2)
	6	10SEP96	40, -15	Minimally Worse (5)
	7	17SEP96	47, -8	Minimally Worse (5)
	8	24SEP96	54, -1	Minimally Worse (5)
	12	22OCT96	82, 28	Very Much Improved (1)
	16	19NOV96	110, 56	Very Much Improved (1)
	20	20DEC96	141, 87	Minimally Worse (5)
	24	21JAN97	173, 119	Much Improved (2)
	28	18FEB97	201, 147	Much Improved (2)
	32	19MAR97	230, 176	Very Much Improved (1)
329.005.00001	1	27APR94	8, .	No Change (4)
	2	04MAY94	15, .	No Change (4)
	3	11MAY94	22, .	Minimally Improved (3)
	4	18MAY94	29, .	Minimally Improved (3)
	5	25MAY94	36, .	Minimally Improved (3)
	6	01JUN94	43, .	Much Improved (2)
	7	08JUN94	50, .	Minimally Improved (3)
	8	15JUN94	57, .	Minimally Improved (3)
329.005.00005	1	08NOV94	8, .	No Change (4)
329.005.00010	1	20DEC94	8, -50	Minimally Improved (3)
	2	27DEC94	15, -43	Much Improved (2)
	3	04JAN95	23, -35	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00010	4	11JAN95	30, -28	Minimally Worse (5)
	5	18JAN95	37, -21	Minimally Worse (5)
	6	25JAN95	44, -14	Much Improved (2)
	7	02FEB95	52, -6	Very Much Improved (1)
	8	08FEB95	58, 1	Very Much Improved (1)
	12	10MAR95	88, 31	Very Much Improved (1)
	16	13APR95	122, 65	Very Much Improved (1)
	20	10MAY95	149, 92	Very Much Improved (1)
	24	06JUN95	176, 119	Much Improved (2)
	32	12JUL95	212, 155	Very Much Improved (1)
	32	09AUG95	240, 183	Very Much Improved (1)
329.005.00012	1	27DEC94	9, -51	No Change (4)
	2	05JAN95	18, -42	Minimally Improved (3)
	3	12JAN95	25, -35	Much Improved (2)
	4	18JAN95	31, -29	Very Much Improved (1)
	5	25JAN95	38, -22	Much Improved (2)
	6	31JAN95	44, -16	Much Improved (2)
	7	08FEB95	52, -8	Much Improved (2)
	8	16FEB95	60, 1	Very Much Improved (1)
	12	27MAR95	99, 40	Much Improved (2)
	20	04MAY95	137, 78	Much Improved (2)
	24	31MAY95	164, 105	Much Improved (2)
329.005.00111	1	18JAN95	8, -49	Minimally Worse (5)
	2	25JAN95	15, -42	Minimally Improved (3)
	3	01FEB95	22, -35	Minimally Worse (5)
	4	08FEB95	29, -28	Much Improved (2)
	5	15FEB95	36, -21	Minimally Improved (3)
	6	22FEB95	43, -14	Very Much Improved (1)
	7	01MAR95	50, -7	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00111	8	08MAR95	57, 1	Much Improved (2)
	12	05APR95	85, 29	Much Improved (2)
	12	19APR95	99, 43	Very Much Improved (1)
	16	03MAY95	113, 57	Very Much Improved (1)
329.005.00114	1	07FEB95	8, -50	Minimally Improved (3)
	2	14FEB95	15, -43	Minimally Improved (3)
	3	21FEB95	22, -36	Very Much Improved (1)
	4	28FEB95	29, -29	Very Much Improved (1)
	5	09MAR95	38, -20	Very Much Improved (1)
	6	15MAR95	44, -14	Very Much Improved (1)
	7	22MAR95	51, -7	Very Much Improved (1)
	8	29MAR95	58, 1	Minimally Worse (5)
	12	26APR95	86, 29	Very Much Worse (7)
	16	17MAY95	107, 50	No Change (4)
329.005.00115	1	13FEB95	8, -64	No Change (4)
	2	20FEB95	15, -57	Much Improved (2)
	3	02MAR95	25, -47	Much Improved (2)
	5	10MAR95	33, -39	Very Much Improved (1)
	6	17MAR95	40, -32	Very Much Improved (1)
	7	28MAR95	51, -21	Much Improved (2)
	8	10APR95	64, -8	Much Improved (2)
	8	18APR95	72, 1	Very Much Improved (1)
	12	27APR95	81, 10	Very Much Improved (1)
329.005.00120	1	07SEP95	9, .	No Change (4)
	2	14SEP95	16, .	Minimally Improved (3)
	3	21SEP95	23, .	Minimally Improved (3)
	4	28SEP95	30, .	Minimally Worse (5)
	5	05OCT95	37, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00120	6	12OCT95	44, .	Much Worse (6)
	7	19OCT95	51, .	No Change (4)
	8	26OCT95	58, .	Minimally Improved (3)
329.005.00253	1	14FEB96	7, .	No Change (4)
	2	21FEB96	14, .	No Change (4)
	3	28FEB96	21, .	No Change (4)
	4	06MAR96	28, .	No Change (4)
	5	14MAR96	36, .	No Change (4)
	6	20MAR96	42, .	No Change (4)
	7	28MAR96	50, .	No Change (4)
	8	03APR96	56, .	No Change (4)
329.005.00254	1	21FEB96	7, -49	Minimally Improved (3)
	2	28FEB96	14, -42	Minimally Improved (3)
	3	06MAR96	21, -35	Very Much Improved (1)
	4	13MAR96	28, -28	Much Improved (2)
	5	20MAR96	35, -21	Much Improved (2)
	6	27MAR96	42, -14	Much Improved (2)
	7	03APR96	49, -7	Much Improved (2)
	8	10APR96	56, 1	Very Much Improved (1)
	12	22MAY96	98, 43	Very Much Improved (1)
	16	12JUN96	119, 64	Very Much Improved (1)
	20	10JUL96	147, 92	Very Much Improved (1)
	24	07AUG96	175, 120	Very Much Improved (1)
	28	12SEP96	211, 156	Very Much Improved (1)
	32	16OCT96	245, 190	Very Much Improved (1)
329.005.00293	1	19MAR97	8, .	Minimally Improved (3)
	2	25MAR97	14, .	Much Improved (2)
	3	02APR97	22, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00293	4	09APR97	29, .	Minimally Improved (3)
	5	16APR97	36, .	Much Improved (2)
	6	23APR97	43, .	Much Improved (2)
	7	30APR97	50, .	Much Improved (2)
	8	07MAY97	57, .	Much Improved (2)
329.005.00298	1	30MAY96	9, -48	Minimally Improved (3)
	2	06JUN96	16, -41	Minimally Improved (3)
	3	12JUN96	22, -35	Minimally Improved (3)
	4	19JUN96	29, -28	Much Improved (2)
	5	26JUN96	36, -21	Much Improved (2)
	6	03JUL96	43, -14	Much Improved (2)
	7	10JUL96	50, -7	Very Much Improved (1)
	8	17JUL96	57, 1	Very Much Improved (1)
	12	07AUG96	78, 22	Very Much Improved (1)
	16	19SEP96	121, 65	Very Much Improved (1)
	20	17OCT96	149, 93	Very Much Improved (1)
	24	14NOV96	177, 121	Very Much Improved (1)
	28	12DEC96	205, 149	Very Much Improved (1)
	32	13JAN97	237, 181	Very Much Improved (1)
329.005.00331	1	27NOV96	7, .	No Change (4)
	2	04DEC96	14, .	Minimally Improved (3)
	3	12DEC96	22, .	Minimally Improved (3)
	4	19DEC96	29, .	Much Improved (2)
	5	26DEC96	36, .	Very Much Improved (1)
	6	02JAN97	43, .	Much Improved (2)
	7	10JAN97	51, .	Very Much Improved (1)
	8	16JAN97	57, .	Much Improved (2)
329.005.00334	1	06FEB97	7, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.005.00334	2	13FEB97	14, .	Minimally Improved (3)
	3	21FEB97	22, .	Much Improved (2)
	4	26FEB97	27, .	No Change (4)
	5	06MAR97	35, .	Minimally Worse (5)
	6	13MAR97	42, .	Very Much Improved (1)
	7	21MAR97	50, .	Very Much Improved (1)
	8	27MAR97	56, .	Very Much Improved (1)
329.006.00037	1	03FEB95	7, .	Minimally Improved (3)
	2	13FEB95	17, .	Minimally Improved (3)
	4	22FEB95	26, .	No Change (4)
329.006.00042	1	13DEC95	7, -51	Minimally Improved (3)
	2	20DEC95	14, -44	Minimally Improved (3)
	3	27DEC95	21, -37	Much Improved (2)
	4	03JAN96	28, -30	Much Improved (2)
	5	10JAN96	35, -23	Much Improved (2)
	6	17JAN96	42, -16	Much Improved (2)
	7	23JAN96	48, -10	Much Improved (2)
	8	02FEB96	58, 1	Much Improved (2)
	12	29FEB96	85, 28	Very Much Improved (1)
	16	26MAR96	111, 54	Very Much Improved (1)
	20	23APR96	139, 82	Very Much Improved (1)
	24	21MAY96	167, 110	Very Much Improved (1)
	28	18JUN96	195, 138	Very Much Improved (1)
	32	16JUL96	223, 166	Very Much Improved (1)
329.006.00259	1	30MAY96	7, .	Minimally Improved (3)
	2	06JUN96	14, .	Minimally Improved (3)
	3	13JUN96	21, .	Minimally Improved (3)
	4	20JUN96	28, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.006.00259	5	27JUN96	35, .	Minimally Improved (3)
	6	03JUL96	41, .	Minimally Improved (3)
	7	10JUL96	48, .	Minimally Improved (3)
	8	17JUL96	55, .	Minimally Improved (3)
329.007.00141	1	28SEP95	8, .	No Change (4)
	2	05OCT95	15, .	Minimally Improved (3)
	3	12OCT95	22, .	Minimally Improved (3)
329.007.00144	1	14DEC95	8, -49	No Change (4)
	2	21DEC95	15, -42	Minimally Improved (3)
	3	28DEC95	22, -35	Much Improved (2)
	4	04JAN96	29, -28	Much Improved (2)
	5	11JAN96	36, -21	Minimally Improved (3)
	6	18JAN96	43, -14	Much Improved (2)
	7	25JAN96	50, -7	Much Improved (2)
	8	01FEB96	57, 1	Much Improved (2)
329.007.00266	1	14MAR96	8, .	Minimally Improved (3)
	3	25MAR96	19, .	Much Improved (2)
	3	28MAR96	22, .	Much Improved (2)
	4	04APR96	29, .	Minimally Worse (5)
	5	11APR96	36, .	Minimally Improved (3)
	6	18APR96	43, .	Minimally Improved (3)
	8	29APR96	54, .	Much Improved (2)
	8	02MAY96	57, .	Very Much Improved (1)
329.007.00267	1	14MAR96	8, .	Minimally Improved (3)
	2	21MAR96	15, .	Much Improved (2)
	3	28MAR96	22, .	Much Improved (2)
	4	04APR96	29, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.007.00267	5	11APR96	36, .	Much Improved (2)
	6	18APR96	43, .	Much Improved (2)
	7	25APR96	50, .	Much Improved (2)
	8	02MAY96	57, .	Very Much Improved (1)
329.007.00311	1	10OCT96	8, -53	Much Improved (2)
	2	17OCT96	15, -46	Much Improved (2)
	4	28OCT96	26, -35	Minimally Improved (3)
	4	31OCT96	29, -32	Much Improved (2)
	5	07NOV96	36, -25	Much Improved (2)
	6	14NOV96	43, -18	Much Improved (2)
	7	22NOV96	51, -10	Minimally Improved (3)
	8	02DEC96	61, 1	Much Improved (2)
	12	02JAN97	92, 32	Minimally Improved (3)
	16	30JAN97	120, 60	Much Improved (2)
	24	13MAR97	162, 102	Much Improved (2)
	28	11APR97	191, 131	No Change (4)
329.008.00158	1	19SEP95	7, -56	Minimally Improved (3)
	2	27SEP95	15, -48	No Change (4)
	3	03OCT95	21, -42	Minimally Improved (3)
	4	10OCT95	28, -35	Much Improved (2)
	5	16OCT95	34, -29	Minimally Improved (3)
	6	24OCT95	42, -21	Minimally Improved (3)
	7	31OCT95	49, -14	Much Improved (2)
	8	14NOV95	63, 1	Much Improved (2)
	16	26DEC95	105, 43	Much Improved (2)
	20	23JAN96	133, 71	Minimally Improved (3)
329.008.00162	1	10NOV95	10, -56	No Change (4)
	3	20NOV95	20, -46	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.008.00162	4	29NOV95	29, -37	Minimally Improved (3)
	5	07DEC95	37, -29	Minimally Improved (3)
	6	14DEC95	44, -22	Much Improved (2)
	7	20DEC95	50, -16	Much Improved (2)
	8	27DEC95	57, -9	Much Improved (2)
	8	05JAN96	66, 1	Much Improved (2)
	16	09FEB96	101, 36	Very Much Improved (1)
	20	08MAR96	129, 64	Much Improved (2)
	24	01MAY96	183, 118	Very Much Improved (1)
	32	05JUN96	218, 153	Very Much Improved (1)
	32	02JUL96	245, 180	Very Much Improved (1)
329.008.00191	2	12FEB96	12, -50	No Change (4)
	3	20FEB96	20, -42	Minimally Improved (3)
	4	27FEB96	27, -35	Much Improved (2)
	5	05MAR96	34, -28	Very Much Improved (1)
	6	12MAR96	41, -21	Much Improved (2)
	7	18MAR96	47, -15	No Change (4)
	8	26MAR96	55, -7	No Change (4)
	8	02APR96	62, 1	No Change (4)
	12	01MAY96	91, 30	Very Much Improved (1)
	16	05JUN96	126, 65	Very Much Improved (1)
	20	12JUN96	133, 72	Very Much Improved (1)
329.009.00128	1	18APR95	8, .	No Change (4)
	2	25APR95	15, .	No Change (4)
329.009.00129	1	18APR95	8, .	No Change (4)
	2	25APR95	15, .	No Change (4)
	3	02MAY95	22, .	No Change (4)
	4	09MAY95	29, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00129	5	16MAY95	36, .	No Change (4)
329.009.00135	1	09OCT95	8, .	No Change (4)
	2	16OCT95	15, .	No Change (4)
	3	23OCT95	22, .	No Change (4)
	4	30OCT95	29, .	No Change (4)
	5	06NOV95	36, .	No Change (4)
329.009.00136	1	10OCT95	8, .	No Change (4)
	2	17OCT95	15, .	No Change (4)
	3	24OCT95	22, .	No Change (4)
	4	03NOV95	32, .	Minimally Improved (3)
	5	07NOV95	36, .	Minimally Improved (3)
	6	14NOV95	43, .	No Change (4)
	7	21NOV95	50, .	No Change (4)
	8	28NOV95	57, .	No Change (4)
329.009.00169	1	07NOV95	8, -58	No Change (4)
	2	14NOV95	15, -51	Much Improved (2)
	3	21NOV95	22, -44	Very Much Improved (1)
	4	28NOV95	29, -37	Very Much Improved (1)
	5	05DEC95	36, -30	Very Much Improved (1)
	6	12DEC95	43, -23	Much Improved (2)
	7	19DEC95	50, -16	Very Much Improved (1)
	8	27DEC95	58, -8	Very Much Improved (1)
	12	23JAN96	85, 20	Minimally Worse (5)
329.009.00174	1	28NOV95	8, -50	No Change (4)
	2	05DEC95	15, -43	No Change (4)
	3	12DEC95	22, -36	Minimally Improved (3)
	4	19DEC95	29, -29	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00174	5	27DEC95	37, -21	Much Improved (2)
	6	02JAN96	43, -15	Very Much Improved (1)
	7	09JAN96	50, -8	Very Much Improved (1)
	8	17JAN96	58, 1	Much Improved (2)
	12	31JAN96	72, 15	Minimally Improved (3)
329.009.00197	1	02JAN96	5, -50	No Change (4)
	1	08JAN96	11, -44	No Change (4)
	3	16JAN96	19, -36	Minimally Improved (3)
	4	23JAN96	26, -29	Much Improved (2)
	5	30JAN96	33, -22	Much Improved (2)
	6	06FEB96	40, -15	Very Much Improved (1)
	7	13FEB96	47, -8	Very Much Improved (1)
	8	20FEB96	54, -1	Very Much Improved (1)
	12	19MAR96	82, 28	Very Much Improved (1)
	16	23APR96	117, 63	Very Much Improved (1)
	20	21MAY96	145, 91	Very Much Improved (1)
	24	25JUN96	180, 126	Very Much Improved (1)
	28	16JUL96	201, 147	Very Much Improved (1)
	32	20AUG96	236, 182	Very Much Improved (1)
329.009.00198	1	08JAN96	7, .	No Change (4)
	2	16JAN96	15, .	No Change (4)
	3	23JAN96	22, .	No Change (4)
	4	30JAN96	29, .	No Change (4)
	5	06FEB96	36, .	No Change (4)
	6	13FEB96	43, .	No Change (4)
	7	20FEB96	50, .	No Change (4)
	8	27FEB96	57, .	No Change (4)
329.009.00200	1	02FEB96	11, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00200	2	06FEB96	15, .	No Change (4)
	3	13FEB96	22, .	No Change (4)
	4	20FEB96	29, .	No Change (4)
	5	28FEB96	37, .	No Change (4)
	6	08MAR96	46, .	Minimally Worse (5)
329.009.00202	1	27FEB96	8, .	No Change (4)
	2	08MAR96	18, .	No Change (4)
	4	19MAR96	29, .	Much Improved (2)
	5	26MAR96	36, .	Much Improved (2)
329.009.00237	1	18NOV96	8, .	No Change (4)
329.009.00238	1	19NOV96	8, .	No Change (4)
	2	26NOV96	15, .	Minimally Improved (3)
	3	03DEC96	22, .	Minimally Improved (3)
	4	10DEC96	29, .	Much Improved (2)
	5	17DEC96	36, .	Much Improved (2)
	6	23DEC96	42, .	Much Improved (2)
	7	31DEC96	50, .	Very Much Improved (1)
	8	07JAN97	57, .	Minimally Improved (3)
329.009.00276	1	28JAN97	8, .	Minimally Improved (3)
	2	04FEB97	15, .	Minimally Improved (3)
	3	11FEB97	22, .	Minimally Improved (3)
	4	18FEB97	29, .	Minimally Improved (3)
	5	25FEB97	36, .	Much Improved (2)
	6	04MAR97	43, .	Much Improved (2)
	7	13MAR97	52, .	Much Improved (2)
	8	18MAR97	57, .	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.009.00302	1	03APR96	8, .	No Change (4)
	2	10APR96	15, .	Minimally Improved (3)
329.009.00306	1	18JUN96	8, .	No Change (4)
	2	25JUN96	15, .	Minimally Worse (5)
	3	02JUL96	22, .	No Change (4)
	4	09JUL96	29, .	Minimally Improved (3)
	5	16JUL96	36, .	Much Improved (2)
	6	23JUL96	43, .	Much Improved (2)
	7	30JUL96	50, .	Much Improved (2)
	8	06AUG96	57, .	Much Improved (2)
329.009.00312	2	15NOV96	12, .	No Change (4)
	2	18NOV96	15, .	Minimally Improved (3)
	4	02DEC96	29, .	No Change (4)
	5	09DEC96	36, .	No Change (4)
	6	16DEC96	43, .	Minimally Improved (3)
	8	27DEC96	54, .	No Change (4)
	8	30DEC96	57, .	No Change (4)
	8	06JAN97	64, .	No Change (4)
329.009.00327	1	23SEP96	8, .	No Change (4)
	2	30SEP96	15, .	No Change (4)
	3	07OCT96	22, .	No Change (4)
	4	14OCT96	29, .	Minimally Worse (5)
	5	21OCT96	36, .	Minimally Worse (5)
329.009.00330	1	28OCT96	8, .	No Change (4)
	2	04NOV96	15, .	No Change (4)
329.010.00183	1	12DEC95	10, .	Minimally Improved (3)

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.010.00183	2	19DEC95	17, .	Minimally Improved (3)
329.010.00263	1	14AUG96	6, .	Minimally Improved (3)
	2	21AUG96	13, .	Much Improved (2)
	3	28AUG96	20, .	No Change (4)
	4	04SEP96	27, .	No Change (4)
	5	11SEP96	34, .	Minimally Improved (3)
	6	18SEP96	41, .	Much Improved (2)
	7	25SEP96	48, .	Minimally Improved (3)
	8	09OCT96	62, .	No Change (4)
329.010.00277	1	08MAR96	8, -49	Minimally Improved (3)
	3	22MAR96	22, -35	Much Improved (2)
	4	29MAR96	29, -28	Much Improved (2)
	6	15APR96	46, -11	Much Improved (2)
	7	19APR96	50, -7	Much Improved (2)
	8	26APR96	57, 1	Very Much Improved (1)
	12	24MAY96	85, 29	Very Much Improved (1)
	16	21JUN96	113, 57	Much Improved (2)
	24	07AUG96	160, 104	Very Much Improved (1)
329.010.00282	1	02AUG96	8, .	No Change (4)
	2	09AUG96	15, .	Much Improved (2)
	3	16AUG96	22, .	Much Improved (2)
	4	26AUG96	32, .	Very Much Improved (1)
	6	03SEP96	40, .	Much Improved (2)
	7	13SEP96	50, .	Much Improved (2)
	8	19SEP96	56, .	Much Improved (2)
	8	27SEP96	64, .	Much Improved (2)
329.011.00164	1	28DEC95	7, .	No Change (4)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.011.00164	2	04JAN96	14, .	Minimally Improved (3)
	3	11JAN96	21, .	Minimally Improved (3)
	4	18JAN96	28, .	No Change (4)
	5	25JAN96	35, .	No Change (4)
329.011.00210	1	03OCT96	6, -61	Minimally Improved (3)
	2	09OCT96	12, -55	Much Worse (6)
	3	17OCT96	20, -47	No Change (4)
	4	24OCT96	27, -40	Minimally Improved (3)
	5	04NOV96	38, -29	Minimally Improved (3)
	6	12NOV96	46, -21	Very Much Improved (1)
	8	22NOV96	56, -11	Very Much Improved (1)
	8	02DEC96	66, -1	Very Much Improved (1)
329.011.00285	1	27MAY96	10, .	Minimally Improved (3)
	2	03JUN96	17, .	Minimally Worse (5)
	3	10JUN96	24, .	Minimally Worse (5)
	5	21JUN96	35, .	Minimally Improved (3)
	6	28JUN96	42, .	Minimally Improved (3)
	7	08JUL96	52, .	Minimally Improved (3)
	8	18JUL96	62, .	Minimally Improved (3)
	8	24JUL96	68, .	Minimally Improved (3)
329.011.00287	1	09JUL96	7, .	Minimally Improved (3)
	2	17JUL96	15, .	Minimally Improved (3)
	3	23JUL96	21, .	Minimally Improved (3)
	4	30JUL96	28, .	Minimally Improved (3)
	5	06AUG96	35, .	Minimally Improved (3)
	6	13AUG96	42, .	Minimally Improved (3)
	7	20AUG96	49, .	Much Improved (2)
	8	27AUG96	56, .	Much Improved (2)

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.012.00027	1	12DEC95	7, .	Minimally Improved (3)
	2	19DEC95	14, .	No Change (4)
	3	27DEC95	22, .	Minimally Improved (3)
	4	02JAN96	28, .	Minimally Improved (3)
329.012.00217	1	31MAY96	11, .	Minimally Worse (5)
	2	07JUN96	18, .	Minimally Improved (3)
	3	14JUN96	25, .	Minimally Improved (3)
	4	19JUN96	30, .	No Change (4)
329.012.00218	1	21JUN96	6, -53	Minimally Improved (3)
	2	28JUN96	13, -46	Much Improved (2)
	3	05JUL96	20, -39	Very Much Improved (1)
	4	12JUL96	27, -32	Very Much Improved (1)
	5	19JUL96	34, -25	Very Much Improved (1)
	6	29JUL96	44, -15	Very Much Improved (1)
	7	06AUG96	52, -7	Very Much Improved (1)
	8	13AUG96	59, 1	Very Much Improved (1)
	12	18SEP96	95, 37	Very Much Improved (1)
329.012.00224	1	24SEP96	9, -58	No Change (4)
	2	03OCT96	18, -49	Minimally Improved (3)
	3	10OCT96	25, -42	Much Improved (2)
	4	17OCT96	32, -35	Very Much Improved (1)
	6	25OCT96	40, -27	Very Much Improved (1)
	7	04NOV96	50, -17	Very Much Improved (1)
	8	12NOV96	58, -9	Much Improved (2)
	8	20NOV96	66, -1	Very Much Improved (1)
	12	19DEC96	95, 29	Very Much Improved (1)
	16	20JAN97	127, 61	Very Much Improved (1)
	24	18FEB97	156, 90	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.4
Listing of CGI Scores by Treatment Group
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	CGI Global Improvement
329.012.00225	1	03DEC96	8, -57	No Change (4)
	2	10DEC96	15, -50	Much Improved (2)
	3	20DEC96	25, -40	Very Much Improved (1)
	4	27DEC96	32, -33	Very Much Improved (1)
	6	06JAN97	42, -23	Minimally Improved (3)
	7	13JAN97	49, -16	Very Much Improved (1)
	8	21JAN97	57, -8	Very Much Improved (1)
	8	29JAN97	65, 1	Very Much Improved (1)
	12	24FEB97	91, 27	Very Much Improved (1)
	16	20MAR97	115, 51	Much Improved (2)
	20	21APR97	147, 83	Much Improved (2)
	24	26MAY97	182, 118	Very Much Improved (1)
	32	30JUN97	217, 153	Very Much Improved (1)
	32	30JUL97	247, 183	Very Much Improved (1)

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.001.00063	SC	02NOV94	-6, .	1	3	0	1	1	2	0	0	0	4	0	1	0	0	0	0	0	0	0	0	0	0	3	4	4	0	0	0	4
329.001.00065	SC	07NOV94	-10, .	2	3	1	3	1	3	1	3	0	0	0	3	2	1	0	0	0	0	2	0	3	0	3	3	3	3	0	0	3
329.001.00068	SC	01FEB95	-7, .	1	2	2	2	1	3	1	1	0	3	0	1	0	1	1	0	0	0	0	0	2	2	4	1	1	0	0	0	1
	8	05APR95	57, .	1	2	2	2	2	3	2	2	1	3	3	1	1	1	1	1	1	1	1	0	3	3	4	2	2	1	1	1	2
329.001.00072	SC	07MAR95	-13, .	1	2	0	3	1	0	0	0	0	2	0	1	0	0	0	0	0	0	0	0	1	0	3	2	0	0	0	0	3
329.001.00121	SC	22MAR95	-13, -69	2	2	1	4	3	4	1	3	0	4	0	3	0	0	1	0	0	0	0	0	4	0	2	3	0	0	0	4	1
	8	30MAY95	57, 1	2	3	1	3	1	3	1	1	1	4	0	3	0	1	1	0	0	0	1	1	4	0	3	3	1	0	0	4	3
329.001.00205	SC	29JAN96	-9, .	1	3	0	0	3	4	0	3	2	3	1	4	0	0	0	0	0	0	1	4	4	3	4	4	4	0	0	0	4
329.001.00206	SC	12FEB96	-9, .	0	3	0	4	2	0	0	1	1	0	0	2	0	0	0	2	0	0	0	0	0	0	1	3	0	0	0	1	1
	8	17APR96	57, .	1	3	0	4	1	0	0	1	0	0	0	1	0	0	0	3	0	0	1	0	0	0	4	4	0	0	0	4	0
329.002.00055	SC	09JUN94	-15, -70	1	1	0	1	0	0	2	0	0	4	0	1	0	0	0	0	0	0	0	0	4	1	4	3	1	0	0	0	2
	8	18AUG94	56, 1	1	2	0	3	0	1	0	0	0	3	2	3	0	0	0	0	0	0	0	0	2	2	2	2	2	0	0	0	2
	20	10NOV94	140, 85	0	4	1	4	0	3	0	0	2	3	3	3	2	0	0	0	0	0	0	0	4	4	4	4	4	4	3	0	4
329.002.00058	SC	08SEP94	-12, -70	1	4	3	2	3	3	0	0	0	4	4	1	0	0	2	0	0	0	0	0	4	2	1	1	0	0	3	0	1
	8	17NOV94	59, 1	1	2	3	4	3	3	1	2	1	4	4	1	0	0	2	0	0	0	0	0	4	0	1	3	0	0	4	4	4
329.002.00099	SC	23FEB95	-7, -62	2	1	3	1	4	0	0	3	0	4	0	2	3	1	4	0	0	0	3	0	0	0	4	2	0	0	0	0	4
	8	25APR95	55, -1	2	2	2	0	1	1	0	1	0	3	0	2	1	0	1	0	0	0	1	0	2	0	3	0	2	0	0	0	4
329.002.00102	SC	03APR95	-10, -64	3	4	2	2	2	3	2	3	1	3	0	0	0	0	1	0	0	0	0	0	0	0	4	3	1	4	0	0	1
	8	06JUN95	55, 1	1	3	1	2	3	3	1	1	1	2	0	1	0	0	0	0	0	0	0	0	0	0	4	4	3	4	0	0	0
	32	05DEC95	237, 183	2	4	1	2	4	4	4	4	3	4	0	0	0	0	1	0	0	0	0	0	0	0	4	4	0	4	4	0	4

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.002.00105	SC	20JUL95	-7, .	0	3	0	0	3	0	0	0	0	3	0	2	0	0	2	0	0	0	0	0	4	4	3	0	0	0	0	0	2
329.002.00106	SC	20JUL95	-7, .	0	4	0	4	0	4	0	0	0	3	0	1	0	0	0	0	0	0	0	0	3	3	4	4	2	0	4	3	1
329.002.00242	SC	26JAN96	-12, -70	0	3	1	4	2	1	0	0	0	3	0	1	0	0	1	0	0	0	0	0	4	0	4	2	1	3	1	1	2
	20	10JUL96	155, 97	0	3	1	2	1	1	0	0	0	3	0	1	0	0	0	0	0	0	0	0	3	0	3	3	1	1	2	1	3
329.002.00245	SC	21MAR96	-7, .	1	3	1	3	3	2	1	1	1	3	0	2	0	0	2	0	1	1	1	0	1	0	4	3	3	3	3	0	4
329.002.00319	SC	23APR96	-7, -63	3	4	2	4	2	3	2	0	0	3	0	3	0	0	1	0	0	0	0	0	1	0	3	3	1	0	4	0	4
	8	25JUN96	57, 1	4	4	3	4	4	4	3	3	1	3	0	3	0	0	3	0	0	0	1	0	4	3	4	4	3	0	4	0	4
	32	17DEC96	232, 176	4	4	3	4	3	4	4	3	0	4	0	3	0	0	1	0	0	0	0	0	3	0	4	4	3	0	4	0	4
329.003.00075	8	22MAR95	57, 1	2	4	1	4	2	4	4	4	3	4	4	2	4	2	0	2	4	2	4	4	4	4	4	4	3	2	4	4	4
	32	13SEP95	232, 176	4	1	0	4	4	3	4	4	3	4	0	3	0	0	0	0	1	0	3	0	4	0	4	4	3	0	4	4	1
329.003.00077	SC	01MAR95	-5, -64	2	3	1	2	2	2	3	4	1	2	0	2	0	1	0	0	0	2	2	2	1	3	2	0	0	0	3	0	2
329.003.00087	SC	23JAN95	-8, .	1	1	0	4	0	1	2	0	0	4	0	0	0	0	0	0	0	0	0	0	4	0	4	4	4	4	4	0	4
329.003.00089	SC	24FEB95	-11, .	2	2	1	0	2	1	1	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	4	1	2	0	0	0	3
	8	02MAY95	57, .	1	2	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4	2	2	1	1	2	4
329.003.00091	SC	14MAR95	-10, -64	3	3	4	4	3	3	3	2	1	4	1	3	0	0	2	0	0	1	1	0	4	4	4	4	4	0	4	4	4
	8	16MAY95	54, -1	3	3	3	3	3	4	3	4	2	4	1	2	0	0	2	0	1	1	1	0	4	3	4	4	4	0	4	0	3
	32	07NOV95	229, 175	3	4	3	3	3	4	4	3	2	4	3	3	2	1	3	1	0	2	2	0	4	4	4	4	4	3	4	3	4
329.003.00248	SC	14FEB96	-16, .	1	4	0	1	3	4	1	0	1	4	0	0	0	0	1	0	0	0	0	0	0	0	4	3	0	0	3	0	4
	8	23APR96	54, .	0	4	1	2	4	3	1	2	0	4	0	1	0	0	1	0	0	0	0	0	4	0	4	4	4	4	4	0	4
329.003.00250	SC	05MAR96	-9, -66	1	3	2	3	4	2	1	3	1	2	0	2	2	1	4	1	1	1	2	0	1	0	4	2	2	0	4	2	2

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.003.00292	SC	02AUG96	-5, -63	3	2	0	4	2	2	2	1	1	0	1	3	2	2	2	3	0	1	1	1	1	1	3	1	3	0	4	0	4
	8	04OCT96	59, 1	2	3	0	4	2	4	4	2	1	1	1	2	2	2	1	2	2	1	1	1	1	0	3	1	2	0	3	0	3
329.003.00313	SC	08MAY96	-9, .	2	3	1	3	3	3	3	1	0	3	.	3	1	0	0	0	1	0	1	0	.	.	0	.	0	0	4	0	1
329.004.00015	SC	30NOV94	-8, -65	1	4	1	2	4	3	0	4	1	4	0	2	3	1	1	0	0	1	0	0	0	4	4	1	4	0	0	0	4
	8	03FEB95	58, 1	1	3	2	2	1	3	2	3	1	3	0	1	0	0	1	0	0	1	2	0	3	3	4	1	1	0	0	0	1
	28	14JUN95	189, 132	1	4	2	0	2	4	0	3	0	4	4	1	4	0	3	0	0	0	3	0	4	4	4	1	3	0	0	0	4
329.004.00017	SC	15MAR95	-7, -63	1	2	1	3	2	4	0	3	0	4	0	0	3	0	1	0	0	0	2	0	4	4	4	4	0	4	2	0	4
	8	17MAY95	57, 1	0	1	1	1	0	1	3	3	2	2	0	0	1	0	3	2	1	1	3	2	2	3	3	1	1	2	2	0	3
	32	01NOV95	225, 169	1	2	1	3	2	3	1	3	0	4	0	2	0	0	1	0	0	0	1	0	3	3	4	3	1	1	4	0	4
329.004.00019	SC	24MAY95	-7, .	3	3	2	3	3	2	2	3	1	2	1	2	0	0	2	0	0	0	2	0	2	0	3	3	3	3	3	2	2
329.004.00212	SC	24MAY96	-10, .	4	4	4	4	3	4	4	3	4	4	4	3	0	3	3	0	0	0	0	0	3	.	4	4	4	4	4	0	4
329.004.00214	SC	27SEP96	-7, -67	2	4	2	4	4	3	1	1	0	4	0	1	0	0	0	0	0	0	0	0	4	0	4	0	2	0	4	0	4
	8	03DEC96	61, 1	2	4	3	4	1	4	2	2	1	4	2	2	1	1	1	1	2	2	1	0	4	3	4	2	2	2	4	2	4
329.005.00002	SC	20MAY94	-5, -61	2	2	1	1	2	2	1	1	1	2	0	3	0	1	1	0	0	1	0	0	2	0	4	3	2	0	0	0	3
329.005.00004	SC	22SEP94	-18, -77	0	2	1	4	1	4	1	1	0	2	0	1	0	0	0	0	0	1	1	0	2	2	3	4	4	3	3	3	3
	8	08DEC94	60, 1	1	2	1	4	1	3	2	1	1	3	1	2	0	0	1	0	0	1	1	2	2	2	4	4	2	4	1	1	1
329.005.00008	SC	10NOV94	-6, -61	2	4	0	0	0	0	0	1	0	4	0	2	0	0	0	0	0	0	0	0	4	0	4	1	1	0	1	0	2
	8	10JAN95	56, 1	3	4	2	4	1	3	0	1	0	4	0	3	0	0	1	0	0	0	1	0	4	0	4	4	0	0	4	0	4
	24	10MAY95	176, 121	3	4	1	2	3	3	0	0	0	4	0	2	0	0	0	0	0	0	0	0	4	0	3	3	0	0	4	0	1
329.005.00011	SC	06DEC94	-7, -63	1	1	3	3	1	3	2	3	2	3	0	1	0	0	0	0	0	0	1	0	4	3	4	4	3	3	1	3	4
	8	07FEB95	57, 1	1	1	3	4	1	3	3	3	2	3	0	2	0	0	0	0	0	0	2	2	3	0	4	4	3	3	0	4	4

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00109	SC	22DEC94	-8, -61	4	4	3	4	4	4	4	4	4	4	4	4	0	0	1	0	0	2	0	0	0	0	3	0	0	2	0	0	0
329.005.00112	SC	17JAN95	-9, -64	1	4	3	4	1	4	0	1	0	0	0	2	0	0	0	0	0	1	1	0	0	0	4	4	0	0	4	0	4
	8	22MAR95	56, 1	1	4	4	4	4	4	4	4	3	4	0	2	0	0	3	0	0	3	3	1	4	0	4	4	4	0	4	4	4
329.005.00116	SC	30JAN95	-8, -66	2	4	1	3	2	3	4	3	1	3	1	3	2	0	0	0	0	0	1	1	4	4	4	4	4	1	4	0	4
	8	06APR95	59, 1	1	3	1	3	2	3	3	1	1	3	0	2	1	0	1	0	1	0	1	0	3	3	4	4	4	2	4	1	4
	24	26JUL95	170, 112	2	4	3	4	3	3	3	3	0	3	0	2	2	1	1	1	1	1	1	1	2	3	4	4	4	4	4	4	4
329.005.00119	SC	27JUN95	-14, -73	1	3	2	3	3	3	4	3	1	3	0	3	0	0	1	0	0	0	0	0	3	0	4	4	4	1	3	0	3
	8	08SEP95	60, 1	2	4	2	4	2	3	3	2	1	2	0	3	0	0	1	0	0	0	0	0	1	0	4	3	3	1	2	0	2
	24	02JAN96	176, 117	2	3	3	4	3	3	2	3	1	4	0	3	0	0	1	0	0	0	1	0	4	0	4	4	4	3	3	0	3
329.005.00151	SC	29AUG95	-8, -65	3	4	1	4	2	3	4	0	0	3	0	4	0	0	0	0	0	2	0	0	1	0	4	4	4	4	3	3	4
	8	02NOV95	58, 1	3	4	1	3	1	4	3	2	1	4	0	3	0	0	0	0	0	1	0	0	4	1	4	4	4	4	3	1	4
	32	01MAY96	239, 182	1	3	0	3	0	4	3	2	0	2	0	1	0	0	0	0	0	1	0	0	1	4	4	4	4	4	4	4	4
329.005.00152	SC	12OCT95	-14, .	0	4	1	4	1	4	2	0	0	4	0	2	0	0	0	0	0	0	0	0	3	1	4	4	4	0	4	0	2
329.005.00257	SC	05MAR96	-6, -62	1	2	1	1	0	2	1	1	0	1	0	2	1	0	0	0	0	0	0	0	0	0	1	2	1	0	0	0	4
	8	06MAY96	57, 1	2	3	1	2	1	1	1	1	0	0	0	2	0	1	0	0	0	0	0	0	0	0	3	3	1	1	1	1	3
	32	21OCT96	225, 169	2	3	1	0	0	3	0	0	0	3	0	3	0	0	1	0	0	0	0	0	0	0	3	2	0	0	0	0	4
329.005.00258	SC	06FEB96	-35, .	1	2	2	3	2	3	1	1	0	4	1	1	3	3	2	0	1	1	1	0	2	0	3	2	1	0	2	1	3
	8	07MAY96	57, .	1	3	0	3	3	3	2	1	0	4	0	1	1	0	1	0	0	0	0	0	4	0	4	3	3	3	4	0	4
329.005.00299	SC	28MAY96	-11, -71	2	3	0	1	1	1	0	0	0	2	0	1	1	0	0	0	0	0	0	0	0	0	3	1	2	0	0	1	1
	8	07AUG96	61, 1	3	3	1	2	2	3	1	3	1	3	1	4	1	1	1	0	0	0	1	0	1	0	4	4	4	4	0	1	3
	20	05NOV96	151, 91	2	3	1	2	3	3	0	2	0	3	0	2	1	1	2	0	0	0	2	0	2	3	4	4	4	4	3	2	4
329.005.00300	SC	12SEP96	-7, .	0	1	0	0	1	2	0	1	0	2	0	3	0	0	0	0	0	0	1	1	1	1	2	2	0	0	0	1	1

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00300	8	14NOV96	57, .	0	1	0	3	2	1	0	0	0	3	0	0	0	0	0	0	0	0	0	1	2	2	4	1	2	0	0	0	0
329.005.00333	SC	15JAN97	-8, .	3	3	1	1	1	1	1	2	1	4	0	2	2	1	2	0	0	0	2	1	3	1	3	4	3	2	1	0	3
329.005.00336	SC	26FEB97	-6, .	0	3	2	0	1	2	1	2	0	3	0	1	1	0	2	0	0	0	0	0	0	0	3	2	0	0	0	0	2
329.006.00038	SC	01FEB95	-14, .	2	4	4	4	4	4	4	4	3	3	0	4	4	2	3	0	0	0	1	0	4	0	4	4	4	0	4	4	3
329.006.00039	SC	03FEB95	-5, -66	2	1	0	2	1	3	0	0	0	4	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	4	3	1	3
	8	05APR95	57, -5	3	2	1	1	1	2	1	0	0	4	0	1	0	0	0	0	0	0	0	0	4	0	2	2	0	4	1	1	3
329.006.00260	SC	12JUL96	-6, -64	2	4	0	0	2	2	0	0	1	4	0	1	0	0	0	0	0	0	0	0	4	0	2	2	1	0	0	0	1
	8	18SEP96	63, 5	1	3	0	0	3	1	1	0	0	4	0	2	0	0	2	0	0	0	0	0	4	0	3	4	2	0	0	0	1
329.006.00261	SC	07NOV96	-19, -77	2	4	1	4	4	4	2	2	0	4	2	2	2	1	2	1	0	0	2	0	2	4	4	0	1	0	4	0	0
329.007.00140	SC	07SEP95	-8, -63	3	3	1	0	0	3	0	1	0	3	0	2	0	0	1	0	0	0	0	0	4	0	3	0	2	0	0	4	3
	8	09NOV95	56, 1	3	3	0	1	1	2	0	1	0	3	0	2	0	0	0	0	0	0	0	0	3	1	4	2	4	0	0	0	4
329.007.00142	SC	12OCT95	-6, .	1	2	0	0	1	1	0	2	0	3	0	2	0	0	0	0	0	0	0	0	4	3	4	4	3	1	1	4	2
	8	21DEC95	65, .	1	2	1	4	2	2	0	0	0	4	0	2	0	0	0	0	0	0	0	0	4	0	4	4	2	0	0	4	1
329.007.00145	SC	04JAN96	-7, -63	1	2	1	3	1	1	0	1	0	0	0	2	1	0	1	0	0	0	1	1	0	0	4	2	2	0	4	0	1
	8	07MAR96	57, 1	1	1	2	1	1	0	1	2	0	0	0	2	2	1	1	1	0	0	1	2	0	0	2	1	1	0	1	0	1
	32	23AUG96	226, 170	2	3	3	2	1	2	1	3	0	3	0	3	2	1	2	0	1	0	1	3	3	0	4	0	4	1	4	1	4
329.007.00265	SC	25JAN96	-7, .	1	1	2	4	2	1	1	4	1	0	0	1	1	0	1	0	0	0	0	0	0	0	4	4	4	0	1	0	0
329.007.00268	SC	21MAR96	-11, -70	0	4	2	2	3	4	1	4	0	4	0	2	0	0	2	0	0	0	3	0	0	0	3	2	3	0	0	2	4
	8	30MAY96	60, 1	2	4	3	4	3	4	3	4	0	4	0	3	0	1	2	0	0	0	4	0	0	0	4	4	4	0	0	0	4
	32	05DEC96	249, 190	3	4	4	4	3	4	3	4	1	4	0	3	1	0	2	0	0	0	2	0	4	0	4	4	4	0	0	0	4

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.007.00294	SC	20FEB97	-8, .	1	3	1	4	2	3	0	3	0	0	0	1	0	0	2	0	0	0	0	0	0	0	2	2	4	0	0	0	1
329.007.00309	SC	02JUL96	-13, -65	1	3	1	4	2	3	2	3	2	0	0	2	0	0	2	2	0	2	0	0	0	0	4	2	2	2	0	1	0
	7	05SEP96	53, 1	1	0	1	3	2	2	3	3	2	1	3	1	0	0	0	3	1	1	0	0	1	0	4	3	4	3	0	0	0
	32	13MAR97	242, 190	1	4	4	4	3	4	4	4	4	4	1	3	0	0	0	0	0	0	0	0	0	0	4	4	4	4	0	0	1
329.007.00310	SC	19SEP96	-7, -67	0	2	0	3	2	1	0	1	0	1	0	2	0	2	1	0	0	0	0	0	0	0	4	0	2	0	0	0	2
	8	25NOV96	61, 1	2	2	1	3	2	2	1	0	0	2	0	2	0	0	1	0	0	0	0	0	1	0	3	2	2	0	0	0	3
	32	12JUN97	260, 200	1	3	1	3	3	3	1	0	0	3	0	2	0	0	2	1	0	1	0	0	0	0	4	4	4	0	0	0	3
329.007.00318	SC	22NOV96	-10, .	0	4	1	4	3	2	0	3	0	2	0	2	0	0	1	0	0	0	0	0	4	4	4	4	2	2	0	0	3
329.008.00157	SC	16AUG95	-14, -69	1	3	1	1	2	4	4	4	2	4	0	1	0	0	0	0	0	1	4	0	0	0	4	4	1	4	1	2	2
	8	24OCT95	56, 1	2	3	0	4	2	4	4	4	2	4	0	1	0	0	0	0	0	2	4	2	4	1	4	4	4	4	1	3	4
329.008.00160	SC	25OCT95	-7, -73	1	4	1	4	4	1	0	2	0	4	0	4	3	3	3	0	0	0	2	0	4	4	4	4	4	0	4	4	4
	8	05JAN96	66, -1	1	1	1	4	4	1	1	3	2	4	1	4	1	3	3	0	0	2	2	0	4	4	4	4	4	0	4	4	4
329.008.00188	SC	14DEC95	-21, .	1	3	1	3	2	3	2	1	1	0	0	2	4	0	2	3	1	0	1	0	0	0	4	2	1	0	3	0	1
	8	27FEB96	55, .	1	3	1	3	3	3	3	1	1	1	0	2	1	0	2	3	1	1	1	0	0	0	4	2	2	0	2	0	1
329.008.00271	SC	25JAN96	-46,-110	2	4	3	3	2	4	3	1	4	2	0	3	1	1	2	0	0	0	0	0	0	0	4	4	4	0	4	4	4
	8	14MAY96	65, 1	3	4	3	2	4	3	3	2	3	4	4	1	2	1	3	1	0	2	1	0	3	4	3	3	3	3	3	2	3
329.008.00275	SC	30APR96	-8, -63	1	4	0	2	4	3	0	1	0	3	0	1	0	0	2	0	0	0	0	0	4	0	4	4	3	0	2	0	3
	8	02JUL96	56, 1	1	3	1	3	3	3	1	1	1	4	0	2	0	0	2	0	0	0	1	0	4	0	4	4	3	1	3	3	4
	32	16DEC96	223, 168	2	3	0	3	3	3	1	2	0	4	0	3	0	0	1	0	0	0	1	0	3	1	4	4	3	4	3	3	3
329.009.00130	SC	12APR95	-6, -62	2	3	2	3	3	2	3	3	0	3	0	2	1	0	1	0	0	0	2	0	0	0	4	2	0	1	2	1	1
	8	13JUN95	57, 1	3	4	4	4	3	4	4	4	1	4	0	3	2	1	2	1	0	0	2	1	0	0	4	4	4	1	3	3	4

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00131	SC	26APR95	-6, -62	2	4	0	0	4	3	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
	8	27JUN95	57, 1	4	4	1	0	4	4	0	0	0	0	0	3	3	0	0	0	0	0	0	0	0	0	4	4	3	0	0	0	0
329.009.00133	SC	07JUN95	-6, .	1	4	2	1	1	3	1	3	0	3	0	0	0	0	1	0	0	0	0	0	0	0	4	3	0	0	3	0	4
329.009.00138	SC	02OCT95	-8, .	0	2	1	2	1	2	0	2	0	2	0	1	0	0	1	0	0	0	0	0	0	0	4	3	0	0	0	0	0
329.009.00170	SC	26OCT95	-12, -69	1	2	0	0	1	3	1	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	1	2	1	0	0	0	2
	8	03JAN96	58, 1	1	3	1	1	2	4	0	2	0	4	0	2	0	0	0	0	0	1	2	0	4	0	3	3	3	0	0	0	3
	32	24JUN96	231, 174	1	2	1	0	1	3	1	2	2	1	0	2	3	0	0	0	0	3	1	0	4	1	4	4	4	0	3	4	4
329.009.00173	SC	08NOV95	-12, -75	3	3	0	4	0	0	1	1	4	1	0	3	1	2	2	0	0	0	1	0	1	0	4	4	4	0	1	1	1
	8	22JAN96	64, 1	2	2	2	2	1	1	1	1	1	2	0	2	0	0	1	0	1	1	1	0	1	0	3	3	3	0	0	0	3
329.009.00193	SC	21NOV95	-7, .	1	3	2	1	3	2	3	2	0	3	0	1	2	2	2	0	0	0	3	0	3	0	2	0	0	0	0	1	2
	8	24JAN96	58, .	2	3	3	4	2	1	2	2	1	3	0	3	3	2	3	0	0	0	2	0	1	0	1	0	0	0	0	1	2
329.009.00196	SC	11DEC95	-7, .	3	2	1	4	2	1	0	4	3	4	0	3	0	1	1	2	0	4	4	3	0	1	4	4	4	4	0	0	3
	8	12FEB96	57, .	3	3	2	4	1	3	1	4	3	3	1	3	2	1	2	3	0	2	4	0	3	4	4	4	3	4	2	2	2
329.009.00201	SC	31JAN96	-6, .	3	3	2	1	2	2	0	4	0	2	0	3	0	1	2	0	0	0	3	3	3	3	4	3	3	0	1	2	3
	8	02APR96	57, .	3	3	2	1	3	3	1	4	1	3	0	3	0	1	2	0	0	1	3	0	3	0	4	3	2	0	1	1	3
329.009.00204	SC	13MAR96	-6, -62	2	2	2	3	2	3	3	3	3	3	0	2	1	1	1	0	0	3	1	1	0	0	2	2	1	2	3	0	3
	8	14MAY96	57, 1	2	4	2	3	4	3	1	2	1	4	0	2	0	1	3	1	0	0	1	0	3	0	4	0	1	3	0	0	4
329.009.00235	SC	10DEC96	-8, -62	3	3	3	0	1	3	0	1	0	0	0	3	1	1	1	0	0	0	0	0	0	0	4	0	0	0	0	0	4
	8	10FEB97	55, 1	4	4	3	0	2	4	1	2	0	1	1	3	4	1	2	0	0	0	0	0	1	0	4	2	0	0	0	0	3
329.009.00240	SC	03JAN97	-11, .	1	3	1	3	3	3	0	1	1	2	0	2	0	0	1	0	0	0	1	1	2	2	4	4	2	0	0	3	3
	7	04MAR97	50, .	1	4	0	0	4	.	3	3	0	0	0	3	0	0	3	0	0	0	3	0	0	0	4	4	3	0	0	4	1

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00303	SC	25MAR96	-8, -64	1	4	1	4	3	3	2	2	1	3	0	1	0	0	1	1	0	0	0	0	0	0	4	4	1	0	0	0	3
	8	28MAY96	57, 1	1	3	0	4	2	2	1	1	0	3	0	1	0	0	0	1	0	0	0	0	1	0	4	4	1	1	0	0	1
	32	10DEC96	253, 197	1	2	1	4	2	2	1	1	1	3	0	1	0	0	0	1	0	0	1	0	3	0	4	3	1	1	0	0	1
329.009.00304	SC	03APR96	-6, -62	1	2	0	4	2	3	1	3	1	4	0	1	0	0	0	3	0	0	1	0	0	0	4	3	1	0	0	0	3
	8	04JUN96	57, 1	1	3	1	4	3	3	2	2	2	4	0	1	0	0	0	1	0	0	0	0	0	0	4	4	4	0	0	0	4
329.009.00324	SC	21OCT96	-7, .	3	4	1	0	3	4	4	3	0	4	0	3	3	2	3	0	0	0	1	0	4	4	4	4	4	4	0	4	4
	8	27DEC96	61, .	3	4	2	2	3	3	3	4	2	4	4	3	2	2	3	2	2	2	2	2	4	4	4	3	4	4	2	2	3
329.009.00328	SC	30SEP96	-7, .	1	1	1	2	1	2	0	1	0	0	0	1	0	0	0	0	0	0	1	0	3	3	4	3	0	1	0	0	2
329.009.00329	SC	01OCT96	-8, .	1	3	0	3	0	0	0	0	0	0	0	3	1	0	1	0	0	0	1	0	0	0	4	2	1	0	0	1	2
	8	03DEC96	56, .	1	3	0	1	0	0	0	0	1	1	0	3	0	0	0	0	0	0	0	0	0	0	4	2	0	0	0	1	3
329.010.00182	SC	05DEC95	-14, .	0	4	1	3	4	4	3	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	4	4	0	2	1	1	3
329.010.00278	SC	02FEB96	-7, -63	2	3	2	4	1	1	2	0	0	3	0	0	0	0	0	0	0	0	0	0	4	4	4	4	4	4	0	0	1
	8	05APR96	57, 1	2	3	2	4	2	4	3	3	2	3	0	2	0	0	1	0	0	0	1	0	3	0	3	3	3	4	0	0	3
	32	19SEP96	224, 168	3	3	3	4	2	3	3	2	1	3	4	2	0	0	0	0	0	0	1	0	0	0	4	4	4	3	0	1	3
329.010.00280	SC	10MAY96	-7, -62	1	4	2	4	2	4	3	0	3	1	0	0	0	0	1	0	0	0	0	0	0	0	4	0	3	0	0	0	0
	8	11JUL96	56, 1	1	2	1	0	3	4	3	0	3	3	0	0	0	0	0	0	0	0	0	0	0	0	4	0	3	0	0	0	1
	12	21AUG96	97, 42	2	4	2	3	4	4	3	1	3	2	0	0	0	0	0	0	0	0	0	0	2	0	4	0	3	0	0	0	0
329.011.00283	SC	30JAN96	-9, -66	4	3	3	2	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4	3	0	0	2	0	0
	8	04APR96	57, -1	3	4	4	3	4	4	1	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4	0	1	0	1	0	2
329.011.00288	SC	01JUL96	-24, .	0	3	2	3	3	4	0	4	1	3	0	1	2	1	3	3	0	2	4	4	4	4	4	4	4	1	0	0	2
329.012.00025	SC	17OCT95	-7, .	1	3	1	1	2	4	3	1	1	3	1	1	0	0	1	0	0	0	0	0	0	0	4	3	0	3	1	0	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.012.00025	8	19DEC95	57, .	0	2	0	1	1	3	1	1	1	3	0	0	0	0	0	0	0	1	0	0	4	0	4	4	1	4	4	0	4
329.012.00220	SC	04JUN96	-13, -73	3	3	1	3	3	1	1	4	1	3	0	2	0	0	1	0	0	1	1	0	0	0	2	4	1	4	4	1	1
	8	16AUG96	61, 1	2	3	0	4	1	3	3	4	0	4	0	3	0	0	1	0	0	0	0	0	4	4	4	3	0	3	4	0	1
329.012.00222	SC	18JUN96	-10, -73	1	4	1	3	3	3	1	3	0	3	1	1	0	0	2	0	0	1	0	0	0	0	4	4	4	0	3	0	1
	8	30AUG96	64, 1	2	3	1	3	1	3	1	1	0	3	1	2	0	1	1	0	0	0	0	0	0	0	4	4	3	0	4	0	0
329.012.00226	SC	26NOV96	-7, .	1	3	0	4	2	3	0	1	0	3	0	1	0	0	1	0	0	0	1	0	2	0	4	4	3	4	4	1	3
329.012.00228	SC	04MAR97	-15, .	1	2	0	1	0	1	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	4	0	1	0	0	0	1
329.012.00231	SC	26FEB97	-9, -70	2	3	4	3	3	3	1	3	0	3	0	2	0	0	1	0	0	0	0	0	3	0	4	3	1	1	3	1	2
	8	07MAY97	62, 1	3	4	3	3	3	3	1	2	0	3	3	1	0	0	2	0	0	0	0	2	3	2	4	1	3	0	3	2	2
	24	19AUG97	166, 105	2	1	2	2	2	2	2	2	1	3	3	2	0	0	0	0	0	0	1	1	2	2	3	3	3	3	3	3	1

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.001.00061	SC	19JUL94	-10, .	2	3	1	0	3	4	0	0	0	2	0	1	3	0	2	0	0	0	0	0	2	0	0	0	2	0	0	0	1
329.001.00066	SC	14NOV94	-8, .	3	3	3	4	3	3	3	2	3	3	0	3	0	0	1	1	0	0	0	0	0	0	4	4	4	4	4	4	4
329.001.00067	SC	15NOV94	-7, .	3	4	0	4	2	2	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	3	3	4	0	0	4	4
329.001.00070	SC	14FEB95	-8, .	1	2	0	3	2	0	1	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0	0	3
329.001.00122	SC	13JUN95	-7, -64	2	3	2	1	2	2	2	3	2	3	0	2	0	0	0	0	0	0	1	0	0	0	3	3	2	4	0	3	2
	8	16AUG95	58, 1	2	4	3	3	2	2	1	3	1	3	0	2	0	0	1	0	0	1	3	1	3	0	3	3	3	4	0	3	3
329.002.00050	SC	10MAR95	-13, .	1	2	2	1	1	4	3	2	0	4	0	2	0	0	0	0	0	0	1	0	4	0	4	4	0	4	4	4	4
	5	28APR95	37, .	1	2	2	1	1	3	3	3	0	4	0	1	0	0	0	0	0	0	2	0	3	3	4	4	4	4	3	4	4
329.002.00056	SC	24JUN94	-25, .	1	1	1	4	1	4	4	0	0	4	0	1	4	1	1	4	4	1	1	0	4	4	4	4	4	4	4	4	4
329.002.00057	SC	11AUG94	-28, -85	1	4	1	3	1	0	0	1	0	0	0	1	0	0	1	0	0	0	0	0	0	1	2	1	0	0	3	0	0
	8	03NOV94	57, -1	0	4	1	2	1	1	1	0	0	4	0	1	0	0	1	0	0	0	0	0	1	3	3	4	0	0	2	0	0
	16	11JAN95	126, 69	0	3	0	2	2	2	2	0	0	2	0	1	0	0	1	0	0	0	0	0	2	0	3	3	1	0	2	0	0
329.002.00098	SC	20DEC94	-14, .	1	4	3	0	4	4	4	4	3	4	4	2	2	0	3	0	3	3	4	0	4	4	4	4	3	0	0	0	4
	8	02MAR95	59, .	2	4	2	0	4	4	4	4	1	4	0	2	0	1	2	0	2	1	3	1	4	0	4	4	0	0	0	0	3
329.002.00100	SC	16FEB95	-19, -77	4	4	4	3	4	3	1	4	0	4	0	3	0	0	2	2	0	0	0	0	0	0	4	4	1	0	0	0	4
	8	04MAY95	59, 1	4	2	4	3	4	3	4	3	2	4	4	3	2	2	2	1	0	0	1	0	4	3	4	3	3	1	2	0	3
	16	06JUL95	122, 64	4	4	4	4	4	3	4	3	1	4	0	2	0	1	3	4	0	0	0	0	0	0	4	4	4	0	4	0	4
329.002.00103	SC	11APR95	-9, -65	2	4	0	4	4	2	2	0	0	4	0	2	0	0	0	0	0	0	0	0	0	0	3	3	2	2	3	3	3
	8	15JUN95	57, 1	3	4	1	1	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4	0	0	4	0	0	4
	16	10AUG95	113, 57	2	4	0	1	2	2	0	1	0	1	0	1	0	0	0	0	0	0	0	0	1	0	3	0	1	4	1	0	4

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.002.00104	SC	28APR95	-6, -62	1	4	1	4	3	2	2	2	1	2	0	2	0	0	1	0	0	0	1	0	3	1	2	3	1	0	1	3	2
	8	29JUN95	57, 1	2	3	1	2	3	2	2	3	0	1	0	2	0	0	2	0	0	0	1	0	3	3	2	0	1	0	2	3	2
	32	02JAN96	244, 188	2	4	1	3	3	3	2	2	1	3	0	2	0	0	1	0	0	1	1	1	3	0	2	2	1	2	0	0	2
329.002.00243	SC	27FEB96	-16, .	3	4	0	4	3	3	0	1	0	2	0	1	0	0	1	0	0	0	0	0	0	0	4	0	1	0	1	0	4
329.002.00244	SC	14MAR96	-7, -64	1	3	3	4	2	4	4	4	1	4	0	3	0	0	1	0	0	1	1	0	3	0	4	4	4	4	1	1	4
	8	16MAY96	57, -1	3	4	3	4	3	4	4	3	1	4	3	3	0	0	1	0	0	1	3	0	4	3	4	4	4	4	3	0	4
329.002.00321	SC	15MAY96	-8, .	2	4	4	3	2	3	1	1	0	0	0	3	0	0	1	0	0	0	0	0	0	0	2	3	0	0	1	1	2
329.002.00322	SC	06JAN97	-3, .	.	.	.	1	1	.	0	0	0	3	2	1	1	0	1	0	0	0	1	1	3	2	3	1	1	0	1	1	0
329.003.00073	SC	11JAN95	-8, .	1	3	2	3	2	3	2	1	1	2	0	0	0	0	1	0	1	1	1	0	1	0	3	1	1	0	3	1	2
329.003.00076	SC	24JAN95	-7, -62	2	4	1	4	3	3	4	2	0	4	2	2	0	1	2	0	0	0	0	0	4	3	4	4	4	3	4	1	1
	32	11OCT95	254, 199	2	4	0	3	2	2	2	1	0	2	2	2	0	1	1	0	0	0	0	0	3	3	4	4	4	4	4	3	3
329.003.00088	SC	06FEB95	-22, .	1	2	2	0	2	3	1	1	0	2	0	2	0	0	1	0	0	0	1	1	2	0	3	0	2	1	1	0	4
329.003.00090	SC	08MAR95	-6, .	3	3	2	2	3	3	2	0	0	4	0	4	0	3	1	0	0	2	1	0	4	3	4	3	1	1	0	0	4
	8	16MAY95	64, .	4	4	1	4	3	4	3	2	0	4	0	4	0	0	3	0	1	1	1	0	4	0	4	1	4	0	0	0	4
329.003.00092	SC	13APR95	-20, -78	2	4	2	2	2	1	1	1	1	4	0	3	0	0	0	0	0	0	1	0	4	0	2	0	1	0	0	0	2
	8	30JUN95	59, 1	2	4	2	2	2	2	1	1	1	4	0	3	0	0	1	0	0	0	0	0	4	0	2	3	1	0	0	0	3
	32	02JAN96	245, 187	2	4	2	3	2	0	0	1	0	0	0	3	0	0	0	0	0	0	0	0	3	2	2	3	1	0	2	0	3
329.003.00093	SC	08JUN95	-13, -76	0	3	2	4	1	2	3	2	0	2	0	1	0	0	0	0	0	0	0	0	0	0	3	4	2	4	4	0	2
	8	22AUG95	63, -1	0	2	1	4	1	3	3	1	1	3	0	1	1	0	0	1	1	2	1	0	4	4	4	4	4	4	4	4	4
	16	03OCT95	105, 42	0	3	0	4	1	3	3	1	0	4	3	2	2	0	0	0	1	1	0	0	1	1	4	4	3	3	3	2	3

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.003.00247	SC	05JAN96	-27, -81	0	3	0	3	3	3	3	1	0	1	0	2	0	0	0	0	0	0	2	0	0	0	4	3	0	0	4	4	2
	8	26MAR96	55, 1	2	3	2	4	2	3	2	3	0	3	0	2	1	0	1	0	0	0	1	0	1	0	4	3	1	0	3	4	2
329.003.00249	SC	01MAR96	-6, .	1	4	0	3	1	3	2	1	0	1	0	1	0	0	0	0	0	0	1	0	2	0	3	3	2	2	3	2	4
	8	30APR96	55, .	1	3	1	4	2	3	.	3	0	1	0	4	1	0	1	0	0	0	1	0	3	0	4	4	1	4	4	4	4
329.003.00289	SC	12FEB96	-16, -72	3	3	0	0	0	0	.	3	1	0	0	3	3	0	0	0	0	3	3	0	0	0	0	0	4	0	0	4	0
	8	24APR96	57, 1	4	4	2	0	4	0	2	2	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
	32	11OCT96	227, 171	0	0	2	3	3	3	4	3	3	3	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
329.003.00290	SC	06MAR96	-5, .	2	4	2	4	2	0	0	0	1	4	4	2	0	1	1	0	0	1	1	0	2	2	2	0	0	0	0	4	2
329.003.00317	SC	12DEC96	-7, .	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	3	3	1
	8	11FEB97	55, .	4	1	3	4	1	2	1	2	2	3	1	3	1	2	1	0	0	1	1	2	4	1	3	2	2	2	4	1	1
329.004.00013	SC	05JUL94	-14, -73	1	3	2	4	1	3	4	4	1	1	3	1	0	0	1	0	0	0	1	4	4	4	4	4	3	4	1	1	3
	8	16SEP94	60, 1	3	4	2	4	2	4	4	4	1	3	4	3	0	0	2	3	1	1	3	3	3	4	4	4	4	4	1	1	4
329.004.00014	SC	22NOV94	-7, .	1	3	0	4	4	4	4	2	2	4	4	4	0	0	2	0	0	2	0	0	0	0	4	4	4	1	4	0	4
329.004.00211	SC	24JAN96	-9, .	1	1	0	1	1	3	0	1	0	4	1	0	0	0	0	0	0	0	0	0	0	0	4	4	4	2	2	1	4
329.004.00215	SC	12MAR97	-8, .	1	1	1	1	1	3	1	0	0	2	0	1	0	0	0	0	0	0	0	0	0	0	2	2	0	2	3	0	4
329.005.00003	SC	12SEP94	-8, .	0	3	4	4	1	1	4	0	4	0	0	4	0	0	4	0	4	4	0	4	4	4	4	4	4	0	0	4	4
329.005.00006	SC	27OCT94	-8, -68	2	3	1	4	1	4	4	1	1	4	0	2	0	0	0	0	0	0	0	0	0	0	3	4	3	4	1	4	3
	8	03JAN95	61, 1	3	4	2	4	4	4	4	4	3	3	3	3	0	0	0	0	0	0	0	0	0	0	4	4	4	4	2	4	4
	24	28APR95	176, 116	4	4	4	4	4	4	3	3	1	2	0	2	0	0	0	0	0	0	0	0	0	0	4	4	4	4	2	4	4
329.005.00007	SC	02NOV94	-7, -70	3	4	4	4	1	2	0	1	0	4	0	1	0	0	0	0	0	0	0	0	4	0	4	0	1	0	1	0	0

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00007	8	11JAN95	64, 1	4	4	4	4	2	3	2	0	0	4	0	0	0	0	0	0	0	0	0	0	4	0	4	1	0	0	1	0	0
	32	09AUG95	274, 211	4	4	4	4	3	4	2	2	0	4	0	4	0	0	1	0	0	0	0	0	4	2	4	3	4	4	4	0	3
329.005.00009	SC	07DEC94	-5, .	4	3	4	1	2	3	4	3	1	4	0	2	1	0	0	0	0	1	0	0	3	0	4	4	3	3	4	4	4
	8	07FEB95	58, .	4	4	4	3	2	3	4	3	1	4	1	1	0	0	0	0	0	1	0	0	4	3	4	4	4	4	4	4	4
329.005.00110	SC	04JAN95	-7, .	4	3	4	4	3	3	4	3	3	2	2	3	0	0	3	0	1	1	2	0	0	0	4	4	4	4	4	4	4
329.005.00113	SC	20JAN95	-10, .	2	1	0	4	2	4	3	4	1	4	4	1	0	1	1	0	0	1	0	0	0	1	4	2	1	4	4	0	4
329.005.00117	SC	06MAR95	-12, .	1	4	1	1	4	4	4	3	1	4	0	1	0	1	2	0	0	1	0	0	4	3	4	0	4	2	0	1	1
	8	15MAY95	59, .	1	3	1	2	2	4	3	3	1	4	0	1	1	1	1	1	1	1	3	0	4	1	4	2	1	1	0	0	1
329.005.00118	SC	09MAY95	-8, .	1	4	1	4	2	4	1	4	0	4	0	4	0	0	0	0	0	0	2	0	4	0	4	4	3	4	1	0	4
329.005.00153	SC	11JAN96	-14, -70	2	1	4	2	2	4	2	3	1	3	1	3	0	1	1	1	0	0	2	1	3	3	4	3	3	3	2	0	1
	8	21MAR96	57, 1	3	4	4	3	3	3	1	4	1	2	2	3	1	1	1	0	0	1	2	2	2	0	4	1	1	1	1	0	2
	32	04SEP96	224, 168	2	3	4	2	2	3	2	3	0	3	0	3	0	0	0	0	0	0	2	1	3	3	4	2	2	0	1	0	1
329.005.00255	SC	26FEB96	-7, .	1	3	2	2	2	2	2	3	2	2	1	3	0	0	2	0	0	3	2	0	0	0	4	4	4	0	2	0	4
	8	29APR96	57, .	2	4	3	1	4	3	2	2	2	2	1	3	0	0	2	0	0	3	1	0	1	1	4	4	4	1	0	0	4
329.005.00256	SC	20FEB96	-14, -70	2	0	2	4	4	4	2	2	0	4	0	3	0	0	0	0	0	0	0	0	4	4	4	0	4	0	4	0	4
	8	30APR96	57, 1	2	4	3	4	4	4	2	2	0	4	0	3	0	0	0	0	0	0	0	0	0	4	4	4	4	4	4	0	4
329.005.00295	SC	21MAR96	-7, .	0	4	0	1	2	3	0	3	0	0	0	2	0	0	3	0	0	2	1	0	0	0	3	2	0	0	3	0	3
	8	22MAY96	56, .	1	3	0	0	2	3	1	3	0	0	0	3	0	0	2	0	0	0	1	0	0	0	3	0	0	0	1	0	3
329.005.00297	SC	28MAR96	-22, .	0	2	0	4	1	3	2	1	2	3	3	0	0	0	0	0	0	1	0	0	3	1	3	4	1	2	0	3	1
329.005.00332	SC	05DEC96	-7, .	1	3	1	4	1	3	1	1	0	4	4	1	0	0	0	0	0	0	0	0	4	4	3	2	1	1	0	0	2

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00332	8	06FEB97	57, .	2	3	0	4	0	3	3	3	0	4	0	3	0	0	0	0	0	0	1	0	3	1	4	3	1	0	0	0	3
329.005.00335	SC	20FEB97	-8, .	1	4	2	4	2	4	2	3	0	4	0	1	0	0	0	0	0	0	0	0	4	0	4	4	4	0	0	0	4
329.006.00040	SC	10FEB95	-6, .	3	1	3	0	1	3	0	3	0	4	0	2	0	0	0	0	0	0	0	0	3	0	4	1	1	1	1	1	1
329.006.00041	SC	22MAR95	-14, -78	1	1	1	3	0	1	1	0	0	3	3	1	0	0	0	0	0	0	0	0	2	1	4	4	1	0	1	0	3
	8	31MAY95	57, -8	1	1	1	4	0	2	2	0	0	4	3	1	0	1	0	1	0	1	0	0	1	1	4	4	4	4	4	4	4
	32	21NOV95	231, 167	3	2	2	4	1	2	4	2	4	4	4	4	3	1	1	3	0	4	2	2	1	3	4	4	4	4	4	4	4
329.007.00139	SC	04MAY95	-4, .	0	3	0	4	1	3	1	3	0	3	0	3	1	0	0	0	0	0	1	0	1	1	2	1	0	0	0	1	1
329.007.00143	SC	26OCT95	-14, .	2	3	2	3	3	3	0	2	0	3	0	2	0	0	0	0	0	0	2	0	0	0	4	4	0	0	0	3	4
329.007.00146	SC	18JAN96	-7, -60	1	4	2	4	4	4	1	4	1	4	0	1	2	1	2	0	0	1	3	1	4	0	4	4	4	0	0	0	4
	8	18MAR96	54, 1	1	4	2	4	4	4	1	4	1	4	0	1	0	0	1	0	0	0	1	0	4	4	4	4	1	0	0	0	4
	32	09SEP96	229, 176	0	3	1	2	3	4	1	4	1	4	4	2	0	0	1	0	0	0	1	0	4	4	4	3	4	0	0	0	3
329.007.00269	SC	04APR96	-7, .	0	3	0	4	2	3	1	1	1	4	0	1	0	0	2	0	0	0	1	0	4	0	3	4	4	0	1	1	4
	3	02MAY96	22, .	0	3	1	4	1	3	0	3	0	4	0	1	0	0	1	0	0	0	1	0	4	0	1	4	1	0	0	0	3
329.007.00270	SC	02MAY96	-7, .	2	3	2	1	3	3	0	0	0	2	0	2	0	0	2	0	0	0	0	0	0	0	4	3	3	0	1	1	2
	7	27JUN96	50, .	3	4	3	0	3	4	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0
329.007.00307	SC	09MAY96	-7, .	3	3	3	3	1	1	2	0	0	1	0	3	1	1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	1
	8	25JUL96	71, .	3	3	4	3	0	1	2	0	1	1	0	3	1	1	0	0	0	0	0	0	0	0	3	1	0	1	0	0	0
329.007.00308	SC	27JUN96	-5, .	0	4	1	3	4	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	4	0	1	0	0	0	0
329.008.00159	SC	06SEP95	-7, -69	2	3	2	3	1	3	3	0	0	3	0	2	1	0	0	0	0	1	1	0	3	1	4	4	4	2	1	0	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.008.00161	SC	31OCT95	-16, -71	2	4	3	3	4	2	0	1	1	3	1	2	0	0	1	0	0	0	1	0	3	0	3	2	0	0	3	1	1
329.008.00187	SC	15NOV95	-14, .	1	4	4	3	3	4	3	3	1	3	0	1	0	0	1	0	0	0	1	0	0	0	4	0	0	0	3	4	3
	8	26JAN96	59, .	1	3	4	3	2	3	2	3	0	4	0	1	0	1	1	0	0	0	0	0	4	0	4	0	0	0	1	0	2
329.008.00192	SC	14FEB96	-20, .	0	2	1	3	1	2	1	1	1	2	0	1	1	0	0	0	0	0	1	0	1	0	4	4	2	0	1	0	2
329.008.00272	SC	19MAR96	-15, -71	1	3	1	3	1	3	0	2	1	0	0	2	3	1	2	0	0	0	2	0	0	0	3	3	3	0	0	0	1
	8	29MAY96	57, 1	2	3	1	3	2	4	0	2	1	3	0	2	3	1	3	1	0	0	3	0	0	0	2	3	4	0	0	0	1
329.008.00273	SC	19APR96	-28, -91	1	3	2	3	2	3	2	0	2	4	0	1	0	0	0	0	0	0	0	0	4	0	3	3	2	0	0	0	3
	8	19JUL96	64, 1	2	3	2	4	3	4	2	1	3	4	0	2	1	2	2	0	0	0	0	0	4	0	4	4	1	4	0	3	4
329.009.00127	SC	03APR95	-7, .	0	4	0	0	3	2	0	0	0	1	0	4	2	0	0	0	0	2	0	0	1	3	4	3	0	0	0	1	2
329.009.00132	SC	17MAY95	-6, -63	2	3	2	4	3	3	1	4	0	4	0	3	2	1	2	1	0	0	3	0	4	4	4	4	4	1	0	0	4
	8	19JUL95	58, 1	2	3	1	4	3	3	0	2	2	1	0	3	3	2	2	0	0	0	1	1	4	0	4	4	4	4	4	4	4
329.009.00134	SC	28JUN95	-8, .	3	4	3	0	2	1	1	1	1	0	0	2	0	0	0	0	0	1	0	0	0	0	2	2	0	0	0	1	0
	8	29AUG95	55, .	4	3	4	1	2	4	2	2	2	4	0	3	0	0	1	0	0	2	1	0	0	0	4	4	1	4	0	4	1
329.009.00137	SC	03OCT95	-7, .	1	3	1	1	3	1	0	2	0	3	0	2	0	0	1	0	0	0	0	0	1	0	1	3	0	0	0	0	1
	8	05DEC95	57, .	2	3	0	3	2	2	0	1	1	4	0	1	0	0	1	0	0	2	0	0	0	0	1	3	0	0	0	0	2
329.009.00171	SC	31OCT95	-7, .	2	3	3	2	3	4	4	3	3	4	4	3	4	3	3	3	3	2	3	3	3	3	4	4	4	0	1	1	1
329.009.00172	SC	06NOV95	-7, -64	2	4	2	4	1	3	0	4	0	4	0	4	0	0	0	0	0	0	1	0	4	0	4	0	4	0	0	0	0
	8	09JAN96	58, 1	4	4	3	4	1	3	0	2	0	4	0	4	0	0	0	0	0	0	1	0	4	0	4	0	4	0	0	0	3
	32	08JUL96	239, 182	3	3	0	3	0	1	0	3	0	3	0	4	0	0	0	0	0	0	3	0	0	0	4	1	4	0	0	1	3
329.009.00194	SC	28NOV95	-7, -63	1	2	1	0	2	0	0	1	0	1	0	1	0	0	1	0	0	0	0	0	0	0	2	1	1	0	0	1	1

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00194	8	30JAN96	57, 1	2	3	1	1	2	2	0	1	0	1	0	1	2	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1	2
	24	04JUN96	183, 127	2	2	1	4	1	1	0	1	1	3	0	2	0	0	1	0	0	0	1	1	2	0	1	1	1	0	0	2	2
329.009.00195	SC	06DEC95	-9, .	1	3	1	1	2	2	1	1	0	4	0	1	0	0	0	0	0	0	0	0	4	0	4	3	1	0	0	4	4
329.009.00199	SC	10JAN96	-6, .	1	4	3	2	2	1	1	1	0	4	0	1	0	0	2	0	0	1	1	1	1	1	3	1	1	1	0	1	0
	8	13MAR96	58, .	3	3	2	4	2	4	3	4	3	3	3	2	0	2	1	1	2	2	2	1	2	2	4	2	4	2	0	3	2
329.009.00203	SC	28FEB96	-5, .	2	2	1	1	3	1	0	0	0	4	0	3	1	0	2	0	0	0	0	0	0	0	4	1	1	0	0	4	1
329.009.00236	SC	17DEC96	-13, .	0	1	0	4	1	3	0	2	0	3	0	1	0	0	1	0	0	0	0	0	3	0	4	4	3	0	0	1	3
	4	27JAN97	29, .	1	1	0	4	1	2	0	1	0	3	0	1	0	0	1	0	0	0	0	0	3	0	4	1	1	1	0	0	1
329.009.00239	SC	11NOV96	-8, -65	1	4	2	1	4	3	1	3	0	4	0	1	0	0	1	0	0	0	1	0	3	0	4	2	1	0	0	3	1
	8	15JAN97	58, 1	3	4	4	1	4	3	2	3	0	4	0	2	0	0	3	0	0	0	3	0	3	3	4	3	3	1	0	3	3
329.009.00262	SC	07FEB97	-10, .	1	3	0	4	3	1	0	3	0	3	0	3	2	0	2	0	0	0	1	2	0	0	1	3	1	0	0	4	4
	8	14APR97	57, .	3	3	2	4	3	3	3	4	0	3	0	3	2	1	1	0	0	0	2	0	1	1	3	3	1	0	0	3	3
329.009.00264	SC	25OCT96	-7, .	1	1	1	2	2	2	1	2	0	4	0	2	0	0	1	0	0	0	0	0	4	1	2	1	1	1	0	0	2
	7	23DEC96	53, .	1	2	1	0	2	1	0	1	0	4	0	1	1	0	1	0	0	0	1	0	0	4	1	1	1	0	0	0	3
329.009.00301	SC	06MAR96	-13, -69	1	3	2	3	4	4	1	3	0	4	1	1	0	1	3	3	0	0	3	0	4	0	4	4	1	0	0	4	4
	8	14MAY96	57, 1	3	4	2	4	2	4	1	3	1	4	0	1	0	0	2	4	0	1	1	0	0	0	4	4	4	1	0	4	4
329.009.00305	SC	01MAY96	-6, -63	1	4	2	1	3	3	0	2	0	0	0	1	0	0	1	0	0	0	0	0	0	0	2	1	0	0	0	0	1
	8	03JUL96	58, 1	1	4	3	0	3	3	0	1	0	3	0	1	0	0	2	0	0	0	0	0	0	0	2	1	0	0	0	0	0
	32	10JAN97	249, 192	2	4	3	3	4	4	0	4	0	3	0	3	0	0	2	0	0	0	1	0	0	0	3	2	0	0	0	0	1
329.009.00325	SC	21AUG96	-6, -61	4	4	4	3	3	4	3	3	0	4	0	4	0	0	1	0	0	0	0	0	0	0	4	4	4	0	0	0	4
	8	21OCT96	56, 1	4	3	4	4	2	4	0	4	1	3	0	3	0	1	2	0	0	0	1	0	1	0	4	4	0	0	4	0	4

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00325	16	16DEC96	112, 57	4	3	4	3	2	3	0	4	0	4	2	3	0	0	1	0	0	1	0	0	0	0	2	4	1	0	1	0	2
329.009.00326	SC	26AUG96	-10, -63	0	3	0	2	4	0	0	3	0	3	0	4	0	0	4	0	0	0	2	3	4	4	3	3	1	0	0	0	3
	8	28OCT96	54, 1	2	4	3	3	4	2	2	4	3	4	4	3	2	2	3	4	1	1	4	1	3	2	4	4	4	1	0	0	2
	16	16DEC96	103, 50	1	3	3	4	4	2	2	3	2	3	2	2	2	2	2	2	0	0	2	0	3	0	3	3	2	0	0	0	2
329.010.00279	SC	08MAR96	-14, -70	1	3	1	4	0	0	0	0	.	4	0	2	1	1	1	1	1	2	0	0	0	0	3	3	3	0	0	4	4
	8	17MAY96	57, 1	1	2	1	3	1	1	0	0	0	3	0	1	1	0	0	0	0	0	0	0	0	0	3	3	2	0	0	2	4
	32	06NOV96	230, 174	2	2	1	3	2	3	1	1	0	3	1	4	4	3	2	0	3	2	3	0	0	0	3	1	1	0	0	4	4
329.010.00281	SC	19JUL96	-7, -68	1	4	1	2	4	1	0	1	0	1	0	2	3	0	2	0	1	0	1	2	1	1	3	0	0	0	0	0	0
	8	25SEP96	62, 1	0	4	0	0	1	1	0	2	0	0	0	1	0	0	0	0	0	0	2	2	0	0	2	0	0	0	0	0	1
	24	03JAN97	162, 101	1	3	1	3	3	3	1	2	1	2	0	1	0	0	0	0	0	0	2	3	2	0	2	1	0	0	0	0	1
329.011.00163	SC	18NOV95	-7, .	1	3	2	1	3	4	4	1	1	4	1	1	0	0	1	0	0	0	1	0	4	4	3	3	1	1	0	0	0
329.011.00208	SC	22AUG96	-15, -74	2	2	0	0	2	1	0	0	1	4	0	2	1	0	0	0	0	1	0	0	3	0	3	2	2	2	3	0	3
	8	03NOV96	59, -1	1	2	2	2	1	1	0	1	1	2	0	2	0	0	0	0	0	2	1	1	1	0	4	3	3	3	4	0	4
329.011.00209	SC	23AUG96	-19, -81	1	1	0	0	0	0	1	0	0	4	0	2	0	0	0	0	0	0	0	0	0	0	3	0	0	2	0	0	2
	8	11NOV96	62, -1	3	2	0	3	1	2	3	0	0	4	0	3	0	0	0	0	0	1	0	1	4	0	4	3	1	2	0	0	2
329.011.00284	SC	13MAR96	-9, -65	1	1	3	2	1	2	2	2	1	3	0	1	0	0	0	1	0	1	2	0	3	3	3	2	2	0	1	1	2
	8	16MAY96	56, -1	2	2	3	3	1	3	3	3	1	3	0	2	0	0	0	1	0	1	3	0	4	0	4	4	4	3	1	1	3
329.011.00286	SC	15MAY96	-22, -90	0	4	1	3	3	2	3	2	0	4	0	2	0	0	1	0	0	0	0	0	0	0	3	2	1	0	0	1	2
	8	09AUG96	65, -4	1	4	1	2	3	2	2	2	0	0	0	2	0	0	1	0	0	0	0	0	0	0	2	1	0	0	0	1	3
329.012.00026	SC	09NOV95	-19, .	0	4	4	2	2	0	0	3	0	4	0	2	2	0	2	0	0	0	2	0	4	0	4	3	1	0	4	0	1
329.012.00219	SC	24MAY96	-7, -67	1	2	1	2	2	2	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2	2	1	1	0	1	3

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.012.00219	8	30JUL96	61, 1	1	3	1	3	2	3	0	2	2	2	0	2	0	0	1	0	0	0	1	0	0	0	2	3	2	3	3	0	3
	32	24JAN97	239, 179	0	3	1	3	3	3	0	0	0	2	2	0	0	0	1	0	0	0	0	0	0	0	2	4	1	1	2	0	1
329.012.00221	SC	18JUN96	-7, -70	1	4	4	3	3	4	0	0	1	4	0	2	4	0	0	2	0	1	0	0	4	4	4	0	0	0	0	1	1
	8	27AUG96	64, 1	3	3	2	2	4	4	2	4	0	4	0	1	0	0	0	3	0	1	0	0	4	4	4	0	0	1	0	0	1
329.012.00223	SC	23AUG96	-7, .	1	4	0	1	4	2	2	0	0	2	0	1	0	0	2	0	0	0	0	0	3	0	3	4	0	0	1	1	3
329.012.00227	SC	12DEC96	-6, -75	1	2	3	4	1	0	4	2	3	4	0	2	0	0	0	0	0	3	1	0	0	0	4	4	3	3	3	1	1
	8	25FEB97	70, 1	3	2	3	4	3	1	1	1	1	4	0	1	0	0	0	1	0	0	0	0	0	0	4	1	1	3	0	1	0
	32	19AUG97	245, 176	2	3	3	4	4	3	3	2	1	3	2	2	0	0	0	0	2	0	0	0	0	0	3	3	3	2	4	4	4
329.012.00230	SC	20FEB97	-8, -77	2	2	0	2	1	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	1	0	0	2	2	2
	8	08MAY97	70, 1	4	3	0	1	2	0	0	1	0	3	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	4	0	0

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.001.00062	SC	06OCT94	-14, .	2	3	3	2	1	2	0	2	0	1	0	1	0	0	0	0	0	0	0	0	1	0	3	1	0	0	0	0	2
329.001.00064	SC	04NOV94	-6, -60	1	2	0	3	1	1	0	3	0	0	0	1	0	0	0	0	0	0	1	0	0	0	4	2	1	0	0	0	0
	8	03JAN95	55, 1	1	2	1	3	1	1	0	3	0	0	0	1	0	0	0	1	0	0	1	0	0	0	4	3	1	0	0	0	1
329.001.00069	SC	07FEB95	-9, .	1	4	3	3	3	3	0	3	0	4	0	3	0	0	1	0	0	0	3	2	0	0	3	3	1	0	0	0	2
	8	13APR95	57, .	1	3	3	4	3	4	0	3	0	3	0	3	0	0	1	0	0	0	3	2	3	3	4	3	1	0	0	0	1
329.001.00071	SC	02FEB95	-21, .	1	3	0	1	1	1	1	0	0	4	0	1	0	0	1	0	0	0	0	0	3	0	4	2	1	1	0	1	1
	8	20APR95	57, .	1	2	0	1	1	1	2	1	1	4	0	1	0	0	0	0	0	0	0	0	0	0	3	2	1	1	0	1	1
329.001.00123	SC	14DEC95	-21, .	1	0	2	2	0	2	3	0	0	4	0	0	0	1	0	0	0	1	0	0	3	0	0	1	1	1	0	0	2
329.001.00207	SC	19FEB96	-9, .	2	4	0	0	2	2	0	1	0	4	0	2	0	0	0	0	0	0	0	0	0	0	4	4	1	3	0	0	4
	8	24APR96	57, .	1	3	0	0	1	3	0	1	0	4	0	2	0	0	0	0	0	0	0	0	0	0	4	4	2	4	0	0	3
329.002.00049	SC	03MAR95	-6, .	1	4	3	2	4	1	0	1	0	1	0	1	0	0	3	0	0	0	1	1	1	0	1	2	1	1	0	0	3
	8	05MAY95	58, .	1	3	3	1	3	3	0	0	0	3	0	1	0	0	1	0	0	0	0	0	0	0	1	2	2	2	0	0	3
329.002.00059	SC	03NOV94	-7, .	0	3	4	0	2	4	3	1	0	4	0	1	0	0	0	0	0	0	2	0	0	0	3	3	0	0	0	0	1
	8	05JAN95	57, .	3	3	3	1	1	3	1	1	0	2	0	2	0	0	0	0	0	0	1	0	2	2	2	2	0	0	0	0	1
329.002.00060	SC	24JAN95	-7, -63	1	2	2	3	2	2	2	3	0	1	0	3	0	0	0	0	0	0	0	0	3	0	4	3	3	0	3	0	1
	8	28MAR95	57, 1	1	3	1	3	1	4	0	4	0	0	0	1	0	0	0	0	0	0	0	0	4	0	4	4	4	0	1	1	1
329.002.00097	SC	20DEC94	-14, -72	3	4	3	0	1	3	4	1	0	4	0	3	0	2	1	0	2	0	1	0	4	0	4	1	1	0	0	0	2
	8	02MAR95	59, 1	3	4	3	0	2	3	4	3	1	4	0	3	0	1	1	0	1	0	1	0	4	0	4	3	1	0	0	0	2
	32	05SEP95	246, 188	3	3	3	3	1	3	4	3	1	4	0	3	1	2	2	0	2	0	2	0	4	0	4	2	1	0	0	0	2
329.002.00101	SC	20MAR95	-8, -66	2	3	1	4	3	1	1	0	1	1	0	1	0	0	1	3	0	0	0	0	1	1	4	0	1	0	1	0	1
	8	25MAY95	59, 1	1	3	2	4	3	2	0	4	0	3	0	2	0	0	0	0	0	0	3	0	4	4	2	4	4	0	4	0	1

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.002.00107	SC	18JAN96	-7, -63	1	3	1	1	2	4	0	4	0	4	0	2	0	0	1	0	0	0	2	0	3	0	4	4	4	0	1	0	3
	8	21MAR96	57, 1	3	4	3	2	3	4	4	4	3	4	0	2	0	0	2	0	0	0	4	0	4	0	4	4	4	0	4	0	4
	32	26SEP96	246, 190	1	4	4	4	4	4	4	4	2	4	0	3	0	0	1	0	0	0	0	0	4	4	4	4	4	0	2	0	4
329.002.00241	SC	25JAN96	-12, -68	1	4	1	4	3	3	2	0	0	3	0	2	0	0	0	0	0	0	0	0	3	1	4	3	3	1	3	3	2
	8	02APR96	57, 1	2	4	1	4	3	3	1	1	0	3	0	2	0	0	0	0	0	0	0	0	3	0	4	4	3	3	4	3	3
329.002.00246	SC	01APR96	-17, .	3	2	3	2	2	1	3	1	0	4	0	2	1	0	1	0	0	0	0	0	4	3	4	2	4	3	0	4	0
	8	18JUN96	62, .	3	3	3	2	2	2	3	2	1	3	1	3	0	1	1	1	1	1	2	2	2	3	3	2	3	2	2	1	1
329.002.00320	SC	09MAY96	-7, -68	2	4	4	4	3	3	2	4	0	4	0	2	2	0	3	0	0	0	0	0	4	0	4	4	4	3	4	0	4
	8	16JUL96	62, 1	2	4	3	4	2	4	4	4	0	4	0	3	0	1	1	0	0	0	2	0	4	0	4	4	4	3	3	0	4
329.002.00323	SC	04NOV96	-8, -66	1	4	1	4	4	4	3	4	1	4	0	0	0	0	0	0	0	0	0	0	4	0	4	4	0	4	0	4	4
	8	09JAN97	59, 1	3	2	4	4	3	4	3	3	1	1	3	2	1	1	1	1	1	1	0	0	2	2	4	4	3	4	3	1	2
	32	12JUN97	213, 155	3	4	4	.	3	4	4	3	2	1	3	2	1	2	2	1	1	1	2	0	1	3	4	4	4	4	1	3	3
329.003.00074	SC	18JAN95	-7, -63	1	2	1	0	0	1	0	4	4	4	0	1	1	1	1	1	0	4	0	0	0	4	4	4	2	0	4	4	4
	8	22MAR95	57, 1	1	4	2	4	4	4	4	4	3	4	0	1	0	0	0	0	0	1	2	0	0	0	4	2	1	0	4	2	3
	32	11OCT95	260, 204	1	1	0	0	0	0	0	4	3	4	3	0	0	0	0	0	0	1	0	0	3	0	4	0	0	0	4	4	4
329.003.00078	SC	11APR95	-15, .	2	3	2	2	1	3	4	3	1	1	0	2	0	0	0	0	0	0	1	0	0	0	4	4	2	1	3	0	3
	8	21JUN95	57, .	3	3	3	2	2	3	3	1	0	1	0	1	0	0	0	0	0	0	0	0	1	0	4	4	4	1	3	0	3
329.003.00080	SC	22NOV95	-5, .	4	4	4	0	4	0	.	4	4	4	4	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	4	4	4
329.003.00085	SC	26OCT94	-13, .	1	3	4	4	1	1	3	0	0	4	0	3	0	0	1	0	0	0	0	0	4	4	4	0	4	0	3	0	3
	8	03JAN95	57, .	3	3	4	4	1	4	4	1	0	4	0	4	0	0	0	0	0	0	0	0	0	4	4	3	4	0	3	0	4
329.003.00086	SC	09NOV94	-19, -76	1	3	0	0	0	2	1	0	0	4	0	1	0	0	0	0	0	0	0	0	4	2	4	4	1	0	0	3	3
	8	23JAN95	57, -1	3	3	0	1	2	2	2	0	0	4	0	3	1	1	1	0	0	0	0	0	4	0	4	4	0	0	0	0	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.003.00086	32	17AUG95	263, 206	3	4	1	4	0	4	0	0	0	4	0	4	1	2	2	2	0	0	0	0	4	0	4	4	4	0	0	0	4
329.003.00094	SC	20OCT95	-4, .	2	1	0	4	1	4	4	3	4	4	0	4	0	1	1	0	0	1	1	0	4	4	4	4	4	0	4	0	4
	8	19DEC95	57, .	0	1	0	0	1	1	1	0	1	1	1	0	0	1	0	0	0	0	0	0	4	4	4	0	3	0	4	0	4
329.003.00252	SC	19MAR96	-22, .	1	1	0	2	1	2	1	1	1	4	0	1	0	0	0	0	0	1	0	0	4	0	4	2	3	1	1	0	4
329.003.00315	SC	29OCT96	-14, .	2	3	1	0	2	2	3	3	1	2	0	1	0	0	0	0	0	2	1	0	0	0	2	3	2	0	2	0	3
	8	07JAN97	57, .	2	3	1	3	1	2	1	3	1	2	0	1	0	0	0	0	0	1	1	0	0	0	2	3	3	1	3	2	4
329.003.00316	SC	05DEC96	-12, .	1	2	2	3	2	2	4	3	2	2	0	0	1	0	1	0	0	1	1	0	3	2	1	3	3	0	3	3	3
	8	11FEB97	57, .	1	3	1	2	2	3	3	3	3	4	1	0	0	0	0	0	2	1	1	0	3	3	3	3	3	0	1	0	0
329.004.00016	SC	01MAR95	-12, .	2	3	3	3	1	2	2	1	1	3	0	2	0	0	0	0	0	0	0	0	3	0	3	2	1	2	1	0	3
329.004.00018	SC	19APR95	-14, .	3	4	4	4	4	4	4	4	4	4	4	4	1	2	4	0	1	1	1	0	4	4	4	4	4	4	4	0	4
	8	29JUN95	58, .	2	4	1	3	4	4	4	1	2	4	4	2	0	1	1	0	1	0	1	0	0	0	4	4	4	1	4	0	4
329.004.00020	SC	02NOV95	-7, .	3	3	0	0	0	1	4	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	4	1	1	0	2	0	3
	2	24NOV95	16, .	1	2	0	1	2	1	4	0	0	1	0	1	0	1	0	1	0	0	0	0	0	0	4	1	0	0	4	0	4
329.004.00213	SC	18JUL96	-15, -69	2	2	0	3	3	0	0	0	0	4	0	1	2	2	1	0	0	0	0	0	4	0	4	2	3	0	3	0	1
	8	24SEP96	54, -1	1	2	0	3	2	1	0	0	0	4	0	1	1	1	1	0	0	0	0	0	4	0	4	0	1	0	4	0	1
	32	19MAR97	230, 176	2	2	0	3	3	1	4	1	0	4	1	1	0	1	2	0	0	0	0	0	4	1	4	1	1	0	4	0	1
329.005.00001	SC	11APR94	-9, .	2	3	4	4	1	4	4	0	1	4	0	1	0	0	1	0	0	1	0	0	0	0	3	1	3	0	0	0	3
	8	15JUN94	57, .	2	4	3	2	2	4	2	3	0	0	0	2	0	0	1	0	0	0	3	0	0	0	4	4	4	0	4	1	4
329.005.00005	SC	24OCT94	-8, .	0	4	0	2	3	2	0	2	0	3	4	0	2	0	2	0	1	0	2	0	2	3	2	0	3	0	0	0	1
329.005.00010	SC	07DEC94	-6, -63	4	4	4	2	3	2	2	4	0	4	0	4	0	3	2	0	1	0	0	0	0	0	3	3	3	0	1	0	3

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00010	8	08FEB95	58, 1	3	4	3	4	3	2	4	3	3	3	0	4	3	1	2	1	1	1	1	0	2	1	4	3	4	1	3	0	2
	32	09AUG95	240, 183	3	3	3	3	3	3	4	3	4	3	2	3	3	2	3	2	1	1	2	1	3	1	3	4	4	1	3	1	3
329.005.00012	SC	12DEC94	-7, -66	4	4	2	0	3	3	2	3	1	0	0	2	0	2	1	0	0	0	1	0	0	0	4	4	1	1	0	1	2
	8	16FEB95	60, 1	4	4	2	3	2	4	2	2	1	3	0	2	0	2	1	0	1	0	2	0	0	0	4	4	4	1	0	1	3
329.005.00111	SC	05JAN95	-6, -62	3	4	3	4	4	3	4	4	4	4	3	4	0	0	3	0	3	3	4	0	0	0	4	3	4	0	4	0	4
	8	08MAR95	57, 1	4	4	3	4	4	4	4	0	3	4	0	2	0	1	1	0	2	1	1	0	0	0	4	4	4	0	4	0	2
	16	03MAY95	113, 57	4	4	4	4	4	4	4	4	4	4	0	2	0	0	3	0	0	3	0	0	0	0	4	4	4	0	4	0	3
329.005.00114	SC	23JAN95	-8, -65	1	3	1	2	2	1	3	3	1	4	0	2	0	0	0	0	0	0	2	0	4	0	4	4	3	4	0	0	4
	8	29MAR95	58, 1	2	4	1	4	4	2	2	3	0	4	0	3	0	0	0	0	0	0	1	1	3	0	4	4	4	4	1	0	4
	16	17MAY95	107, 50	1	3	1	4	2	2	1	2	0	3	0	4	0	0	0	0	0	0	1	0	4	4	4	4	4	4	1	0	4
329.005.00115	SC	27JAN95	-10, -81	2	3	4	4	2	3	0	0	0	4	0	2	0	0	1	2	0	0	0	0	0	0	3	2	2	0	0	0	0
	8	18APR95	72, 1	4	1	4	4	4	4	4	1	1	4	1	4	2	1	2	3	1	2	1	0	1	0	4	3	3	0	0	0	3
329.005.00120	SC	22AUG95	-8, .	2	3	0	2	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	2	0	3	0	0	4
	8	26OCT95	58, .	1	3	0	0	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	4	2	3	0	4	0	0	4
329.005.00253	SC	31JAN96	-8, .	2	2	4	4	3	2	2	3	3	3	2	2	0	0	2	4	4	2	2	0	4	2	4	4	4	4	0	0	3
	8	03APR96	56, .	2	3	3	3	3	3	3	3	0	3	3	3	0	1	0	2	2	0	2	0	0	0	3	3	3	4	0	4	3
329.005.00254	SC	08FEB96	-7, -62	3	3	4	4	3	3	2	0	0	3	0	2	1	0	0	0	0	0	0	0	1	1	4	2	1	1	1	1	4
	8	10APR96	56, 1	3	4	3	4	4	3	3	1	1	2	0	3	0	1	1	1	0	1	0	0	1	1	4	3	4	4	0	4	3
329.005.00293	SC	06MAR97	-6, .	2	3	1	0	2	3	1	2	2	3	0	1	3	0	2	0	2	2	1	0	2	0	3	4	3	3	0	0	0
	8	07MAY97	57, .	1	3	1	4	3	3	3	2	2	2	0	1	3	1	2	1	3	0	1	0	1	2	4	4	3	3	0	0	0
329.005.00298	SC	15MAY96	-7, -63	1	4	1	0	1	2	1	1	0	4	0	1	2	0	1	0	0	0	0	0	4	3	4	1	1	0	0	0	2
	8	17JUL96	57, 1	2	4	2	1	1	3	2	2	1	4	0	2	2	1	2	0	0	0	1	0	4	1	4	1	1	0	1	0	1

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00298	32	13JAN97	237, 181	2	4	2	0	2	3	2	1	1	4	0	3	3	1	2	0	0	0	1	0	4	0	4	3	0	0	0	0	4
329.005.00331	SC	14NOV96	-7, .	2	4	2	4	3	4	4	2	1	4	1	3	1	1	3	1	0	1	1	0	4	0	4	4	4	0	3	3	2
	8	16JAN97	57, .	2	4	3	4	4	4	3	3	1	4	1	3	1	2	4	3	1	1	1	1	4	4	4	4	3	0	3	2	3
329.005.00334	SC	24JAN97	-7, .	2	3	2	2	3	3	0	1	0	1	0	2	0	0	2	0	0	0	2	0	0	0	3	0	1	1	1	0	3
	8	27MAR97	56, .	2	2	2	2	3	3	1	1	1	2	2	2	0	0	1	0	0	0	0	0	1	1	3	0	0	0	1	0	2
329.006.00037	SC	20JAN95	-8, .	3	4	4	4	3	4	4	4	2	4	2	2	0	1	2	1	1	2	0	0	4	3	4	4	4	4	1	4	4
329.006.00042	SC	01DEC95	-6, -63	1	4	0	2	3	4	1	4	1	0	0	2	0	0	1	0	0	0	0	0	0	0	3	3	3	4	2	1	4
	8	02FEB96	58, 1	1	4	1	3	3	3	1	3	1	4	0	3	0	0	1	0	0	0	1	0	0	0	4	4	3	4	2	0	4
	32	16JUL96	223, 166	2	4	2	4	4	3	2	2	2	0	0	3	0	0	1	0	0	0	1	0	0	4	4	3	3	3	0	0	4
329.006.00259	SC	22APR96	-32, .	3	3	0	4	2	2	0	4	1	0	0	3	0	0	1	3	0	1	1	0	1	0	4	4	4	0	0	4	3
	8	17JUL96	55, .	3	4	0	4	3	1	1	4	2	0	0	2	1	0	0	2	0	1	0	0	0	0	4	4	4	0	0	4	4
329.007.00141	SC	14SEP95	-7, .	2	4	1	2	3	3	0	4	0	3	0	2	0	1	1	0	0	0	4	0	1	0	3	4	4	0	0	0	4
329.007.00144	SC	30NOV95	-7, -63	3	3	2	4	2	0	0	0	0	4	0	2	0	0	1	0	0	0	0	0	1	0	4	2	0	1	0	1	1
	8	01FEB96	57, 1	3	2	3	0	1	0	0	0	0	2	0	3	0	1	1	0	0	0	1	0	0	0	1	1	1	2	0	2	1
329.007.00266	SC	29FEB96	-7, .	2	2	2	3	1	1	0	1	0	0	0	2	2	0	0	0	0	0	0	0	0	0	3	0	1	0	0	0	1
	8	02MAY96	57, .	1	2	3	1	1	0	0	0	0	1	0	2	2	0	1	0	0	0	0	0	1	1	3	0	1	1	0	0	2
329.007.00267	SC	29FEB96	-7, .	2	3	1	4	2	3	1	3	1	0	0	1	1	0	1	0	0	1	1	1	1	0	4	3	2	3	2	0	0
	8	02MAY96	57, .	2	4	2	4	4	4	1	3	3	4	0	1	0	1	1	3	0	0	2	0	3	0	4	4	3	2	0	0	2
329.007.00311	SC	26SEP96	-7, -67	3	4	0	4	0	0	0	4	0	4	0	2	0	0	0	0	0	0	0	0	2	0	4	4	4	0	0	4	1
	8	02DEC96	61, 1	0	4	0	4	4	2	0	4	0	4	0	0	0	0	0	0	0	0	4	0	0	3	4	4	4	0	0	4	2

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.008.00158	SC	06SEP95	-7, -69	2	3	1	2	1	3	3	1	0	3	1	2	2	0	0	0	0	0	0	0	3	1	4	3	3	0	3	0	4
329.008.00162	SC	26OCT95	-6, -71	0	2	3	3	2	3	2	3	0	4	0	1	0	0	0	0	0	0	1	0	0	0	3	3	1	0	1	1	1
	32	02JUL96	245, 180	1	2	4	4	2	3	3	3	0	1	0	2	0	1	1	1	0	0	1	0	1	0	3	4	4	3	1	2	1
329.008.00191	SC	12JAN96	-20, -81	1	3	3	3	4	3	4	3	4	3	0	3	3	2	4	4	0	4	1	0	4	0	4	4	4	3	3	4	3
	8	02APR96	62, 1	1	3	4	4	4	3	4	3	4	4	0	2	3	1	4	4	0	4	1	0	3	0	4	4	4	4	4	4	4
329.009.00128	SC	05APR95	-6, .	1	1	0	0	0	0	0	1	0	4	0	2	0	0	0	0	0	0	1	0	4	0	3	2	1	0	0	1	4
329.009.00129	SC	22MAR95	-20, .	4	3	2	0	1	1	1	0	0	4	0	2	0	1	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0
329.009.00135	SC	25SEP95	-7, .	1	2	3	0	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	4	2	2	0	0	0	4
329.009.00136	SC	26SEP95	-7, .	0	4	1	2	1	0	0	0	0	4	0	0	0	0	1	0	0	1	0	0	2	2	4	0	0	0	0	3	1
	8	28NOV95	57, .	1	3	1	2	1	3	0	1	0	4	4	1	1	0	1	0	0	1	0	0	3	3	3	2	0	0	3	4	3
329.009.00169	SC	25OCT95	-6, -71	0	3	1	2	3	3	3	2	1	2	0	1	3	0	2	2	1	2	2	0	4	3	4	0	0	0	0	4	3
	8	27DEC95	58, -8	0	4	2	0	4	3	1	1	1	2	0	1	0	0	2	0	0	1	2	0	3	0	4	1	1	1	1	1	4
329.009.00174	SC	14NOV95	-7, -64	1	4	3	0	2	1	0	2	0	4	0	2	0	1	1	0	0	0	1	0	0	0	4	2	1	0	0	1	1
	8	17JAN96	58, 1	3	4	4	0	3	3	0	4	0	4	0	3	0	0	0	0	0	0	1	0	0	0	4	3	0	0	0	0	1
329.009.00197	SC	20DEC95	-9, -63	0	4	0	0	4	2	0	1	0	2	0	1	1	0	1	0	0	0	0	0	3	2	3	1	0	0	0	0	1
	8	20FEB96	54, -1	1	3	0	4	1	1	1	0	0	4	0	1	0	1	0	0	0	0	0	0	4	0	1	0	0	0	0	0	2
	32	20AUG96	236, 182	1	3	1	0	1	1	0	1	0	1	0	1	1	0	1	0	0	0	1	0	1	0	1	0	0	0	0	0	1
329.009.00198	SC	19DEC95	-14, .	1	2	3	4	0	1	3	0	0	3	3	0	1	0	1	0	0	0	0	0	0	0	4	4	3	1	0	0	1
	8	27FEB96	57, .	0	1	3	3	2	3	1	0	0	2	3	2	0	0	1	1	0	0	0	0	0	1	4	4	4	4	1	1	1
329.009.00200	SC	17JAN96	-6, .	0	3	1	3	1	1	2	0	1	3	0	0	0	0	1	2	0	1	0	0	3	0	3	4	1	0	0	0	1

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00202	SC	14FEB96	-6, .	2	4	2	1	2	4	3	2	1	4	1	1	0	0	1	0	0	0	0	0	4	4	4	3	4	0	0	4	4
329.009.00237	SC	04NOV96	-7, .	2	3	4	4	3	4	2	3	1	3	1	1	0	0	1	0	0	0	1	1	0	0	3	3	2	0	0	1	1
329.009.00238	SC	28OCT96	-15, .	1	1	1	4	1	1	4	3	0	4	0	1	0	0	0	0	0	0	0	0	0	0	4	4	0	0	0	4	4
	8	07JAN97	57, .	1	3	1	4	1	1	4	4	0	0	4	2	0	0	0	0	0	0	0	0	0	0	4	2	2	0	0	1	4
329.009.00276	SC	17JAN97	-4, .	1	3	1	0	1	3	0	1	0	4	0	2	0	0	0	0	0	0	1	0	0	0	4	4	3	0	0	0	3
	8	18MAR97	57, .	1	1	1	0	0	1	0	0	0	4	0	1	0	0	0	0	0	0	1	0	3	0	3	3	3	0	0	0	3
329.009.00302	SC	20MAR96	-7, .	1	2	0	4	1	1	1	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	3	2	1	1	0	1	1
329.009.00306	SC	03JUN96	-8, .	0	3	3	4	3	3	3	3	2	1	1	1	0	0	0	0	0	3	0	0	3	3	3	0	0	0	0	0	3
	8	06AUG96	57, .	1	0	2	1	2	1	1	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	1	0	0	1
329.009.00312	SC	30OCT96	-5, .	3	3	4	4	2	4	1	3	3	4	4	1	0	1	1	0	0	0	0	0	1	1	4	1	2	0	4	0	3
329.009.00327	SC	09SEP96	-7, .	1	2	1	4	1	3	2	0	0	1	0	2	0	0	1	1	0	0	0	0	0	0	3	4	1	3	1	1	1
	5	21OCT96	36, .	1	2	0	3	0	2	3	0	0	4	0	1	0	2	0	2	0	0	0	0	4	0	2	2	2	3	1	2	1
329.009.00330	SC	15OCT96	-6, .	4	4	3	3	3	3	1	3	1	4	3	4	1	2	2	0	0	0	2	0	4	4	4	3	0	0	1	0	0
329.010.00183	SC	21NOV95	-12, .	1	3	3	2	1	3	1	1	0	3	0	2	0	0	1	0	0	0	0	1	0	1	2	1	0	0	0	0	1
329.010.00263	SC	24JUL96	-16, .	3	3	3	3	3	2	1	0	1	0	0	2	1	0	2	0	1	3	1	0	0	1	4	0	2	0	0	0	2
	8	09OCT96	62, .	3	4	3	3	3	2	1	3	1	3	1	1	0	0	1	0	0	3	2	0	0	0	4	2	2	0	0	2	2
329.010.00277	SC	23FEB96	-7, -63	0	3	4	4	3	4	3	3	1	4	3	2	0	3	3	0	0	3	3	0	4	4	4	4	4	1	3	3	3
	8	26APR96	57, 1	3	4	4	4	4	4	3	3	0	4	0	3	4	3	4	0	1	1	3	0	4	0	4	4	4	0	3	1	3
	24	07AUG96	160, 104	3	4	3	4	3	4	2	2	0	4	0	3	0	1	3	0	1	1	2	0	4	3	4	4	4	0	4	1	4

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.010.00282	SC	19JUL96	-7, .	0	3	2	1	3	3	1	2	0	4	0	1	0	0	3	0	0	0	1	0	4	0	4	1	1	0	1	1	1
	8	27SEP96	64, .	1	3	2	2	3	3	2	3	1	4	0	1	0	0	3	0	0	0	2	0	0	0	4	4	3	0	1	1	1
329.011.00164	SC	15DEC95	-7, .	3	4	0	2	4	4	3	4	2	2	0	2	0	1	2	0	1	3	4	0	1	0	4	4	1	0	4	4	4
329.011.00210	SC	13SEP96	-15, -81	1	2	1	4	2	3	0	1	0	4	0	1	0	1	1	0	0	0	0	0	4	0	3	4	0	0	0	0	1
	8	02DEC96	66, -1	1	3	1	3	1	3	4	1	0	3	0	1	0	0	0	0	0	0	1	0	0	0	4	3	0	0	0	0	1
329.011.00285	SC	08MAY96	-10, .	2	2	3	4	1	4	0	3	0	3	0	2	0	0	0	0	0	0	1	1	4	0	4	4	4	0	0	0	4
	8	24JUL96	68, .	2	3	2	3	3	4	1	4	0	0	0	3	0	0	0	0	0	0	2	1	4	0	4	4	4	0	0	0	4
329.011.00287	SC	25JUN96	-8, .	0	3	0	0	2	0	0	0	0	4	0	4	0	0	1	0	2	0	0	0	4	0	4	0	4	0	0	0	0
	8	27AUG96	56, .	0	4	1	0	2	4	1	0	0	3	0	1	1	0	1	0	0	0	0	0	0	0	4	4	1	0	0	1	0
329.012.00027	SC	23NOV95	-13, .	4	4	4	4	1	1	4	4	2	4	2	2	0	0	2	0	0	2	2	0	2	2	4	4	4	4	4	4	4
329.012.00217	SC	14MAY96	-7, .	1	4	1	3	2	2	1	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	3	1	0	0	3	1	2
329.012.00218	SC	04JUN96	-12, -70	1	3	2	4	3	4	4	0	0	4	0	0	0	0	1	0	0	0	0	0	0	0	4	4	0	0	4	1	3
	8	13AUG96	59, 1	1	4	1	4	3	4	4	1	0	4	0	1	0	0	1	0	0	0	0	0	1	0	4	4	0	3	4	0	4
329.012.00224	SC	30AUG96	-17, -83	3	2	1	3	1	3	1	1	0	0	0	2	0	0	1	0	0	0	0	0	4	0	4	3	3	0	0	0	4
	8	20NOV96	66, -1	3	3	2	3	1	2	0	1	0	3	0	2	0	2	2	2	0	0	0	0	4	0	4	3	3	0	0	0	3
329.012.00225	SC	19NOV96	-7, -71	1	3	1	2	3	1	0	1	0	1	0	2	0	0	3	0	0	0	0	0	1	0	1	1	1	0	0	2	3
	8	29JAN97	65, 1	2	3	2	3	1	0	1	0	1	0	1	3	0	0	1	0	0	0	0	0	1	0	2	1	1	0	0	2	3
	32	30JUL97	247, 183	1	2	3	2	1	1	0	1	0	0	0	3	0	0	1	0	0	0	0	0	0	0	1	1	3	0	2	3	3

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.001.00063	SC	02NOV94	-6, .	0	0	2	1	2	4	0	0	0	3	0	0	0	2	1	3	0	1	0	0	0	0	0	0	0	1	0	1	3
329.001.00065	SC	07NOV94	-10, .	3	0	2	1	3	3	0	1	1	1	3	3	2	3	1	1	1	1	2	.	1	0	1	2	1	2	2	1	2
329.001.00068	SC	01FEB95	-7, .	0	0	3	1	2	1	1	2	0	1	2	0	1	3	2	0	4	0	0	2	0	0	1	2	0	0	1	1	1
	8	05APR95	57, .	2	1	2	1	1	2	1	2	1	1	3	0	1	4	4	1	3	1	1	1	1	1	1	3	1	0	1	1	1
329.001.00072	SC	07MAR95	-13, .	0	0	1	1	2	2	2	2	2	1	2	1	0	4	1	3	0	0	1	1	1	0	0	3	3	2	0	0	1
329.001.00121	SC	22MAR95	-13, -69	0	0	2	3	3	3	1	1	3	3	1	2	3	4	2	3	1	1	3	1	1	1	1	2	2	2	2	1	2
	8	30MAY95	57, 1	1	0	3	3	3	4	2	1	3	3	3	3	1	3	1	3	1	1	3	1	1	3	1	1	1	4	1	2	3
329.001.00205	SC	29JAN96	-9, .	0	0	2	1	2	2	2	1	2	1	1	2	2	2	2	3	1	2	0	1	0	3	1	1	2	4	2	1	2
329.001.00206	SC	12FEB96	-9, .	0	0	1	3	4	3	0	3	3	0	4	0	1	3	3	3	0	0	0	4	0	0	1	4	3	1	1	0	1
	8	17APR96	57, .	0	0	1	4	4	4	0	4	0	3	4	1	1	3	3	3	0	0	0	4	0	0	2	3	4	4	0	0	1
329.002.00055	SC	09JUN94	-15, -70	0	0	4	0	4	2	0	1	0	0	0	0	0	4	1	1	1	0	0	2	0	0	1	0	0	0	0	0	1
	8	18AUG94	56, 1	0	0	4	2	1	2	1	2	1	1	0	2	1	3	1	2	2	0	0	2	0	0	4	1	0	0	0	1	4
	20	10NOV94	140, 85	0	0	4	3	3	3	0	4	3	0	3	0	0	3	3	3	0	0	0	3	0	0	2	0	0	0	0	0	0
329.002.00058	SC	08SEP94	-12, -70	0	0	4	1	3	2	0	1	3	0	1	0	0	4	4	0	0	0	0	1	1	0	0	1	0	0	1	0	2
	8	17NOV94	59, 1	0	0	4	4	4	3	3	3	3	1	3	3	0	3	4	2	0	0	0	3	0	0	1	2	0	1	1	2	3
329.002.00099	SC	23FEB95	-7, -62	0	0	3	2	3	2	2	1	1	3	2	3	1	3	1	2	1	0	3	3	1	1	2	0	1	3	2	1	3
	8	25APR95	55, -1	0	0	3	2	3	4	1	1	1	2	3	3	1	3	1	3	0	0	2	1	0	2	2	1	0	2	2	1	3
329.002.00102	SC	03APR95	-10, -64	4	0	4	1	1	4	3	2	2	1	2	1	0	3	2	1	1	0	0	2	0	0	0	1	0	4	1	1	1
	8	06JUN95	55, 1	4	0	4	2	1	3	3	1	3	2	4	1	1	3	1	1	2	0	0	2	0	0	1	2	0	4	2	1	1
	32	05DEC95	237, 183	4	0	4	3	3	4	4	0	4	3	4	4	0	4	1	1	1	0	0	1	0	0	0	3	0	4	1	0	2

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.002.00105	SC	20JUL95	-7, .	0	0	4	.	2	3	0	4	0	0	4	3	0	3	0	3	0	0	0	.	0	0	0	3	.	4	2	1	1
329.002.00106	SC	20JUL95	-7, .	0	0	3	2	2	3	0	0	1	1	2	0	0	3	3	0	0	0	0	0	0	0	0	2	0	0	1	1	1
329.002.00242	SC	26JAN96	-12, -70	0	3	3	2	1	3	3	2	3	2	2	1	0	3	1	1	1	1	0	1	0	0	1	1	1	2	1	0	2
	20	10JUL96	155, 97	2	0	3	1	1	1	1	2	2	1	2	0	0	3	1	1	0	0	0	1	0	0	2	2	0	1	1	1	1
329.002.00245	SC	21MAR96	-7, .	0	0	4	4	3	3	0	3	2	1	3	0	1	4	4	2	2	1	0	4	0	0	3	3	0	1	0	1	3
329.002.00319	SC	23APR96	-7, -63	0	0	4	3	3	3	3	1	1	3	4	3	4	2	3	2	1	0	0	3	1	3	3	3	0	0	2	4	3
	8	25JUN96	57, 1	0	0	4	4	4	4	3	2	3	4	3	4	4	3	4	2	1	4	0	1	0	3	3	4	1	0	3	4	3
	32	17DEC96	232, 176	0	0	4	4	3	4	3	3	3	4	4	4	3	3	4	3	2	1	0	3	1	2	3	4	1	4	3	3	3
329.003.00075	8	22MAR95	57, 1	2	0	4	4	4	4	4	4	4	3	4	2	2	4	1	2	4	2	4	.	3	3	4	2	4	4	2	2	0
	32	13SEP95	232, 176	0	0	4	4	4	4	4	4	4	2	4	4	2	4	2	0	4	4	4	.	4	0	4	4	1	4	2	3	1
329.003.00077	SC	01MAR95	-5, -64	0	0	3	1	1	2	2	0	1	1	2	3	0	3	3	3	0	3	0	.	1	3	1	1	0	0	1	2	2
329.003.00087	SC	23JAN95	-8, .	4	0	1	2	4	4	4	4	2	4	4	3	3	3	0	1	0	0	2	.	3	0	0	4	4	1	0	4	4
329.003.00089	SC	24FEB95	-11, .	0	0	3	3	3	4	2	2	3	2	3	2	1	4	4	4	3	2	3	.	2	0	1	3	3	1	0	1	2
	8	02MAY95	57, .	1	0	2	2	3	4	3	4	3	1	2	2	0	4	4	4	2	0	1	3	1	0	1	4	4	3	0	1	3
329.003.00091	SC	14MAR95	-10, -64	0	0	4	3	4	4	2	3	4	2	3	2	2	4	3	2	2	2	2	3	1	0	1	3	0	2	2	3	2
	8	16MAY95	54, -1	0	0	4	4	4	3	3	3	4	3	3	3	4	4	3	2	3	3	3	.	3	2	3	3	0	3	3	3	3
	32	07NOV95	229, 175	0	0	4	4	4	4	4	4	4	3	3	4	4	4	3	2	3	2	2	3	3	2	3	3	2	3	3	3	3
329.003.00248	SC	14FEB96	-16, .	1	0	2	1	1	2	1	0	0	1	1	0	1	3	1	1	0	2	0	1	1	0	0	1	0	1	0	1	1
	8	23APR96	54, .	0	0	3	2	1	2	1	3	2	1	3	0	1	3	0	3	0	1	0	.	3	3	0	1	4	3	1	0	1
329.003.00250	SC	05MAR96	-9, -66	0	0	4	2	3	3	3	3	3	2	1	2	2	4	2	1	1	2	2	2	1	1	0	2	2	0	2	1	1

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.003.00292	SC	02AUG96	-5, -63	0	0	0	1	2	3	3	3	3	4	3	1	2	1	2	3	0	1	3	0	0	2	1	1	3	3	1	2	1
	8	04OCT96	59, 1	0	0	0	2	2	3	3	3	3	3	2	4	3	1	3	3	3	2	3	0	1	3	1	1	3	0	1	3	2
329.003.00313	SC	08MAY96	-9, .	0	0	4	3	3	3	2	2	2	2	3	2	2	2	1	1	2	0	0	.	0	0	1	2	0	0	0	2	1
329.004.00015	SC	30NOV94	-8, -65	0	0	4	2	1	4	0	1	3	0	3	0	0	2	2	2	2	0	1	.	4	0	0	2	0	0	1	0	2
	8	03FEB95	58, 1	0	0	2	1	1	3	3	1	2	1	3	0	0	3	3	3	3	3	2	3	0	0	1	2	0	1	2	0	2
	28	14JUN95	189, 132	0	0	3	0	3	4	2	0	3	0	4	0	2	4	2	4	1	0	0	4	0	0	1	3	0	3	0	0	3
329.004.00017	SC	15MAR95	-7, -63	4	0	4	4	4	4	0	0	0	4	0	0	3	4	2	4	0	0	3	.	4	4	1	3	0	4	1	4	2
	8	17MAY95	57, 1	2	0	3	1	2	3	2	1	3	3	3	1	4	3	3	3	0	0	3	.	4	3	0	2	0	2	0	2	1
	32	01NOV95	225, 169	3	0	4	4	4	1	1	1	3	4	2	4	4	4	2	2	0	0	3	.	3	1	0	2	2	1	1	4	3
329.004.00019	SC	24MAY95	-7, .	1	.	0	3	0	2	2	3	2	1	2	1	1	2	1	0	1	3	3	1	1	1	2	2	0	3	2	1	1
329.004.00212	SC	24MAY96	-10, .	0	4	4	2	3	3	0	4	2	0	3	3	0	3	1	0	0	0	0	1	0	0	1	2	0	0	1	0	1
329.004.00214	SC	27SEP96	-7, -67	0	0	4	3	4	4	4	3	1	4	0	3	3	1	2	2	1	2	1	1	1	0	0	0	0	1	1	4	1
	8	03DEC96	61, 1	2	2	4	2	4	4	4	3	2	4	1	4	2	4	3	3	1	2	1	2	2	1	1	1	1	1	3	4	2
329.005.00002	SC	20MAY94	-5, -61	0	0	4	3	2	3	3	4	3	3	3	2	2	2	1	1	1	1	1	3	0	0	2	3	1	2	2	2	1
329.005.00004	SC	22SEP94	-18, -77	3	0	4	4	4	4	4	4	4	2	4	0	2	2	1	2	0	0	2	.	2	2	1	2	2	3	1	1	3
	8	08DEC94	60, 1	4	0	4	2	4	4	3	4	4	2	4	2	2	3	1	2	0	1	2	.	2	2	1	2	2	3	1	1	3
329.005.00008	SC	10NOV94	-6, -61	0	0	2	2	4	4	4	3	2	2	0	2	0	1	0	2	0	0	0	1	0	0	1	1	0	0	1	0	1
	8	10JAN95	56, 1	4	0	3	3	3	3	3	3	2	1	0	1	0	2	1	2	0	2	0	1	0	0	1	1	0	0	1	0	2
	24	10MAY95	176, 121	2	0	3	3	4	4	2	3	3	2	0	1	1	2	0	2	0	0	0	2	0	0	2	2	0	0	1	0	2
329.005.00011	SC	06DEC94	-7, -63	4	4	3	1	3	3	3	3	3	2	3	4	0	4	1	1	1	0	0	.	2	0	1	2	2	3	1	1	2
	8	07FEB95	57, 1	4	4	4	1	3	3	4	3	3	2	4	3	1	4	1	3	1	0	0	.	1	0	1	3	1	4	1	1	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.005.00109	SC	22DEC94	-8, -61	0	4	2	2	0	2	0	0	1	3	0	4	4	4	4	3	1	2	1	.	1	0	4	4	4	0	1	0	4
329.005.00112	SC	17JAN95	-9, -64	0	0	4	2	4	3	0	4	0	2	0	4	0	3	0	4	0	0	0	.	0	.	1	1	1	4	1	2	4
	8	22MAR95	56, 1	0	0	3	1	4	4	4	0	4	3	3	4	0	3	0	3	1	0	2	0	0	0	3	4	0	4	1	2	4
329.005.00116	SC	30JAN95	-8, -66	0	0	4	4	3	4	1	3	4	2	4	3	1	2	1	1	1	0	0	2	1	0	1	1	1	2	1	1	1
	8	06APR95	59, 1	0	0	2	2	2	2	3	3	3	2	3	2	0	2	1	1	1	1	1	.	1	1	1	2	2	1	0	1	2
	24	26JUL95	170, 112	4	0	3	3	3	3	3	3	3	2	3	3	1	4	1	1	2	1	1	3	3	1	2	4	2	3	2	1	2
329.005.00119	SC	27JUN95	-14, -73	1	0	4	3	3	4	3	4	4	2	4	2	0	3	1	2	2	1	1	3	1	0	4	4	1	1	1	2	1
	8	08SEP95	60, 1	1	0	4	2	3	3	3	4	3	3	3	1	0	4	1	2	2	2	2	2	1	0	3	3	1	2	1	1	2
	24	02JAN96	176, 117	2	0	4	3	3	3	1	4	4	3	3	2	1	4	2	3	2	2	1	.	1	0	2	3	2	2	1	2	2
329.005.00151	SC	29AUG95	-8, -65	4	0	4	3	4	4	4	4	4	4	3	4	3	2	2	0	1	0	1	1	1	.	2	3	1	3	0	3	2
	8	02NOV95	58, 1	4	0	3	2	4	3	3	3	4	3	3	4	3	2	1	1	1	0	0	.	1	0	3	3	2	3	1	3	2
	32	01MAY96	239, 182	4	0	4	2	3	3	3	2	3	3	3	4	3	4	4	1	2	0	1	.	1	0	0	3	0	4	1	2	1
329.005.00152	SC	12OCT95	-14, .	0	0	4	1	3	1	1	2	3	3	4	.	.	4	1	2	3	0	0	.	0	0	2	3	0	1	3	1	3
329.005.00257	SC	05MAR96	-6, -62	1	0	1	1	2	2	1	1	0	2	1	2	0	3	4	1	0	0	1	0	0	0	0	0	1	1	1	1	2
	8	06MAY96	57, 1	1	1	3	3	3	2	1	2	1	3	1	3	1	2	4	2	0	1	1	.	0	0	0	0	1	0	2	1	2
	32	21OCT96	225, 169	0	0	4	3	3	3	0	1	2	3	3	2	1	3	4	2	0	1	2	.	0	0	0	0	0	1	0	1	2
329.005.00258	SC	06FEB96	-35, .	1	0	1	1	2	1	0	1	2	2	2	1	0	3	2	1	1	1	3	3	1	1	2	2	2	1	1	1	1
	8	07MAY96	57, .	1	0	2	2	2	3	3	2	3	2	2	0	4	2	1	2	0	0	0	1	1	0	0	2	0	1	0	0	3
329.005.00299	SC	28MAY96	-11, -71	2	0	4	2	2	1	1	1	1	1	0	1	1	3	1	0	2	0	0	2	0	0	1	1	0	0	1	0	0
	8	07AUG96	61, 1	1	0	4	3	3	3	1	4	0	2	3	3	1	3	1	1	3	0	0	.	2	0	2	4	2	4	2	1	1
	20	05NOV96	151, 91	1	0	4	3	2	1	1	3	2	2	0	2	0	3	1	2	3	1	0	.	0	0	2	3	3	4	1	1	0
329.005.00300	SC	12SEP96	-7, .	0	0	1	3	3	3	0	0	0	2	0	1	0	2	0	0	0	0	0	3	0	0	0	0	1	0	1	1	1

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.005.00300	8	14NOV96	57, .	0	0	2	1	3	4	1	0	1	0	0	3	0	1	1	0	0	0	0	.	4	0	0	1	1	0	0	0	0
329.005.00333	SC	15JAN97	-8, .	2	0	4	1	3	2	2	1	1	4	1	1	2	0	2	1	0	0	2	1	0	2	1	0	1	4	1	3	3
329.005.00336	SC	26FEB97	-6, .	0	0	3	0	0	0	0	0	2	2	1	1	1	2	0	0	0	0	0	3	0	0	1	0	0	1	.	.	.
329.006.00038	SC	01FEB95	-14, .	0	0	4	1	4	2	3	4	4	3	4	2	1	3	0	3	3	1	0	3	0	3	1	3	0	4	2	3	1
329.006.00039	SC	03FEB95	-5, -66	3	0	4	2	4	3	1	1	1	4	1	4	4	2	3	0	0	2	2	3	3	0	0	0	0	2	0	1	3
	8	05APR95	57, -5	4	0	4	3	4	4	2	2	4	4	2	4	4	4	3	1	1	1	3	.	4	0	2	1	0	3	1	3	3
329.006.00260	SC	12JUL96	-6, -64	0	0	3	1	2	4	0	0	2	1	0	2	0	2	0	3	1	0	0	1	1	1	1	1	0	2	0	0	1
	8	18SEP96	63, 5	0	0	3	1	3	3	0	0	4	2	4	0	0	1	1	4	0	0	2	0	0	1	1	1	0	0	2	1	3
329.006.00261	SC	07NOV96	-19, -77	4	0	4	2	4	4	0	4	4	4	4	3	4	4	4	3	2	4	4	.	4	4	2	4	4	4	2	4	3
329.007.00140	SC	07SEP95	-8, -63	0	0	4	2	2	3	2	4	4	3	3	1	1	4	3	3	0	3	2	4	0	0	0	0	2	2	1	2	1
	8	09NOV95	56, 1	1	0	4	3	2	4	2	4	2	2	2	1	0	4	4	2	1	3	3	3	2	1	1	1	3	2	2	2	2
329.007.00142	SC	12OCT95	-6, .	0	0	2	2	4	3	2	1	1	1	0	0	0	2	2	1	0	0	0	0	0	0	0	1	0	0	0	0	1
	8	21DEC95	65, .	0	0	2	2	3	2	2	1	2	1	1	1	1	2	1	0	0	2	0	1	0	0	0	1	0	0	0	0	0
329.007.00145	SC	04JAN96	-7, -63	0	0	3	2	1	4	1	1	1	1	3	1	0	4	1	4	2	1	0	0	0	0	4	2	0	1	1	1	2
	8	07MAR96	57, 1	0	0	1	4	2	4	2	1	3	1	1	1	0	4	1	4	1	3	0	0	0	.	4	2	4	2	1	0	3
	32	23AUG96	226, 170	0	0	3	4	2	3	1	1	4	1	4	1	1	4	2	3	3	3	3	1	0	1	4	3	4	4	2	1	4
329.007.00265	SC	25JAN96	-7, .	0	0	4	0	3	1	4	3	3	1	0	0	0	4	0	0	1	0	0	4	0	0	0	4	0	4	1	1	0
329.007.00268	SC	21MAR96	-11, -70	0	0	4	2	4	3	2	2	1	2	3	2	0	3	1	3	2	3	2	4	0	0	4	4	2	4	1	1	4
	8	30MAY96	60, 1	0	0	4	3	4	4	3	3	0	2	4	1	0	3	1	4	2	0	1	4	0	0	3	0	2	4	1	1	4
	32	05DEC96	249, 190	0	0	4	3	4	4	4	2	3	2	4	2	0	4	3	3	2	4	0	0	0	0	1	2	2	4	0	1	3

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.007.00294	SC	20FEB97	-8, .	0	0	3	2	2	1	2	1	2	1	2	2	0	2	2	0	3	0	2	4	1	0	2	4	0	0	1	0	1
329.007.00309	SC	02JUL96	-13, -65	0	3	3	2	3	2	2	2	3	0	3	0	1	2	2	0	0	0	0	2	0	0	0	1	1	1	0	0	1
	7	05SEP96	53, 1	0	3	3	2	3	1	0	2	1	2	2	1	2	2	0	1	0	0	0	2	0	0	0	1	1	0	1	1	1
	32	13MAR97	242, 190	3	3	4	2	3	3	0	3	2	0	4	3	1	2	1	0	0	1	0	1	0	0	0	1	1	4	1	0	2
329.007.00310	SC	19SEP96	-7, -67	0	0	3	2	2	1	3	2	3	3	3	0	0	2	1	1	2	0	0	1	0	0	1	1	0	3	1	0	2
	8	25NOV96	61, 1	0	0	3	3	3	3	1	3	3	2	3	1	0	3	1	1	2	0	0	2	0	0	1	2	1	2	2	1	2
	32	12JUN97	260, 200	1	0	4	3	3	3	0	2	2	3	3	2	1	2	1	1	1	0	0	2	0	0	1	2	1	3	2	2	2
329.007.00318	SC	22NOV96	-10, .	2	0	2	4	4	4	4	2	2	1	2	2	0	4	0	4	0	0	1	0	0	0	2	0	3	3	0	0	2
329.008.00157	SC	16AUG95	-14, -69	4	4	3	3	3	4	2	3	2	1	2	3	1	3	1	3	0	1	1	.	0	0	1	1	0	3	1	1	3
	8	24OCT95	56, 1	4	0	2	4	3	4	4	1	2	2	3	4	1	3	1	2	0	2	0	.	0	1	2	3	0	4	1	1	3
329.008.00160	SC	25OCT95	-7, -73	3	0	1	1	1	1	1	4	3	2	4	1	1	4	4	4	1	2	4	.	4	3	1	4	4	4	3	3	4
	8	05JAN96	66, -1	4	0	1	2	1	.	4	4	3	1	1	.	.	4	4	4	1	3	3	4	4	1	4	1	4	4	2	2	4
329.008.00188	SC	14DEC95	-21, .	0	0	3	1	1	2	1	2	1	1	2	1	1	3	0	0	0	0	0	3	1	0	1	1	0	2	2	1	2
	8	27FEB96	55, .	0	0	3	1	1	3	1	2	1	1	1	1	1	4	0	0	0	0	0	2	1	0	1	3	0	1	2	1	2
329.008.00271	SC	25JAN96	-46,-110	0	0	3	2	3	4	0	2	3	1	0	4	3	4	1	1	1	0	0	4	1	0	1	4	0	4	1	1	3
	8	14MAY96	65, 1	3	0	3	1	2	3	3	3	3	1	3	3	3	4	1	2	2	1	0	4	0	2	2	3	3	3	1	0	3
329.008.00275	SC	30APR96	-8, -63	0	0	4	1	2	2	1	1	2	2	2	2	0	2	1	1	0	0	0	2	1	0	0	0	0	1	0	1	2
	8	02JUL96	56, 1	1	0	4	2	3	4	2	1	2	2	3	3	2	3	1	2	0	0	1	3	2	0	1	2	0	1	2	2	3
	32	16DEC96	223, 168	4	0	4	3	2	3	2	4	3	2	3	3	3	3	2	1	0	0	0	3	1	0	1	2	0	1	1	2	3
329.009.00130	SC	12APR95	-6, -62	1	0	2	2	3	3	2	3	2	3	1	2	0	2	0	3	3	0	0	3	1	0	1	3	1	2	2	2	2
	8	13JUN95	57, 1	0	0	4	4	4	2	1	3	3	3	3	2	2	3	1	2	1	1	0	4	0	0	2	2	2	2	2	1	2

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.009.00131	SC	26APR95	-6, -62	0	0	1	0	1	4	3	0	0	1	0	1	3	3	1	0	0	2	0	4	0	0	0	0	0	0	0	1	3
	8	27JUN95	57, 1	0	3	3	4	4	4	3	3	0	4	0	4	4	4	4	3	0	0	0	0	0	0	0	0	0	0	0	4	4
329.009.00133	SC	07JUN95	-6, .	0	0	4	1	4	3	0	1	3	2	3	1	4	4	1	0	1	2	0	4	0	0	0	4	0	1	2	3	2
329.009.00138	SC	02OCT95	-8, .	0	0	3	0	3	3	2	4	2	1	3	0	0	4	1	0	1	1	1	4	0	0	1	2	0	1	1	0	2
329.009.00170	SC	26OCT95	-12, -69	0	0	4	1	2	4	2	0	1	2	0	0	0	3	2	0	0	0	0	2	1	0	1	3	0	0	1	0	2
	8	03JAN96	58, 1	0	0	4	3	3	4	2	1	3	3	3	0	0	3	3	1	1	1	1	3	1	0	1	3	1	1	2	1	3
	32	24JUN96	231, 174	0	0	4	1	4	3	1	1	1	2	2	0	0	3	3	1	2	2	1	3	1	0	1	4	0	0	1	1	2
329.009.00173	SC	08NOV95	-12, -75	0	0	3	3	2	2	3	0	2	2	1	0	0	4	2	1	1	0	3	1	2	0	0	0	3	0	1	1	2
	8	22JAN96	64, 1	0	0	3	1	2	1	3	0	0	1	1	0	0	4	2	1	0	.	0	3	0	0	1	0	0	2	1	1	1
329.009.00193	SC	21NOV95	-7, .	0	0	3	1	0	3	2	1	0	0	0	0	2	3	1	1	0	0	1	2	0	0	0	2	0	1	2	0	1
	8	24JAN96	58, .	0	0	3	1	1	0	2	0	0	1	1	0	0	3	1	3	0	0	0	0	0	0	0	1	0	0	2	0	1
329.009.00196	SC	11DEC95	-7, .	1	1	3	3	4	3	0	4	0	4	4	0	1	3	1	4	3	0	3	3	2	2	1	1	4	1	2	3	2
	8	12FEB96	57, .	4	4	3	3	4	3	3	4	4	4	4	3	4	4	2	4	4	0	4	4	3	3	0	2	3	2	3	4	2
329.009.00201	SC	31JAN96	-6, .	3	0	4	2	4	3	2	4	4	2	3	3	1	3	1	4	1	1	1	2	1	1	2	3	1	2	2	1	2
	8	02APR96	57, .	0	0	4	4	4	4	3	4	3	2	4	2	1	3	1	3	1	0	0	2	1	0	2	2	1	2	2	1	2
329.009.00204	SC	13MAR96	-6, -62	3	0	3	2	3	3	3	2	1	1	1	2	2	3	1	2	1	3	2	3	1	3	1	3	2	3	1	3	1
	8	14MAY96	57, 1	4	0	4	3	3	4	2	3	2	3	2	2	3	2	1	2	0	2	1	.	3	0	2	3	3	4	1	3	2
329.009.00235	SC	10DEC96	-8, -62	0	0	4	3	3	2	2	2	2	3	2	2	1	4	3	1	2	1	4	3	0	1	1	2	2	1	3	1	2
	8	10FEB97	55, 1	0	0	4	4	4	3	3	3	3	3	4	3	4	4	2	2	1	1	0	.	1	0	3	3	3	3	4	3	2
329.009.00240	SC	03JAN97	-11, .	0	0	2	1	1	1	1	2	1	0	2	1	0	3	0	2	0	3	3	4	0	0	3	1	0	2	1	0	2
	7	04MAR97	50, .	0	0	4	2	3	4	0	4	3	1	4	4	1	2	1	3	1	2	0	3	0	1	2	3	1	0	1	1	2

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.009.00303	SC	25MAR96	-8, -64	1	0	4	3	3	4	1	1	3	3	3	2	3	3	1	1	1	0	1	2	0	1	0	1	3	4	1	2	1
	8	28MAY96	57, 1	1	0	4	3	3	4	1	2	2	3	1	1	1	4	1	3	1	0	0	1	0	1	0	1	2	3	1	2	1
	32	10DEC96	253, 197	1	0	3	3	2	4	2	2	2	2	3	3	1	3	1	1	1	0	1	3	0	.	0	3	1	2	1	2	1
329.009.00304	SC	03APR96	-6, -62	0	0	4	2	4	3	1	3	3	2	4	1	0	2	1	1	0	1	0	1	0	1	0	2	0	2	1	1	2
	8	04JUN96	57, 1	0	0	2	2	4	4	2	3	3	0	4	1	0	2	1	1	0	1	0	1	0	0	0	1	0	3	0	0	1
329.009.00324	SC	21OCT96	-7, .	4	0	4	3	3	4	4	4	4	2	3	3	0	3	3	3	2	1	0	3	1	2	1	4	3	4	2	2	4
	8	27DEC96	61, .	4	0	4	3	2	4	4	3	3	3	3	2	2	4	2	3	2	2	2	3	1	2	1	4	3	3	2	2	3
329.009.00328	SC	30SEP96	-7, .	1	1	4	2	4	2	1	4	2	2	2	1	1	3	0	3	0	0	1	3	0	0	0	4	0	1	1	0	0
329.009.00329	SC	01OCT96	-8, .	0	0	2	2	2	3	0	2	0	1	1	0	0	3	0	4	1	2	0	.	0	0	1	1	0	1	1	1	0
	8	03DEC96	56, .	0	0	2	2	3	3	0	2	0	0	0	0	0	4	1	4	1	0	0	2	1	0	1	1	0	2	2	0	0
329.010.00182	SC	05DEC95	-14, .	2	2	1	1	2	1	1	2	1	1	1	1	1	4	1	3	0	1	1	4	1	1	1	1	1	2	1	1	1
329.010.00278	SC	02FEB96	-7, -63	4	4	4	2	2	4	0	2	4	2	4	3	4	2	0	2	0	1	0	3	0	1	2	3	1	3	1	1	2
	8	05APR96	57, 1	4	4	4	4	3	4	3	3	4	3	4	4	4	3	1	3	1	2	2	.	1	2	2	3	1	4	1	2	3
	32	19SEP96	224, 168	4	4	4	4	3	4	4	3	4	4	4	3	4	3	1	3	3	3	1	3	2	3	3	3	3	3	2	3	3
329.010.00280	SC	10MAY96	-7, -62	0	0	4	3	1	2	1	2	0	1	1	0	0	4	2	3	3	0	0	.	0	0	2	3	0	0	1	0	3
	8	11JUL96	56, 1	0	0	4	4	1	2	1	1	0	2	1	1	0	4	3	3	3	0	0	.	1	0	3	3	0	0	0	0	3
	12	21AUG96	97, 42	0	0	4	3	2	3	0	4	0	2	0	0	0	4	4	3	4	1	0	.	0	0	3	4	0	0	1	0	2
329.011.00283	SC	30JAN96	-9, -66	0	0	4	1	2	3	0	2	1	0	2	0	0	2	0	0	1	0	0	1	0	0	0	1	1	0	0	1	2
	8	04APR96	57, -1	0	0	4	3	2	4	0	4	3	1	2	0	0	4	1	1	1	0	0	3	0	0	1	3	0	0	1	1	1
329.011.00288	SC	01JUL96	-24, .	0	0	2	1	2	3	0	3	2	0	2	0	3	0	1	1	0	3	0	2	0	3	0	1	0	3	0	0	1
329.012.00025	SC	17OCT95	-7, .	2	0	4	2	4	1	0	2	0	1	0	0	0	4	4	1	1	0	0	3	0	0	1	3	0	2	0	1	1

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.012.00025	8	19DEC95	57, .	4	0	4	2	2	2	0	1	2	2	1	0	0	4	4	0	1	1	0	4	0	0	1	1	0	1	0	1	1
329.012.00220	SC	04JUN96	-13, -73	4	0	4	2	2	2	1	2	2	1	1	2	1	2	1	3	0	1	1	1	1	1	1	3	2	3	2	2	2
	8	16AUG96	61, 1	1	0	4	2	4	4	1	1	2	2	4	0	0	3	2	4	0	1	1	3	2	0	2	0	2	0	2	2	1
329.012.00222	SC	18JUN96	-10, -73	0	0	4	1	3	2	0	0	0	1	0	0	0	4	0	1	1	1	0	3	0	0	2	3	0	4	1	1	2
	8	30AUG96	64, 1	0	0	4	1	3	3	0	2	3	2	2	0	0	4	1	0	1	0	0	4	0	0	1	2	0	2	3	1	1
329.012.00226	SC	26NOV96	-7, .	4	0	3	2	2	3	1	3	3	2	3	1	1	2	1	1	0	0	0	2	0	0	0	1	0	3	0	0	1
329.012.00228	SC	04MAR97	-15, .	0	0	4	2	3	3	0	1	0	1	0	0	0	3	1	2	4	0	0	3	0	0	2	0	0	0	0	1	1
329.012.00231	SC	26FEB97	-9, -70	0	0	3	1	1	3	2	3	3	1	2	1	1	4	1	1	2	0	3	3	2	0	1	3	2	2	2	1	1
	8	07MAY97	62, 1	0	0	2	1	1	3	2	3	1	1	2	1	2	3	2	1	3	1	3	3	3	1	2	3	3	3	2	1	2
	24	19AUG97	166, 105	1	1	3	3	3	3	3	3	3	3	3	1	0	3	3	2	2	1	2	3	3	1	3	3	3	1	1	0	2

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.001.00061	SC	19JUL94	-10, .	0	0	2	2	4	1	0	1	3	1	2	1	0	3	2	1	3	0	0	.	0	0	0	2	0	1	2	1	3
329.001.00066	SC	14NOV94	-8, .	4	4	4	2	4	4	3	3	3	3	3	4	4	4	3	0	1	1	1	4	1	0	0	3	3	4	1	4	2
329.001.00067	SC	15NOV94	-7, .	0	0	4	2	2	2	1	1	2	1	2	3	1	3	3	3	2	1	0	2	0	0	0	0	1	0	2	0	1
329.001.00070	SC	14FEB95	-8, .	0	0	3	3	4	3	0	1	1	2	1	1	0	2	2	1	0	1	0	1	0	0	1	3	1	1	1	2	3
329.001.00122	SC	13JUN95	-7, -64	4	4	3	2	3	2	1	1	3	3	2	3	0	3	1	1	0	1	0	2	0	1	1	2	0	4	2	1	2
	8	16AUG95	58, 1	4	1	4	4	3	3	3	1	2	3	2	4	1	3	1	3	1	2	0	1	1	0	3	2	0	4	3	1	3
329.002.00050	SC	10MAR95	-13, .	4	0	4	2	3	0	0	1	1	0	1	1	1	3	2	3	0	0	0	2	2	0	0	4	0	3	1	0	3
	5	28APR95	37, .	3	0	4	3	3	1	1	1	1	1	2	0	1	2	1	3	0	0	0	2	4	3	0	4	1	2	1	1	3
329.002.00056	SC	24JUN94	-25, .	4	4	4	1	2	0	1	0	0	3	3	0	0	2	1	0	0	1	0	2	0	0	0	3	0	4	2	3	1
329.002.00057	SC	11AUG94	-28, -85	0	0	4	1	2	1	0	2	0	0	0	0	0	4	0	0	0	0	0	3	0	0	1	2	0	0	1	0	2
	8	03NOV94	57, -1	0	0	4	2	4	4	0	3	3	2	2	0	0	4	2	2	1	0	0	4	0	0	2	3	0	0	0	0	2
	16	11JAN95	126, 69	0	0	4	2	3	4	0	3	2	1	2	.	.	4	0	1	0	0	0	1	2	0	1	1	0	1	0	1	0
329.002.00098	SC	20DEC94	-14, .	0	0	4	3	4	4	4	4	3	3	4	2	2	4	1	1	1	0	4	3	1	0	3	4	0	4	2	0	2
	8	02MAR95	59, .	0	0	4	2	4	4	3	3	4	2	3	2	1	4	0	3	2	0	0	4	1	0	1	2	0	3	3	2	4
329.002.00100	SC	16FEB95	-19, -77	0	0	4	4	4	4	4	1	3	3	3	3	3	4	1	2	2	0	1	3	1	4	2	3	0	4	4	1	2
	8	04MAY95	59, 1	3	0	4	4	4	4	3	1	4	2	3	1	3	4	3	3	3	1	2	.	1	2	2	3	0	3	3	2	2
	16	06JUL95	122, 64	0	0	4	4	4	4	4	4	4	4	4	3	4	3	2	2	3	0	0	3	0	0	2	3	0	4	4	1	3
329.002.00103	SC	11APR95	-9, -65	3	0	4	4	3	4	2	4	3	3	4	2	0	3	3	2	3	2	0	2	0	0	2	2	2	3	1	3	4
	8	15JUN95	57, 1	4	0	4	4	3	4	3	3	2	3	3	2	2	3	1	1	1	0	0	4	1	0	3	4	1	3	1	3	3
	16	10AUG95	113, 57	4	0	4	4	4	4	3	4	3	4	2	3	3	4	3	2	2	1	0	4	1	1	3	4	3	4	2	3	3

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.002.00104	SC	28APR95	-6, -62	0	0	3	3	2	3	2	2	2	2	1	2	0	2	2	3	1	1	3	1	1	0	2	1	3	1	1	1	2
	8	29JUN95	57, 1	0	0	3	3	3	4	2	1	2	2	2	2	1	2	2	3	1	1	2	1	1	2	1	1	2	2	1	1	2
	32	02JAN96	244, 188	3	0	3	2	3	4	1	2	3	3	3	3	1	2	2	2	1	1	2	3	1	1	2	1	3	2	2	2	2
329.002.00243	SC	27FEB96	-16, .	0	0	4	2	2	4	2	2	4	4	4	0	4	4	4	1	0	0	0	4	0	0	1	1	3	1	1	3	2
329.002.00244	SC	14MAR96	-7, -64	4	0	4	3	4	3	2	3	3	3	3	3	3	3	3	3	1	1	1	.	3	1	1	3	0	3	2	3	2
	8	16MAY96	57, -1	4	0	4	3	4	4	3	3	3	4	3	3	3	3	4	3	1	0	0	.	3	0	2	3	1	4	2	4	3
329.002.00321	SC	15MAY96	-8, .	0	0	4	2	3	3	0	2	3	1	0	0	0	2	0	1	0	0	0	4	0	0	1	1	1	0	0	0	2
329.002.00322	SC	06JAN97	-3, .	0	0	3	2	2	1	1	1	2	1	1	2	0	4	1	1	0	3	0	3	0	0	1	2	1	3	1	1	3
329.003.00073	SC	11JAN95	-8, .	0	0	4	1	2	2	2	2	2	0	3	3	1	2	2	1	1	0	0	2	2	1	1	2	2	1	1	1	1
329.003.00076	SC	24JAN95	-7, -62	3	3	4	1	4	4	4	3	3	2	2	2	3	4	3	4	4	3	4	.	4	4	3	4	3	4	2	2	4
	32	11OCT95	254, 199	0	0	3	3	3	4	4	4	3	2	2	2	4	4	3	1	4	2	1	.	3	4	.	3	3	3	2	3	4
329.003.00088	SC	06FEB95	-22, .	2	0	3	3	3	2	2	2	3	3	1	2	0	2	1	0	1	0	0	.	1	0	1	2	2	1	2	3	3
329.003.00090	SC	08MAR95	-6, .	1	0	4	4	3	3	3	3	4	3	3	4	0	2	0	2	2	0	0	.	0	0	1	2	0	2	1	1	4
	8	16MAY95	64, .	0	0	4	4	4	4	0	4	4	3	3	4	0	3	0	2	3	0	0	.	0	0	1	3	1	4	4	1	3
329.003.00092	SC	13APR95	-20, -78	0	0	3	2	1	1	1	1	0	2	0	0	0	2	1	2	0	1	1	.	2	0	2	0	0	2	1	1	2
	8	30JUN95	59, 1	0	0	3	3	2	2	1	2	1	2	1	3	1	2	2	2	0	2	2	.	1	1	2	1	1	2	3	2	3
	32	02JAN96	245, 187	0	0	2	1	3	4	0	1	2	2	0	4	0	2	1	2	0	3	0	.	0	0	2	0	0	0	2	1	4
329.003.00093	SC	08JUN95	-13, -76	4	0	4	2	2	3	3	4	3	3	4	2	2	4	0	0	2	0	2	.	0	0	3	3	0	0	1	0	0
	8	22AUG95	63, -1	4	4	4	2	3	4	4	4	3	2	3	2	2	4	1	1	4	1	3	3	1	2	4	4	0	4	2	2	1
	16	03OCT95	105, 42	3	0	4	3	3	4	4	4	2	2	3	1	2	4	1	2	3	1	3	4	1	0	1	4	1	3	1	1	2

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.003.00247	SC	05JAN96	-27, -81	0	0	3	1	1	2	2	3	1	2	3	0	1	4	1	2	0	0	4	4	1	1	2	3	3	0	1	1	2
	8	26MAR96	55, 1	0	0	4	3	3	3	2	4	3	3	4	2	1	3	1	1	0	0	4	3	1	0	1	3	2	1	1	1	1
329.003.00249	SC	01MAR96	-6, .	4	0	3	2	2	2	1	1	1	2	3	4	2	2	3	1	0	0	1	1	1	0	0	0	0	0	1	1	0
	8	30APR96	55, .	4	0	3	3	3	4	1	1	1	3	1	3	2	3	3	1	0	0	2	.	1	0	0	2	1	0	1	1	2
329.003.00289	SC	12FEB96	-16, -72	0	0	3	3	0	0	0	0	0	0	0	0	0	4	4	2	0	0	0	.	0	0	2	0	0	3	0	0	0
	8	24APR96	57, 1	0	0	0	3	0	3	0	0	0	0	0	0	0	2	3	2	0	0	0	.	0	0	0	0	0	2	2	0	0
	32	11OCT96	227, 171	0	0	3	3	3	0	0	0	0	0	0	0	.	3	3	3	3	0	0	.	2	0	2	0	2	2	2	0	0
329.003.00290	SC	06MAR96	-5, .	0	0	4	1	4	4	0	0	0	4	0	3	4	0	3	4	0	4	0	.	0	4	0	0	0	0	1	0	4
329.003.00317	SC	12DEC96	-7, .	0	0	.	4	4	2	2	1	3	3	3	2	1	2	1	1	1	1	1	.	1	0	0	1	0	0	3	1	2
	8	11FEB97	55, .	0	0	2	2	3	1	1	1	1	3	2	3	2	3	1	1	1	1	1	.	1	1	0	1	0	0	1	1	1
329.004.00013	SC	05JUL94	-14, -73	4	4	4	3	4	3	3	1	3	4	2	1	2	4	4	3	0	1	0	3	1	4	1	3	1	4	1	3	2
	8	16SEP94	60, 1	4	4	4	3	4	4	1	1	3	4	2	3	3	3	2	3	1	2	0	3	1	4	1	3	1	4	3	3	3
329.004.00014	SC	22NOV94	-7, .	0	0	4	4	4	4	4	4	4	0	4	0	0	3	0	0	0	0	0	2	0	0	0	0	0	2	0	0	2
329.004.00211	SC	24JAN96	-9, .	0	4	4	3	2	4	3	4	4	4	4	3	4	4	2	0	1	0	2	3	0	0	0	2	1	3	0	4	3
329.004.00215	SC	12MAR97	-8, .	4	0	4	3	2	3	1	1	2	3	0	3	1	3	3	3	0	0	4	2	0	2	0	2	0	0	0	3	1
329.005.00003	SC	12SEP94	-8, .	0	0	4	4	4	4	4	4	4	1	4	1	1	4	4	4	4	4	3	4	0	4	4	4	4	0	0	0	4
329.005.00006	SC	27OCT94	-8, -68	3	2	4	4	4	4	4	4	3	4	4	4	4	4	2	1	1	0	3	.	4	2	2	2	2	3	2	3	2
	8	03JAN95	61, 1	4	4	4	4	4	4	4	4	4	4	4	4	4	3	2	1	2	0	2	.	4	4	1	2	3	4	2	4	3
	24	28APR95	176, 116	4	0	4	4	4	4	4	4	4	4	4	4	4	4	3	2	2	1	4	.	4	4	3	3	3	4	3	4	3
329.005.00007	SC	02NOV94	-7, -70	0	0	4	3	4	3	0	1	0	4	3	0	0	3	1	1	0	0	0	.	2	0	0	2	4	0	3	2	3

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.005.00007	8	11JAN95	64, 1	0	0	4	3	3	2	1	1	0	4	1	3	0	4	2	2	0	0	0	.	1	0	1	1	3	0	3	2	1
	32	09AUG95	274, 211	4	0	4	4	4	4	2	1	3	4	4	4	1	4	3	3	1	0	0	.	3	0	3	4	0	4	3	3	3
329.005.00009	SC	07DEC94	-5, .	3	0	4	4	3	4	3	2	1	3	3	3	3	4	4	4	1	1	3	4	4	3	1	2	1	2	1	4	3
	8	07FEB95	58, .	4	0	4	2	2	4	2	3	2	3	4	4	0	4	4	2	3	0	0	3	3	0	1	3	1	4	3	3	3
329.005.00110	SC	04JAN95	-7, .	4	0	4	0	4	4	3	3	4	3	4	4	4	3	2	0	2	0	0	3	1	0	0	2	0	4	4	2	2
329.005.00113	SC	20JAN95	-10, .	4	4	4	4	4	3	4	4	0	0	4	4	0	4	4	0	4	0	1	.	0	0	0	4	2	4	1	0	1
329.005.00117	SC	06MAR95	-12, .	2	0	4	1	3	3	0	0	0	0	2	1	0	3	1	1	1	1	0	2	0	1	1	3	4	2	1	1	2
	8	15MAY95	59, .	2	0	4	3	4	2	1	1	1	1	1	2	1	4	2	3	2	2	1	1	1	1	1	2	3	3	2	2	2
329.005.00118	SC	09MAY95	-8, .	4	0	3	2	3	4	1	4	2	1	4	1	0	4	2	4	0	0	0	.	0	2	3	0	2	0	0	1	2
329.005.00153	SC	11JAN96	-14, -70	0	0	4	3	3	4	2	3	3	2	3	1	1	4	1	3	2	0	0	3	0	2	2	2	0	1	2	1	2
	8	21MAR96	57, 1	0	0	4	3	3	4	2	3	2	3	3	2	0	3	1	2	1	3	0	2	0	0	2	1	0	0	2	2	2
	32	04SEP96	224, 168	0	0	4	2	4	4	2	2	2	3	2	0	1	4	1	2	.	0	0	3	0	2	2	3	0	0	1	0	2
329.005.00255	SC	26FEB96	-7, .	4	0	4	4	4	4	0	2	3	3	3	1	2	3	3	1	2	3	3	3	2	3	3	3	3	4	2	2	3
	8	29APR96	57, .	3	0	4	4	4	4	0	2	4	3	3	3	3	3	4	2	2	2	2	.	1	3	3	3	1	3	2	2	2
329.005.00256	SC	20FEB96	-14, -70	0	0	3	2	1	2	0	2	3	3	3	4	2	4	4	0	3	3	0	.	0	0	0	3	0	0	1	1	2
	8	30APR96	57, 1	0	0	4	1	2	4	0	0	4	4	4	4	0	4	4	1	0	0	0	3	0	4	0	4	0	3	1	2	1
329.005.00295	SC	21MAR96	-7, .	0	0	2	3	2	3	2	3	2	1	3	0	0	3	4	1	0	0	0	3	0	0	2	3	0	3	1	1	1
	8	22MAY96	56, .	0	0	3	3	3	4	3	2	2	1	2	0	0	2	4	1	0	0	0	3	0	0	1	2	0	2	3	1	2
329.005.00297	SC	28MAR96	-22, .	0	1	1	1	0	1	2	3	2	1	2	0	1	3	0	1	0	0	0	.	.	0	0	1	0	3	1	1	2
329.005.00332	SC	05DEC96	-7, .	0	0	4	3	2	4	1	4	4	3	4	3	0	4	0	1	0	1	4	2	0	1	0	1	0	4	1	1	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.005.00332	8	06FEB97	57, .	3	0	4	3	4	4	3	3	3	3	3	3	1	4	1	1	0	0	3	3	0	0	0	1	3	2	1	2	2
329.005.00335	SC	20FEB97	-8, .	0	0	4	4	4	4	4	4	3	3	4	3	4	4	1	1	1	1	3	.	3	0	0	3	3	3	0	1	2
329.006.00040	SC	10FEB95	-6, .	3	0	4	4	3	0	1	1	1	3	1	.	0	4	0	0	1	0	0	1	0	0	1	2	0	0	3	2	3
329.006.00041	SC	22MAR95	-14, -78	0	0	4	4	4	3	3	2	0	4	3	4	4	4	3	4	3	0	2	.	2	1	1	4	1	0	0	4	2
	8	31MAY95	57, -8	4	4	4	4	4	4	4	1	4	4	4	4	4	4	.	1	4	0	1	.	4	4	3	4	2	4	0	4	2
	32	21NOV95	231, 167	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	0	1	4	4	4	4	4	2	4	1	4	4
329.007.00139	SC	04MAY95	-4, .	0	0	1	1	1	3	1	2	1	1	2	2	1	2	2	3	1	1	1	.	1	2	3	2	1	4	3	1	2
329.007.00143	SC	26OCT95	-14, .	0	0	2	1	1	3	0	0	0	3	0	0	0	3	3	3	0	3	1	4	2	0	0	0	0	0	2	2	2
329.007.00146	SC	18JAN96	-7, -60	0	0	3	0	2	4	4	1	2	2	0	2	3	2	1	1	1	2	2	1	1	0	0	1	1	3	1	2	1
	8	18MAR96	54, 1	0	0	2	0	2	3	3	2	1	1	2	1	1	2	1	1	1	3	0	2	0	0	0	1	2	3	1	1	1
	32	09SEP96	229, 176	1	0	1	0	2	3	3	1	2	1	0	0	1	2	1	3	2	3	0	0	0	1	1	1	0	3	1	0	1
329.007.00269	SC	04APR96	-7, .	0	0	3	1	2	3	1	1	2	1	4	1	0	2	3	3	0	1	0	1	0	1	0	1	0	1	1	1	1
	3	02MAY96	22, .	0	0	3	1	2	3	0	0	2	0	4	1	0	3	2	4	0	1	0	2	0	0	0	1	0	1	1	0	1
329.007.00270	SC	02MAY96	-7, .	0	0	4	3	4	3	2	1	2	1	1	0	0	3	2	2	1	0	0	1	1	1	0	1	0	0	1	0	1
	7	27JUN96	50, .	0	0	3	4	4	3	0	3	2	0	0	2	0	1	0	0	0	0	0	0	0	0	0	0	0	4	3	0	2
329.007.00307	SC	09MAY96	-7, .	0	0	4	2	4	3	1	1	1	1	1	2	0	2	1	0	0	0	0	1	0	0	0	0	0	2	2	1	1
	8	25JUL96	71, .	1	0	3	3	4	1	0	0	0	2	0	1	0	2	0	0	0	0	0	0	0	0	0	1	0	1	1	0	0
329.007.00308	SC	27JUN96	-5, .	0	0	1	0	0	1	0	1	0	0	0	0	0	4	0	4	1	0	1	1	0	0	1	4	0	0	0	0	1
329.008.00159	SC	06SEP95	-7, -69	3	0	4	3	4	4	2	3	3	3	3	2	1	3	1	4	3	3	1	.	1	3	1	3	2	1	1	2	2

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.008.00161	SC	31OCT95	-16, -71	0	0	3	2	3	3	1	2	2	0	2	.	.	3	1	1	0	1	0	3	0	0	0	1	1	2	2	1	1
329.008.00187	SC	15NOV95	-14, .	0	0	4	4	3	2	1	2	2	3	1	0	3	3	1	1	0	0	0	2	3	0	0	4	0	0	1	3	1
	8	26JAN96	59, .	0	0	4	4	3	1	0	1	3	4	3	3	4	3	1	1	0	0	0	2	3	0	0	3	3	0	1	4	2
329.008.00192	SC	14FEB96	-20, .	1	0	2	2	2	2	0	2	1	1	1	0	0	3	3	2	1	1	0	.	0	1	0	0	1	2	1	1	2
329.008.00272	SC	19MAR96	-15, -71	0	0	2	3	3	2	0	0	0	1	0	1	0	1	1	2	0	1	0	0	0	0	1	0	0	0	1	0	1
	8	29MAY96	57, 1	0	0	1	3	3	2	1	2	2	1	1	3	0	1	2	2	1	1	0	1	0	0	1	0	0	1	0	0	1
329.008.00273	SC	19APR96	-28, -91	2	3	2	1	2	4	2	4	4	4	4	2	3	2	3	0	0	1	4	.	1	3	0	3	1	4	1	4	3
	8	19JUL96	64, 1	4	0	3	2	3	1	0	3	4	3	1	3	0	4	2	4	1	4	1	4	0	4	3	2	0	1	2	4	3
329.009.00127	SC	03APR95	-7, .	0	0	4	0	1	4	2	0	0	3	0	0	0	4	4	2	1	0	0	0	1	0	1	1	0	0	1	2	4
329.009.00132	SC	17MAY95	-6, -63	2	0	2	2	3	3	3	1	2	1	2	2	4	2	2	1	1	3	2	.	1	1	1	0	0	3	2	1	3
	8	19JUL95	58, 1	4	0	3	3	3	3	3	2	2	1	3	4	2	1	1	1	1	1	1	1	1	2	2	1	1	3	2	1	2
329.009.00134	SC	28JUN95	-8, .	0	1	4	3	3	2	1	1	1	3	1	1	2	2	2	1	0	0	1	1	0	0	0	2	0	1	2	1	2
	8	29AUG95	55, .	2	0	4	3	3	4	1	3	3	3	3	3	2	3	3	2	1	0	3	2	1	1	1	3	0	2	2	3	4
329.009.00137	SC	03OCT95	-7, .	0	0	3	3	2	2	0	0	3	2	1	0	0	2	2	2	0	0	0	3	1	1	2	0	0	2	2	0	2
	8	05DEC95	57, .	0	0	2	2	2	3	1	1	0	1	0	1	0	3	2	3	0	0	0	0	3	1	2	2	1	1	1	0	1
329.009.00171	SC	31OCT95	-7, .	0	0	3	0	2	2	2	0	1	3	3	2	0	2	1	2	2	1	1	1	2	0	1	.	1	1	3	0	3
329.009.00172	SC	06NOV95	-7, -64	0	0	4	3	4	4	3	4	4	3	2	2	1	3	1	3	1	3	4	4	0	0	2	1	4	3	3	3	3
	8	09JAN96	58, 1	0	0	4	3	4	4	3	4	4	3	4	3	1	3	1	3	2	2	3	3	3	0	0	4	3	3	3	4	4
	32	08JUL96	239, 182	0	0	4	4	4	4	0	4	4	4	4	3	0	4	2	0	3	0	3	1	0	0	1	1	3	4	2	3	3
329.009.00194	SC	28NOV95	-7, -63	0	0	1	1	1	1	0	1	2	2	0	0	0	1	1	1	0	1	1	1	0	0	0	0	0	0	1	1	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.009.00194	8	30JAN96	57, 1	0	0	1	2	2	3	2	1	1	3	1	0	0	1	1	3	0	1	2	1	0	0	0	0	0	0	1	1	2
	24	04JUN96	183, 127	0	0	2	2	3	3	2	3	0	2	0	0	1	2	4	2	0	2	2	4	0	1	1	1	1	3	1	1	2
329.009.00195	SC	06DEC95	-9, .	0	0	4	3	3	3	3	4	3	2	3	1	2	4	1	2	2	1	2	1	0	1	1	1	3	3	1	1	1
329.009.00199	SC	10JAN96	-6, .	0	0	4	3	4	4	2	1	1	0	2	2	0	4	4	2	0	0	0	1	1	0	3	1	0	1	1	0	1
	8	13MAR96	58, .	0	0	4	4	4	4	2	3	1	2	3	3	1	4	4	3	2	4	4	1	1	1	4	3	1	2	3	3	3
329.009.00203	SC	28FEB96	-5, .	0	0	1	1	0	2	1	2	2	0	2	1	0	4	4	2	1	0	3	1	1	0	2	2	1	4	2	0	2
329.009.00236	SC	17DEC96	-13, .	3	0	2	1	3	1	0	0	3	1	3	0	0	4	1	1	1	3	4	3	1	0	1	2	0	2	1	1	3
	4	27JAN97	29, .	1	0	1	1	2	1	0	1	1	2	2	2	0	4	1	1	1	1	3	2	0	0	1	1	0	2	0	1	2
329.009.00239	SC	11NOV96	-8, -65	0	0	3	2	3	4	2	3	3	1	3	0	0	3	2	1	1	1	1	2	1	0	0	3	3	1	1	0	2
	8	15JAN97	58, 1	0	0	4	2	4	3	2	4	3	2	3	1	1	3	3	3	1	1	2	3	0	0	0	3	3	0	2	1	3
329.009.00262	SC	07FEB97	-10, .	0	0	3	3	2	4	3	1	2	3	0	4	4	2	2	3	0	1	1	2	0	3	1	1	1	2	1	2	3
	8	14APR97	57, .	0	0	4	4	3	4	4	1	1	3	1	4	3	2	3	3	0	0	0	.	0	1	1	1	1	2	2	2	3
329.009.00264	SC	25OCT96	-7, .	1	0	4	3	3	3	1	4	3	1	1	1	1	2	1	1	1	1	2	3	0	0	1	3	3	1	1	1	3
	7	23DEC96	53, .	0	0	3	1	3	4	0	2	0	0	0	2	1	2	1	1	1	0	1	1	0	0	0	1	1	1	1	0	3
329.009.00301	SC	06MAR96	-13, -69	0	0	4	2	3	4	1	3	3	1	3	1	0	4	1	2	0	0	0	2	0	0	1	2	0	0	1	1	1
	8	14MAY96	57, 1	1	0	4	3	3	4	2	3	3	1	4	3	1	4	0	2	0	.	2	3	0	0	0	2	0	0	1	1	1
329.009.00305	SC	01MAY96	-6, -63	0	0	3	2	4	1	0	0	2	2	2	3	0	2	0	2	0	0	2	.	1	0	0	2	0	2	1	0	2
	8	03JUL96	58, 1	0	0	3	2	4	3	0	1	3	0	2	3	0	4	2	3	0	0	4	.	2	0	0	2	0	1	2	0	3
	32	10JAN97	249, 192	0	3	4	3	3	3	3	2	4	3	4	4	0	4	2	3	0	0	4	.	3	2	0	1	0	3	3	0	3
329.009.00325	SC	21AUG96	-6, -61	0	0	4	2	2	4	1	1	2	3	3	1	2	4	2	2	3	3	0	3	0	0	1	3	0	0	4	3	2
	8	21OCT96	56, 1	0	0	4	3	3	4	1	2	1	4	4	4	4	2	2	3	1	1	0	0	0	0	1	2	0	0	3	4	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.009.00325	16	16DEC96	112, 57	0	0	4	1	1	2	1	3	1	3	3	1	1	2	1	3	1	1	0	1	0	0	1	2	0	0	2	3	1
329.009.00326	SC	26AUG96	-10, -63	0	0	2	1	1	3	0	0	2	0	0	1	2	4	0	0	0	0	0	4	0	0	0	2	0	4	4	1	4
	8	28OCT96	54, 1	0	0	3	4	4	2	2	3	2	2	2	1	1	4	0	4	0	0	0	4	0	0	0	4	0	2	2	2	3
	16	16DEC96	103, 50	0	0	4	3	2	1	2	1	1	1	2	2	1	4	1	0	0	0	0	4	0	0	0	3	0	4	2	2	2
329.010.00279	SC	08MAR96	-14, -70	0	0	2	3	2	2	0	4	3	2	0	3	0	4	4	3	1	0	2	.	1	3	3	4	0	4	2	1	1
	8	17MAY96	57, 1	0	0	2	3	2	3	2	1	1	2	1	3	0	4	4	1	1	0	2	.	2	0	3	3	0	4	1	2	2
	32	06NOV96	230, 174	0	0	3	4	3	4	3	2	3	3	2	3	2	4	4	2	1	2	1	.	2	1	2	4	2	4	3	2	3
329.010.00281	SC	19JUL96	-7, -68	0	0	2	2	1	3	0	2	2	0	1	0	0	2	0	2	0	0	0	.	2	0	3	0	1	0	1	0	1
	8	25SEP96	62, 1	0	0	1	1	1	3	1	3	2	0	0	0	0	4	0	2	0	0	0	4	3	0	1	2	0	0	1	0	2
	24	03JAN97	162, 101	2	0	1	1	1	3	1	2	1	0	0	0	0	2	0	3	0	2	0	1	0	0	4	2	0	2	1	0	2
329.011.00163	SC	18NOV95	-7, .	1	0	4	2	2	1	1	0	1	2	1	1	0	3	0	0	1	0	0	3	0	0	1	4	1	2	1	1	1
329.011.00208	SC	22AUG96	-15, -74	2	2	2	2	3	3	3	1	1	3	2	0	2	2	3	2	1	1	2	3	3	1	3	2	2	1	2	3	2
	8	03NOV96	59, -1	4	0	2	2	3	3	3	2	3	4	3	2	3	2	2	4	1	1	3	2	2	3	3	2	2	2	2	4	3
329.011.00209	SC	23AUG96	-19, -81	2	0	3	3	3	2	2	0	3	1	0	0	0	4	1	2	0	0	0	3	0	2	2	3	0	0	1	0	0
	8	11NOV96	62, -1	1	0	3	3	4	3	3	4	3	4	3	2	0	3	1	3	1	0	0	4	0	3	1	3	2	2	2	4	3
329.011.00284	SC	13MAR96	-9, -65	0	0	2	1	2	1	1	1	1	0	1	0	1	4	1	1	1	0	1	3	0	0	1	1	0	1	1	0	0
	8	16MAY96	56, -1	0	0	3	2	2	3	1	1	3	2	3	1	1	3	1	2	1	1	4	4	1	2	1	2	0	1	3	1	2
329.011.00286	SC	15MAY96	-22, -90	0	0	3	1	1	2	1	1	3	1	2	0	0	3	2	1	2	0	0	1	0	0	1	3	1	2	0	1	2
	8	09AUG96	65, -4	0	0	4	2	2	3	1	2	2	3	3	0	0	3	2	2	2	0	0	1	0	0	2	3	0	0	1	0	1
329.012.00026	SC	09NOV95	-19, .	0	0	3	1	2	1	1	0	1	1	0	1	0	1	1	4	0	0	0	.	1	0	0	0	0	1	1	0	2
329.012.00219	SC	24MAY96	-7, -67	2	0	3	3	2	4	1	2	2	2	3	0	1	2	1	3	1	2	1	1	0	0	2	3	3	3	1	1	2

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.012.00219	8	30JUL96	61, 1	3	0	3	2	3	3	2	2	4	2	2	2	2	2	1	3	2	1	1	2	1	1	1	2	0	4	1	0	2
	32	24JAN97	239, 179	3	0	3	2	3	4	1	2	3	2	3	0	0	3	2	2	1	0	1	3	0	0	0	1	2	0	0	1	0
329.012.00221	SC	18JUN96	-7, -70	1	0	4	4	4	4	3	3	4	4	3	4	4	4	0	3	0	0	1	.	0	0	2	0	0	2	3	4	4
	8	27AUG96	64, 1	3	0	2	3	4	4	4	2	0	4	2	4	2	4	1	3	0	0	4	2	1	2	2	1	0	3	0	4	4
329.012.00223	SC	23AUG96	-7, .	0	0	4	1	1	3	0	1	3	1	0	0	1	2	2	1	1	1	0	0	0	0	1	1	0	1	1	0	2
329.012.00227	SC	12DEC96	-6, -75	1	0	4	2	3	4	3	3	4	4	4	0	2	4	3	3	0	4	4	3	3	4	0	1	0	2	1	1	3
	8	25FEB97	70, 1	3	3	4	3	4	4	1	3	3	2	4	3	2	4	3	3	0	3	4	.	1	4	1	1	1	4	3	2	3
	32	19AUG97	245, 176	2	2	2	3	3	3	3	3	1	1	1	2	1	4	1	2	2	3	3	4	2	1	2	2	2	2	2	1	1
329.012.00230	SC	20FEB97	-8, -77	1	0	4	1	2	3	0	1	2	1	1	1	0	2	1	2	0	0	0	3	1	0	1	3	1	1	1	0	2
	8	08MAY97	70, 1	0	0	4	2	3	3	2	0	2	0	0	3	0	0	2	4	1	1	0	1	0	0	1	1	0	0	0	0	2

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.001.00062	SC	06OCT94	-14, .	0	0	3	2	3	2	2	1	1	2	2	1	1	3	2	1	2	0	0	.	1	0	1	1	1	1	1	1	1
329.001.00064	SC	04NOV94	-6, -60	0	0	1	1	4	2	0	2	1	1	2	0	0	4	1	4	0	1	0	1	0	0	1	1	0	0	1	0	1
	8	03JAN95	55, 1	0	0	2	2	3	2	0	3	3	2	2	0	0	3	2	3	0	1	0	.	3	0	1	1	0	1	1	0	2
329.001.00069	SC	07FEB95	-9, .	0	0	3	1	2	4	0	3	4	0	3	2	0	3	1	4	0	0	1	1	0	3	0	0	1	0	2	0	1
	8	13APR95	57, .	0	0	4	2	3	4	1	4	3	2	3	2	1	3	2	3	0	0	3	2	0	2	1	0	2	1	2	2	2
329.001.00071	SC	02FEB95	-21, .	2	0	3	1	4	3	2	3	2	2	1	2	1	2	3	1	3	1	2	4	1	0	1	3	1	2	0	2	2
	8	20APR95	57, .	4	0	3	1	4	4	1	2	1	3	1	2	0	2	3	1	2	1	2	4	1	0	1	4	1	3	0	2	3
329.001.00123	SC	14DEC95	-21, .	0	0	3	1	3	1	1	0	0	0	0	1	1	3	1	1	1	0	0	2	2	0	0	0	0	1	1	0	1
329.001.00207	SC	19FEB96	-9, .	3	0	2	2	3	4	1	1	4	2	3	1	0	3	1	3	0	2	0	1	0	0	0	2	0	0	0	1	3
	8	24APR96	57, .	0	0	4	2	4	4	2	2	4	3	4	1	0	4	1	2	0	0	0	4	4	0	1	2	0	0	0	0	3
329.002.00049	SC	03MAR95	-6, .	1	0	3	2	2	3	1	0	0	2	0	3	0	4	3	4	1	2	4	.	1	0	0	0	0	0	2	2	1
	8	05MAY95	58, .	3	0	4	1	1	0	0	0	0	2	0	4	0	4	4	4	1	0	4	0	0	3	0	2	0	1	1	2	2
329.002.00059	SC	03NOV94	-7, .	0	0	4	3	3	0	0	0	1	1	0	3	3	4	0	0	0	0	0	1	1	0	0	0	0	0	2	0	2
	8	05JAN95	57, .	0	0	3	2	2	0	0	0	2	0	0	3	1	3	1	1	1	0	0	1	0	0	1	1	0	1	3	1	2
329.002.00060	SC	24JAN95	-7, -63	0	0	3	1	0	3	0	4	3	3	3	0	0	4	1	1	1	0	0	1	0	0	1	2	0	1	1	0	2
	8	28MAR95	57, 1	0	0	2	2	1	3	0	3	1	3	3	0	0	3	1	0	3	0	0	3	0	0	1	1	0	0	1	1	3
329.002.00097	SC	20DEC94	-14, -72	0	0	4	4	4	4	2	2	2	3	2	2	0	2	0	2	1	0	0	1	2	0	1	2	0	1	2	2	4
	8	02MAR95	59, 1	0	0	4	3	3	4	3	4	4	2	2	3	1	3	0	1	1	1	0	.	2	0	1	3	0	1	3	4	4
	32	05SEP95	246, 188	0	0	4	4	4	4	1	4	3	3	2	3	1	3	1	1	1	1	0	4	1	0	2	3	0	1	4	3	4
329.002.00101	SC	20MAR95	-8, -66	0	0	3	1	2	2	1	4	2	0	2	1	0	4	1	1	2	0	0	3	1	0	4	3	1	1	0	1	1
	8	25MAY95	59, 1	4	0	4	4	4	4	4	4	3	0	4	3	0	4	0	0	2	3	0	4	0	0	4	3	3	4	1	0	4

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.002.00107	SC	18JAN96	-7, -63	0	0	4	1	1	4	0	0	3	1	3	1	1	3	4	3	1	0	0	1	0	0	1	1	1	1	1	1	4
	8	21MAR96	57, 1	0	0	4	1	2	4	2	1	4	0	3	1	0	4	4	4	1	1	3	4	0	0	0	0	0	1	2	3	4
	32	26SEP96	246, 190	0	0	4	4	2	4	0	4	4	3	3	1	3	4	4	4	2	1	0	2	2	0	3	3	0	2	1	3	4
329.002.00241	SC	25JAN96	-12, -68	1	0	4	3	3	4	2	4	2	2	3	1	0	3	1	3	1	1	2	2	0	2	2	1	2	1	1	1	1
	8	02APR96	57, 1	1	0	4	3	3	4	3	4	2	2	3	2	0	3	1	3	0	0	0	3	1	0	3	2	0	0	1	1	1
329.002.00246	SC	01APR96	-17, .	4	0	4	3	4	4	2	2	4	3	4	2	2	3	1	4	2	0	0	3	3	3	2	4	0	3	2	1	2
	8	18JUN96	62, .	2	1	4	3	4	2	2	2	2	2	3	2	2	3	2	2	2	1	1	3	3	2	1	3	2	1	2	2	2
329.002.00320	SC	09MAY96	-7, -68	4	0	4	3	3	4	4	4	3	4	4	3	4	4	4	2	2	0	0	1	0	0	1	2	0	0	3	3	1
	8	16JUL96	62, 1	3	0	4	3	3	4	4	1	3	3	4	3	4	4	3	2	2	0	0	3	0	0	2	1	0	0	3	2	1
329.002.00323	SC	04NOV96	-8, -66	4	0	4	0	2	4	0	2	2	1	4	1	1	2	2	1	0	0	0	1	0	0	0	1	0	4	0	0	2
	8	09JAN97	59, 1	4	4	4	3	4	2	3	3	4	2	4	4	3	3	3	2	1	1	1	4	2	3	2	3	1	4	3	2	2
	32	12JUN97	213, 155	4	4	4	3	4	4	4	3	3	3	4	4	3	1	1	1	1	1	2	2	1	1	1	2	0	4	3	2	2
329.003.00074	SC	18JAN95	-7, -63	2	0	3	3	4	4	4	2	2	4	4	0	4	0	3	3	0	0	0	.	3	0	2	0	0	0	0	4	4
	8	22MAR95	57, 1	0	0	4	4	4	4	2	2	3	1	2	3	1	4	4	1	1	0	2	3	1	2	1	4	0	1	1	1	1
	32	11OCT95	260, 204	0	0	1	4	4	4	4	1	0	4	3	4	4	0	3	0	0	0	0	.	0	0	1	0	0	0	0	4	4
329.003.00078	SC	11APR95	-15, .	1	0	4	2	2	3	0	1	2	1	0	2	0	4	2	1	0	0	0	2	1	0	0	2	0	3	2	0	2
	8	21JUN95	57, .	1	0	4	2	3	4	1	2	3	1	1	3	0	4	2	1	1	0	1	.	0	0	1	2	1	1	2	1	3
329.003.00080	SC	22NOV95	-5, .	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	.	0	0	0	0	0	0	4	0	0
329.003.00085	SC	26OCT94	-13, .	0	0	4	3	0	3	0	2	3	2	0	3	2	4	4	1	4	0	0	0	0	0	2	2	0	4	4	2	3
	8	03JAN95	57, .	0	0	4	1	4	4	0	2	3	2	0	2	0	4	4	0	3	0	0	.	1	0	1	2	0	4	3	0	2
329.003.00086	SC	09NOV94	-19, -76	0	0	4	3	1	3	3	0	2	0	3	0	0	4	2	3	0	0	0	3	0	0	0	3	0	3	0	0	3
	8	23JAN95	57, -1	0	0	4	4	2	3	2	1	3	0	4	0	0	3	3	3	0	1	0	.	2	0	0	2	0	1	1	1	4

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.003.00086	32	17AUG95	263, 206	0	0	4	4	2	4	0	1	3	1	3	2	0	3	3	3	0	0	0	.	2	0	1	2	0	2	2	0	2
329.003.00094	SC	20OCT95	-4, .	3	0	4	2	4	4	3	4	0	4	1	4	0	4	4	4	2	1	1	3	4	2	2	3	0	0	2	2	1
	8	19DEC95	57, .	0	0	4	0	4	4	2	2	0	4	0	4	1	4	3	1	3	1	2	0	0	3	1	1	0	0	0	3	2
329.003.00252	SC	19MAR96	-22, .	0	0	4	3	2	3	2	3	3	1	1	0	0	3	1	1	1	0	0	0	1	0	1	1	1	0	0	0	1
329.003.00315	SC	29OCT96	-14, .	1	0	3	1	3	1	1	2	1	1	1	3	1	4	2	1	1	0	0	1	.	0	1	2	0	2	1	0	2
	8	07JAN97	57, .	2	0	4	1	2	2	0	1	2	1	1	3	1	4	4	1	2	0	0	1	0	0	1	2	0	1	1	1	2
329.003.00316	SC	05DEC96	-12, .	0	0	2	2	2	0	0	0	3	0	3	2	0	3	1	0	1	0	0	.	2	0	1	2	0	0	0	0	1
	8	11FEB97	57, .	0	0	2	2	2	0	0	0	2	1	3	2	0	4	2	0	0	0	.	1	1	0	1	2	0	0	1	1	2
329.004.00016	SC	01MAR95	-12, .	3	2	4	2	2	3	1	3	3	3	3	3	3	3	2	3	0	0	0	.	1	1	0	1	3	1	1	1	2
329.004.00018	SC	19APR95	-14, .	0	0	4	2	2	0	3	1	4	2	4	0	0	1	0	0	1	0	0	3	3	0	0	4	0	0	4	1	4
	8	29JUN95	58, .	0	0	4	1	2	4	0	1	1	2	0	4	0	2	2	0	1	1	0	.	1	1	3	4	0	0	3	1	1
329.004.00020	SC	02NOV95	-7, .	3	0	4	4	4	4	3	4	3	1	3	1	0	4	3	1	0	0	2	.	0	0	2	3	0	0	0	1	1
	2	24NOV95	16, .	1	0	4	4	1	4	1	4	4	1	4	4	0	4	0	1	0	0	0	.	4	0	2	4	4	1	1	0	1
329.004.00213	SC	18JUL96	-15, -69	0	0	4	2	3	4	2	3	2	2	1	1	1	4	3	2	2	0	1	4	1	1	1	4	0	0	0	2	3
	8	24SEP96	54, -1	0	0	4	3	2	3	1	3	3	2	2	1	1	4	3	2	1	1	0	4	0	0	1	4	0	0	1	1	2
	32	19MAR97	230, 176	0	0	4	4	3	4	1	3	4	3	4	0	1	4	4	3	2	3	0	4	1	0	1	4	0	1	1	3	4
329.005.00001	SC	11APR94	-9, .	0	0	4	4	3	2	3	0	4	3	1	4	3	2	3	0	1	2	1	0	0	0	3	1	1	2	2	3	3
	8	15JUN94	57, .	0	0	4	3	4	3	2	2	4	3	3	4	0	2	2	0	1	1	2	.	0	2	2	1	1	2	2	2	2
329.005.00005	SC	24OCT94	-8, .	0	0	2	2	2	2	0	1	1	0	0	1	0	4	0	2	1	3	3	.	2	0	1	1	0	2	1	0	1
329.005.00010	SC	07DEC94	-6, -63	0	0	4	2	4	2	1	1	1	2	2	2	0	4	1	2	1	0	0	.	2	1	1	2	0	3	4	4	2

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.005.00010	8	08FEB95	58, 1	0	0	4	4	4	4	1	4	3	3	4	3	3	4	2	3	3	1	1	.	1	0	1	2	1	4	3	3	4
	32	09AUG95	240, 183	1	1	4	4	4	4	2	4	3	3	3	4	2	4	4	4	4	3	2	.	4	2	2	3	2	4	4	4	4
329.005.00012	SC	12DEC94	-7, -66	1	0	4	2	2	4	2	1	1	3	3	4	1	3	3	1	1	0	3	2	1	3	1	3	0	3	2	2	2
	8	16FEB95	60, 1	1	0	4	4	2	2	3	1	1	3	3	4	1	2	2	1	2	2	4	.	2	3	1	4	0	3	2	3	2
329.005.00111	SC	05JAN95	-6, -62	0	0	4	1	4	4	4	3	3	3	3	3	3	2	3	2	3	0	2	.	3	0	2	2	0	3	3	3	3
	8	08MAR95	57, 1	0	0	4	4	4	4	4	4	4	2	4	2	3	2	2	3	4	0	0	3	0	0	2	2	0	4	3	1	3
	16	03MAY95	113, 57	0	0	4	3	4	4	4	4	3	4	4	3	4	4	4	4	4	0	3	4	0	3	3	3	0	4	3	4	4
329.005.00114	SC	23JAN95	-8, -65	4	4	3	3	2	3	0	1	3	1	3	2	1	3	3	4	0	0	1	4	1	1	3	4	0	3	1	1	2
	8	29MAR95	58, 1	4	0	4	4	2	4	3	2	3	3	4	2	3	3	2	4	0	0	1	4	1	2	3	3	0	3	1	2	2
	16	17MAY95	107, 50	3	3	2	3	1	4	1	1	3	3	3	1	0	4	2	3	0	0	3	3	0	1	3	4	0	3	1	2	2
329.005.00115	SC	27JAN95	-10, -81	0	0	4	4	4	3	1	1	1	2	1	1	3	3	0	1	0	0	0	.	1	0	0	2	0	3	2	0	1
	8	18APR95	72, 1	0	0	4	3	4	4	3	4	4	3	4	2	4	4	1	2	2	0	0	4	0	2	2	4	0	4	3	3	4
329.005.00120	SC	22AUG95	-8, .	3	0	1	1	1	0	0	0	0	1	0	1	0	1	2	2	1	0	0	.	2	0	1	2	0	0	2	0	0
	8	26OCT95	58, .	4	0	1	1	1	1	0	0	0	2	0	0	0	1	1	2	1	1	1	1	1	0	1	1	0	0	1	1	2
329.005.00253	SC	31JAN96	-8, .	4	4	4	4	4	4	2	4	4	4	4	4	2	2	2	3	2	2	3	.	3	3	2	2	1	4	2	3	3
	8	03APR96	56, .	4	4	4	2	4	4	0	4	4	3	3	2	2	2	1	2	0	0	3	.	0	0	2	2	0	4	3	3	3
329.005.00254	SC	08FEB96	-7, -62	1	0	4	3	2	3	2	1	1	3	3	2	3	4	3	1	4	0	0	.	0	0	1	3	0	1	2	3	1
	8	10APR96	56, 1	4	0	4	3	2	4	4	3	3	3	3	3	3	4	2	2	3	0	1	4	0	0	1	3	3	0	3	3	3
329.005.00293	SC	06MAR97	-6, .	3	3	3	2	2	0	1	0	2	3	0	3	1	2	0	0	0	0	0	1	0	0	1	2	0	2	2	2	0
	8	07MAY97	57, .	0	3	3	3	2	1	1	2	1	1	2	1	2	2	0	0	0	0	0	2	0	0	0	2	0	2	1	0	2
329.005.00298	SC	15MAY96	-7, -63	0	0	4	2	1	3	0	3	3	3	0	1	0	0	1	1	1	0	0	4	0	0	1	2	3	0	1	2	3
	8	17JUL96	57, 1	0	0	4	2	3	1	2	3	3	3	2	3	0	4	1	1	1	0	1	4	1	0	1	2	4	2	2	2	3

* days relative to start of acute phase, days relative to start of continuation phase

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.005.00298	32	13JAN97	237, 181	1	0	4	3	3	3	1	3	4	3	1	3	0	4	1	2	1	1	0	4	3	1	2	1	4	1	2	3	3
329.005.00331	SC	14NOV96	-7, .	0	0	4	2	2	3	2	3	3	3	4	4	3	3	2	2	1	0	1	.	2	1	3	1	2	1	3	3	3
	8	16JAN97	57, .	0	0	3	3	3	3	2	3	3	3	3	2	1	4	3	2	1	1	0	.	2	1	3	2	3	0	2	3	3
329.005.00334	SC	24JAN97	-7, .	3	0	4	3	4	1	0	4	0	3	0	0	0	2	2	2	0	0	3	3	0	0	1	2	4	2	2	3	3
	8	27MAR97	56, .	2	0	4	4	4	3	3	3	3	3	3	2	0	2	2	2	0	1	1	.	3	0	2	2	3	2	1	2	2
329.006.00037	SC	20JAN95	-8, .	4	4	4	4	3	4	3	2	3	4	4	4	4	4	4	1	4	3	4	.	1	4	3	4	0	4	2	4	2
329.006.00042	SC	01DEC95	-6, -63	0	4	2	1	3	4	1	3	3	2	3	2	3	4	3	3	0	0	0	1	1	0	1	0	3	0	0	1	1
	8	02FEB96	58, 1	0	4	3	3	4	4	4	4	4	3	4	1	1	4	3	3	0	1	0	1	0	0	0	0	2	1	0	1	1
	32	16JUL96	223, 166	0	4	3	2	4	4	4	4	4	3	4	3	3	3	3	3	1	0	0	1	0	0	1	1	1	3	1	2	2
329.006.00259	SC	22APR96	-32, .	0	0	4	4	4	4	4	3	4	4	4	2	2	3	4	0	1	1	4	.	1	4	1	2	0	1	1	1	2
	8	17JUL96	55, .	0	0	4	4	4	3	4	2	3	3	3	3	4	4	4	0	2	4	4	1	1	2	1	3	0	1	1	3	2
329.007.00141	SC	14SEP95	-7, .	0	0	3	3	3	3	1	1	0	3	1	1	0	1	2	3	1	1	2	3	1	1	2	0	2	2	3	3	2
329.007.00144	SC	30NOV95	-7, -63	1	0	4	2	1	1	0	2	0	1	0	0	1	4	0	0	3	1	0	1	0	0	2	2	0	0	3	0	1
	8	01FEB96	57, 1	1	0	4	3	2	2	1	2	2	2	0	0	1	4	1	1	4	2	1	1	1	1	1	1	0	0	2	0	2
329.007.00266	SC	29FEB96	-7, .	2	0	3	3	4	3	2	2	1	2	1	1	0	3	2	1	2	0	0	2	0	0	1	1	0	0	2	1	2
	8	02MAY96	57, .	2	0	3	3	3	3	1	3	2	2	2	2	1	3	3	3	3	1	3	2	0	0	0	0	0	2	2	1	2
329.007.00267	SC	29FEB96	-7, .	3	0	2	2	2	3	1	2	2	1	2	1	1	2	1	1	1	1	1	2	0	1	1	1	0	3	1	0	1
	8	02MAY96	57, .	2	0	3	2	3	3	1	4	4	2	0	0	0	4	3	2	0	0	0	3	0	0	3	3	0	2	1	1	2
329.007.00311	SC	26SEP96	-7, -67	2	0	4	4	2	4	4	2	2	0	4	1	0	4	0	2	0	0	0	2	0	0	2	2	3	4	1	0	4
	8	02DEC96	61, 1	0	0	4	4	4	4	4	2	2	3	4	3	2	4	0	2	0	1	0	1	0	0	2	2	3	3	2	2	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.008.00158	SC	06SEP95	-7, -69	0	0	4	3	4	4	1	2	3	3	2	3	2	3	2	2	3	3	1	2	3	2	2	4	2	4	2	3	3
329.008.00162	SC	26OCT95	-6, -71	0	0	4	3	4	0	0	1	1	1	1	1	0	3	2	1	1	0	0	1	0	0	1	2	0	2	1	1	2
	32	02JUL96	245, 180	4	1	4	3	4	1	1	1	1	1	0	3	3	2	2	1	2	0	0	.	1	0	1	1	0	4	1	1	1
329.008.00191	SC	12JAN96	-20, -81	4	4	4	3	4	2	4	2	3	3	3	3	2	1	4	1	2	3	4	3	3	2	1	2	2	2	2	3	2
	8	02APR96	62, 1	4	4	3	2	3	4	4	3	3	3	4	4	4	4	4	0	4	3	4	3	4	3	2	3	4	4	1	3	1
329.009.00128	SC	05APR95	-6, .	0	0	3	2	2	4	0	1	4	3	1	1	0	1	3	4	0	1	1	3	3	3	2	3	1	1	1	1	3
329.009.00129	SC	22MAR95	-20, .	0	1	4	2	3	4	0	0	3	1	1	2	0	2	1	0	0	2	0	4	1	0	1	2	0	4	1	1	4
329.009.00135	SC	25SEP95	-7, .	0	0	4	0	4	4	0	0	0	4	4	0	0	2	0	0	1	0	1	0	0	0	1	3	0	0	0	4	1
329.009.00136	SC	26SEP95	-7, .	3	0	0	0	2	0	0	0	0	0	1	2	0	0	0	0	0	0	0	1	1	0	0	2	0	2	0	1	1
	8	28NOV95	57, .	0	0	1	0	2	0	2	0	0	1	1	2	0	4	3	2	2	1	0	0	0	0	0	0	0	3	0	1	2
329.009.00169	SC	25OCT95	-6, -71	0	0	4	2	4	3	3	3	3	1	4	1	2	4	1	3	0	1	4	3	1	4	2	3	0	2	1	2	2
	8	27DEC95	58, -8	0	0	3	2	2	4	4	4	2	2	3	2	1	4	3	4	1	1	3	4	4	3	3	2	3	0	0	2	2
329.009.00174	SC	14NOV95	-7, -64	0	0	4	2	4	3	2	1	2	2	3	1	0	4	0	0	1	0	0	1	0	0	1	2	0	0	2	1	1
	8	17JAN96	58, 1	0	0	4	2	4	4	0	3	0	2	4	0	1	3	0	0	1	0	0	1	0	0	0	1	0	0	3	0	1
329.009.00197	SC	20DEC95	-9, -63	0	0	1	1	1	2	0	0	0	0	0	0	0	1	0	2	0	0	0	1	0	2	0	1	0	2	1	0	3
	8	20FEB96	54, -1	0	0	4	3	3	3	0	2	2	2	0	0	0	1	1	3	0	3	0	.	3	0	1	0	2	1	0	1	1
	32	20AUG96	236, 182	0	0	1	1	1	1	0	1	3	3	1	1	1	1	1	2	0	2	0	2	0	0	1	2	0	2	1	1	1
329.009.00198	SC	19DEC95	-14, .	0	1	4	4	4	0	1	1	1	2	0	0	0	4	0	0	0	0	0	1	1	0	0	1	0	2	0	0	0
	8	27FEB96	57, .	1	0	4	2	2	2	2	3	2	1	1	1	1	3	0	0	0	0	0	1	0	0	0	2	0	0	2	1	1
329.009.00200	SC	17JAN96	-6, .	0	0	3	2	3	3	1	3	2	1	1	1	1	3	1	1	1	0	0	3	3	0	0	3	0	4	1	0	1

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.009.00202	SC	14FEB96	-6, .	0	0	4	3	4	4	3	4	3	2	4	1	4	4	4	4	3	2	1	3	1	1	1	2	1	0	1	2	2
329.009.00237	SC	04NOV96	-7, .	1	0	4	2	3	3	2	3	1	2	4	1	2	4	1	2	1	0	0	1	0	0	2	2	0	3	2	1	1
329.009.00238	SC	28OCT96	-15, .	0	0	4	3	2	4	1	4	0	2	4	2	1	4	1	0	2	1	1	3	0	1	0	2	2	4	2	3	3
	8	07JAN97	57, .	0	0	3	2	3	4	2	2	3	2	4	3	2	4	1	1	3	0	0	.	0	1	0	4	2	3	1	3	3
329.009.00276	SC	17JAN97	-4, .	0	0	2	2	3	1	0	0	2	1	1	0	0	4	3	3	1	0	0	3	1	0	0	1	0	0	1	1	3
	8	18MAR97	57, .	0	0	2	1	3	3	0	1	1	3	0	3	0	3	3	3	1	0	0	3	1	0	1	3	0	3	2	3	3
329.009.00302	SC	20MAR96	-7, .	0	1	4	3	3	4	3	4	4	2	0	1	2	2	0	3	0	0	0	1	0	0	0	1	0	3	0	1	2
329.009.00306	SC	03JUN96	-8, .	0	0	3	3	3	3	0	0	0	0	0	1	0	3	1	3	0	2	0	3	2	2	3	.	0	0	0	0	0
	8	06AUG96	57, .	0	0	2	2	2	2	0	1	0	0	0	3	0	4	1	1	0	1	0	2	1	0	3	4	0	0	4	0	3
329.009.00312	SC	30OCT96	-5, .	0	0	4	1	4	4	2	0	0	3	4	1	3	3	2	2	2	2	0	2	0	2	1	2	0	2	3	3	1
329.009.00327	SC	09SEP96	-7, .	2	2	4	3	4	1	0	1	3	2	2	2	0	4	0	0	1	0	0	2	0	1	1	3	0	3	1	1	1
	5	21OCT96	36, .	3	3	3	3	2	1	1	1	2	1	1	3	1	1	0	0	0	0	0	2	0	0	0	1	0	3	1	1	1
329.009.00330	SC	15OCT96	-6, .	0	0	4	4	4	4	1	3	3	3	4	0	0	3	1	0	0	2	0	4	2	0	3	4	0	4	4	1	2
329.010.00183	SC	21NOV95	-12, .	0	0	1	1	1	0	0	2	3	1	2	0	0	4	0	3	0	1	0	.	0	0	2	2	0	3	2	1	2
329.010.00263	SC	24JUL96	-16, .	0	0	3	2	2	1	1	0	1	1	1	0	0	4	1	0	2	0	0	1	0	0	3	2	0	2	2	1	1
	8	09OCT96	62, .	2	0	3	2	3	1	2	1	1	3	1	1	0	3	1	1	3	1	1	.	1	1	3	0	0	2	2	1	1
329.010.00277	SC	23FEB96	-7, -63	0	0	4	1	4	1	0	2	2	2	2	1	0	4	2	3	0	0	0	.	3	1	1	3	1	3	3	2	3
	8	26APR96	57, 1	0	0	4	2	4	4	0	1	4	3	3	3	4	4	1	4	0	1	0	.	4	0	1	4	0	3	2	2	3
	24	07AUG96	160, 104	0	0	4	2	4	4	3	2	3	3	3	3	1	4	1	1	0	0	0	.	4	0	1	4	1	3	3	1	3

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58
329.010.00282	SC	19JUL96	-7, .	0	0	4	2	3	2	2	1	3	2	2	3	0	3	1	1	1	1	0	3	0	0	1	3	0	3	0	0	2
	8	27SEP96	64, .	0	0	4	2	4	2	3	3	1	2	2	1	0	3	1	1	1	2	0	3	0	0	0	3	0	3	1	0	3
329.011.00164	SC	15DEC95	-7, .	0	0	4	3	4	4	0	3	3	1	3	2	0	4	2	2	1	1	1	2	0	0	2	2	0	0	3	1	2
329.011.00210	SC	13SEP96	-15, -81	0	0	3	2	3	2	0	4	3	1	4	0	0	4	1	1	0	1	1	3	0	0	3	3	1	2	1	1	2
	8	02DEC96	66, -1	0	0	4	3	3	3	2	4	3	1	3	0	0	4	1	1	0	0	0	.	0	0	2	2	0	1	1	0	2
329.011.00285	SC	08MAY96	-10, .	0	0	2	3	4	4	0	2	0	2	0	4	4	4	3	4	0	0	0	0	4	4	0	0	2	0	1	4	2
	8	24JUL96	68, .	0	0	2	3	3	4	0	1	1	.	0	4	4	4	3	4	0	0	0	0	0	4	0	0	4	4	2	.	3
329.011.00287	SC	25JUN96	-8, .	0	0	4	4	4	4	0	0	0	0	1	0	0	4	4	0	4	0	0	1	2	0	2	0	0	1	0	0	0
	8	27AUG96	56, .	0	0	4	4	4	2	0	2	2	0	0	0	0	4	2	0	3	0	0	1	4	0	3	3	0	0	0	0	2
329.012.00027	SC	23NOV95	-13, .	4	0	4	4	2	1	2	0	4	3	2	2	1	2	1	1	1	3	2	.	1	1	1	1	1	3	3	1	2
329.012.00217	SC	14MAY96	-7, .	0	0	4	1	0	1	0	0	0	2	3	1	1	3	1	1	4	0	2	3	0	0	2	4	0	0	0	1	1
329.012.00218	SC	04JUN96	-12, -70	0	0	4	4	4	4	2	2	3	1	4	1	0	3	1	0	0	0	1	.	3	0	3	2	0	1	1	0	1
	8	13AUG96	59, 1	4	0	4	4	4	4	1	4	3	1	4	2	1	3	2	1	1	0	1	3	0	0	1	2	0	1	1	0	1
329.012.00224	SC	30AUG96	-17, -83	0	0	4	3	4	3	0	1	2	3	0	3	0	3	3	3	1	2	3	2	4	1	0	1	2	0	2	2	3
	8	20NOV96	66, -1	0	0	3	3	4	3	0	2	2	3	0	2	0	4	4	4	1	4	4	2	1	0	0	0	2	4	2	1	3
329.012.00225	SC	19NOV96	-7, -71	2	0	3	2	2	2	1	1	1	2	1	2	0	3	2	1	1	1	0	0	0	0	1	0	0	1	2	1	1
	8	29JAN97	65, 1	2	0	3	2	2	3	1	2	3	2	2	2	0	3	2	1	1	1	0	0	0	2	1	1	0	1	2	2	2
	32	30JUL97	247, 183	0	0	4	3	4	3	3	1	2	3	3	2	1	3	2	1	1	1	0	.	0	0	1	0	0	0	1	1	2

* days relative to start of acute phase, days relative to start of continuation phase

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.001.00063	SC	02NOV94	-6, .	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	55
329.001.00065	SC	07NOV94	-10, .	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No	No	97
329.001.00068	SC	01FEB95	-7, .	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	64
	8	05APR95	57, .	Yes	No	No	No	No	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	97
329.001.00072	SC	07MAR95	-13, .	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No	63
329.001.00121	SC	22MAR95	-13, -69	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes	No	No	105
	8	30MAY95	57, 1	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	No	Yes	115
329.001.00205	SC	29JAN96	-9, .	No	No	Yes	No	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	105
329.001.00206	SC	12FEB96	-9, .	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	77
	8	17APR96	57, .	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	No	No	89
329.002.00055	SC	09JUN94	-15, -70	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	50
	8	18AUG94	56, 1	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	68
	20	10NOV94	140, 85	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	102
329.002.00058	SC	08SEP94	-12, -70	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	73
	8	17NOV94	59, 1	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	No	Yes	Yes	No	No	Yes	113
329.002.00099	SC	23FEB95	-7, -62	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	No	Yes	Yes	No	No	No	100
	8	25APR95	55, -1	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	79
329.002.00102	SC	03APR95	-10, -64	No	Yes	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	No	No	85
	8	06JUN95	55, 1	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	90
	32	05DEC95	237, 183	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	117

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.002.00105	SC	20JUL95	-7, .	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	No	73
329.002.00106	SC	20JUL95	-7, .	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	68
329.002.00242	SC	26JAN96	-12, -70	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	81
	20	10JUL96	155, 97	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	65
329.002.00245	SC	21MAR96	-7, .	Yes	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	No	No	No	Yes	Yes	No	No	Yes	107
329.002.00319	SC	23APR96	-7, -63	Yes	Yes	No	No	Yes	No	No	No	Yes	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	115
	8	25JUN96	57, 1	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	151
	32	17DEC96	232, 176	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	149
329.003.00075	8	22MAR95	57, 1	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	196
	32	13SEP95	232, 176	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	No	Yes	No	157
329.003.00077	SC	01MAR95	-5, -64	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	88
329.003.00087	SC	23JAN95	-8, .	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	No	Yes	No	Yes	No	Yes	Yes	No	No	No	118
329.003.00089	SC	24FEB95	-11, .	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	89
	8	02MAY95	57, .	Yes	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	89
329.003.00091	SC	14MAR95	-10, -64	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	149
	8	16MAY95	54, -1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	162
	32	07NOV95	229, 175	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	185
329.003.00248	SC	14FEB96	-16, .	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	60
	8	23APR96	54, .	Yes	Yes	No	No	No	No	No	No	No	No	No	No	Yes	No	No	Yes	No	No	Yes	Yes	100

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.003.00250	SC	05MAR96	-9, -66	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	113
329.003.00292	SC	02AUG96	-5, -63	No	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	Yes	Yes	Yes	Yes	107
	8	04OCT96	59, 1	.	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	125
329.003.00313	SC	08MAY96	-9, .	Yes	Yes	Yes	Yes	No	No	.	No	No	No	No	No	No	No	No	No	No	No	No	No	83
329.004.00015	SC	30NOV94	-8, -65	Yes	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	92
	8	03FEB95	58, 1	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No	No	91
	28	14JUN95	189, 132	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	No	No	No	No	109
329.004.00017	SC	15MAR95	-7, -63	Yes	No	No	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	Yes	Yes	Yes	No	No	124
	8	17MAY95	57, 1	No	No	No	No	Yes	Yes	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	Yes	104
	32	01NOV95	225, 169	Yes	No	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	121
329.004.00019	SC	24MAY95	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	109
329.004.00212	SC	24MAY96	-10, .	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	123
329.004.00214	SC	27SEP96	-7, -67	No	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	No	Yes	No	No	.	No	Yes	101
	8	03DEC96	61, 1	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	Yes	142
329.005.00002	SC	20MAY94	-5, -61	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	No	No	No	Yes	No	No	No	No	98
329.005.00004	SC	22SEP94	-18, -77	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	125
	8	08DEC94	60, 1	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	129
329.005.00008	SC	10NOV94	-6, -61	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	69
	8	10JAN95	56, 1	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	96
	24	10MAY95	176, 121	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	90

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.005.00011	SC	06DEC94	-7, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	123
	8	07FEB95	57, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	132
329.005.00109	SC	22DEC94	-8, -61	No	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	119
329.005.00112	SC	17JAN95	-9, -64	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	91
	8	22MAR95	56, 1	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	141
329.005.00116	SC	30JAN95	-8, -66	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	125
	8	06APR95	59, 1	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	109
	24	26JUL95	170, 112	Yes	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	149
329.005.00119	SC	27JUN95	-14, -73	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	No	No	No	122
	8	08SEP95	60, 1	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	112
	24	02JAN96	176, 117	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	131
329.005.00151	SC	29AUG95	-8, -65	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No	136
	8	02NOV95	58, 1	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	134
	32	01MAY96	239, 182	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	123
329.005.00152	SC	12OCT95	-14, .	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	97
329.005.00257	SC	05MAR96	-6, -62	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	55
	8	06MAY96	57, 1	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	75
	32	21OCT96	225, 169	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	74
329.005.00258	SC	06FEB96	-35, .	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	92
	8	07MAY96	57, .	Yes	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	Yes	94
329.005.00299	SC	28MAY96	-11, -71	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	50

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*		Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.005.00299	8	07AUG96	61,	1	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	No	116
	20	05NOV96	151,	91	Yes	No	No	Yes	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	110
329.005.00300	SC	12SEP96	-7,	.	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	46
	8	14NOV96	57,	.	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	49
329.005.00333	SC	15JAN97	-8,	.	Yes	No	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	107
329.005.00336	SC	26FEB97	-6,	.	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	51
329.006.00038	SC	01FEB95	-14,	.	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	No	No	No	No	149
329.006.00039	SC	03FEB95	-5,	-66	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	87
	8	05APR95	57,	-5	Yes	No	Yes	No	No	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	No	Yes	No	No	112
329.006.00260	SC	12JUL96	-6,	-64	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	56
	8	18SEP96	63,	5	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	72
329.006.00261	SC	07NOV96	-19,	-77	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	168
329.007.00140	SC	07SEP95	-8,	-63	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	Yes	98
	8	09NOV95	56,	1	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	Yes	No	No	No	Yes	108
329.007.00142	SC	12OCT95	-6,	.	No	No	Yes	No	No	No	No	Yes	No	No	Yes	No	No	No	Yes	No	Yes	No	No	No	66
	8	21DEC95	65,	.	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	65
329.007.00145	SC	04JAN96	-7,	-63	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	76
	8	07MAR96	57,	1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	Yes	Yes	Yes	No	Yes	87
	32	23AUG96	226,	170	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	136

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.007.00265	SC	25JAN96	-7, .	Yes	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	75
329.007.00268	SC	21MAR96	-11, -70	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	Yes	No	No	No	No	118
	8	30MAY96	60, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	126
	32	05DEC96	249, 190	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	133
329.007.00294	SC	20FEB97	-8, .	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No	No	77
329.007.00309	SC	02JUL96	-13, -65	Yes	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	80
	7	05SEP96	53, 1	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	80
	32	13MAR97	242, 190	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No	Yes	110
329.007.00310	SC	19SEP96	-7, -67	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	71
	8	25NOV96	61, 1	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	No	Yes	No	No	83
	32	12JUN97	260, 200	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	Yes	Yes	Yes	No	No	98
329.007.00318	SC	22NOV96	-10, .	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	100
329.008.00157	SC	16AUG95	-14, -69	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	118
	8	24OCT95	56, 1	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	143
329.008.00160	SC	25OCT95	-7, -73	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	Yes	155
	8	05JAN96	66, -1	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	161
329.008.00188	SC	14DEC95	-21, .	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	Yes	84
	8	27FEB96	55, .	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	Yes	87
329.008.00271	SC	25JAN96	-46,-110	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	118
	8	14MAY96	65, 1	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No	142

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.008.00275	SC	30APR96	-8, -63	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	73
	8	02JUL96	56, 1	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	Yes	No	No	No	Yes	113
	32	16DEC96	223, 168	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	Yes	Yes	No	No	Yes	121
329.009.00130	SC	12APR95	-6, -62	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	Yes	Yes	No	No	No	98
	8	13JUN95	57, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No	Yes	Yes	Yes	No	No	140
329.009.00131	SC	26APR95	-6, -62	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	Yes	46
	8	27JUN95	57, 1	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	92
329.009.00133	SC	07JUN95	-6, .	Yes	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	87
329.009.00138	SC	02OCT95	-8, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	67
329.009.00170	SC	26OCT95	-12, -69	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	48
	8	03JAN96	58, 1	Yes	No	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	95
	32	24JUN96	231, 174	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	98
329.009.00173	SC	08NOV95	-12, -75	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	86
	8	22JAN96	64, 1	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	67
329.009.00193	SC	21NOV95	-7, .	Yes	Yes	Yes	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	69
	8	24JAN96	58, .	Yes	Yes	Yes	No	Yes	No	.	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	68
329.009.00196	SC	11DEC95	-7, .	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	139
	8	12FEB96	57, .	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	179
329.009.00201	SC	31JAN96	-6, .	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	126
	8	02APR96	57, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	121

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.009.00204	SC	13MAR96	-6, -62	No	No	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	Yes	117
	8	14MAY96	57, 1	No	Yes	Yes	No	No	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	124
329.009.00235	SC	10DEC96	-8, -62	Yes	Yes	No	No	No	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	Yes	No	No	No	No	93
	8	10FEB97	55, 1	Yes	Yes	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No	121
329.009.00240	SC	03JAN97	-11, .	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	84
	7	04MAR97	50, .	Yes	No	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	Yes	102
329.009.00303	SC	25MAR96	-8, -64	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No	100
	8	28MAY96	57, 1	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	88
	32	10DEC96	253, 197	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No	93
329.009.00304	SC	03APR96	-6, -62	Yes	No	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	85
	8	04JUN96	57, 1	Yes	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	Yes	87
329.009.00324	SC	21OCT96	-7, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	155
	8	27DEC96	61, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	173
329.009.00328	SC	30SEP96	-7, .	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	75
329.009.00329	SC	01OCT96	-8, .	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	Yes	No	No	54
	8	03DEC96	56, .	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	54
329.010.00182	SC	05DEC95	-14, .	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	84
329.010.00278	SC	02FEB96	-7, -63	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	Yes	Yes	117
	8	05APR96	57, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	147
	32	19SEP96	224, 168	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	161

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.010.00280	SC	10MAY96	-7, -62	Yes	No	Yes	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	73
	8	11JUL96	56, 1	Yes	No	Yes	No	Yes	No	No	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	No	75
	12	21AUG96	97, 42	Yes	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	87
329.011.00283	SC	30JAN96	-9, -66	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	54
	8	04APR96	57, -1	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	79
329.011.00288	SC	01JUL96	-24, .	Yes	Yes	Yes	No	No	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes	108
329.012.00025	SC	17OCT95	-7, .	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	79
	8	19DEC95	57, .	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	80
329.012.00220	SC	04JUN96	-13, -73	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	Yes	100
	8	16AUG96	61, 1	Yes	No	No	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	109
329.012.00222	SC	18JUN96	-10, -73	Yes	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No	Yes	83
	8	30AUG96	64, 1	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	85
329.012.00226	SC	26NOV96	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	96
329.012.00228	SC	04MAR97	-15, .	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	49
329.012.00231	SC	26FEB97	-9, -70	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	100
	8	07MAY97	62, 1	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	122
	24	19AUG97	166, 105	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	119

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.001.00061	SC	19JUL94	-10, .	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	67
329.001.00066	SC	14NOV94	-8, .	Yes	Yes	No	No	No	No	Yes	.	Yes	Yes	No	No	No	No	No	Yes	Yes	Yes	No	Yes	151
329.001.00067	SC	15NOV94	-7, .	Yes	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	84
329.001.00070	SC	14FEB95	-8, .	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	No	Yes	No	No	Yes	Yes	61
329.001.00122	SC	13JUN95	-7, -64	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	99
	8	16AUG95	58, 1	Yes	No	Yes	Yes	Yes	No	No	No	No	No	No	Yes	Yes	No	No	Yes	Yes	No	No	Yes	126
329.002.00050	SC	10MAR95	-13, .	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	Yes	101
	5	28APR95	37, .	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No	112
329.002.00056	SC	24JUN94	-25, .	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	119
329.002.00057	SC	11AUG94	-28, -85	Yes	No	Yes	No	No	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	47
	8	03NOV94	57, -1	Yes	Yes	No	No	No	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	78
	16	11JAN95	126, 69	Yes	Yes	No	No	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	No	No	No	67
329.002.00098	SC	20DEC94	-14, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	153
	8	02MAR95	59, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	No	No	No	No	127
329.002.00100	SC	16FEB95	-19, -77	Yes	Yes	No	No	No	No	Yes	Yes	No	No	No	No	Yes	Yes	No	No	No	Yes	No	Yes	129
	8	04MAY95	59, 1	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	Yes	No	Yes	152
	16	06JUL95	122, 64	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	Yes	No	Yes	147
329.002.00103	SC	11APR95	-9, -65	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	No	No	No	No	120
	8	15JUN95	57, 1	Yes	No	No	No	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	Yes	No	No	Yes	98
	16	10AUG95	113, 57	Yes	No	No	No	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	121

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.002.00104	SC	28APR95	-6, -62	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	99
	8	29JUN95	57, 1	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	No	Yes	Yes	No	Yes	Yes	102
	32	02JAN96	244, 188	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	No	No	No	Yes	Yes	No	No	No	111
329.002.00243	SC	27FEB96	-16, .	Yes	Yes	Yes	No	Yes	No	No	No	No	No	No	No	Yes	No	No	Yes	No	Yes	No	No	96
329.002.00244	SC	14MAR96	-7, -64	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	No	No	No	Yes	141
	8	16MAY96	57, -1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	163
329.002.00321	SC	15MAY96	-8, .	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	68
329.002.00322	SC	06JAN97	-3, .	Yes	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	71
329.003.00073	SC	11JAN95	-8, .	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	Yes	Yes	89
329.003.00076	SC	24JAN95	-7, -62	Yes	Yes	Yes	No	No	No	No	Yes	No	No	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes	164
	32	11OCT95	254, 199	Yes	Yes	No	No	No	No	No	Yes	No	No	Yes	Yes	Yes	No	No	No	No	No	No	Yes	141
329.003.00088	SC	06FEB95	-22, .	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	87
329.003.00090	SC	08MAR95	-6, .	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	No	Yes	No	No	No	114
	8	16MAY95	64, .	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	No	124
329.003.00092	SC	13APR95	-20, -78	Yes	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	65
	8	30JUN95	59, 1	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	93
	32	02JAN96	245, 187	Yes	No	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	76
329.003.00093	SC	08JUN95	-13, -76	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	103
	8	22AUG95	63, -1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	No	No	153
	16	03OCT95	105, 42	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	No	132

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.003.00247	SC	05JAN96	-27, -81	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	93
	8	26MAR96	55, 1	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	108
329.003.00249	SC	01MAR96	-6, .	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	Yes	No	Yes	Yes	83
	8	30APR96	55, .	Yes	No	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	No	Yes	Yes	No	No	Yes	111
329.003.00289	SC	12FEB96	-16, -72	No	No	No	No	No	No	No	No	No	No	Yes	Yes	.	.	.	.	.	.	.	.	61
	8	24APR96	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	Yes	40
	32	11OCT96	227, 171	Yes	Yes	No	No	No	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	69
329.003.00290	SC	06MAR96	-5, .	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	88
329.003.00317	SC	12DEC96	-7, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	73
	8	11FEB97	55, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	Yes	94
329.004.00013	SC	05JUL94	-14, -73	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	151
	8	16SEP94	60, 1	Yes	Yes	Yes	Yes	Yes	Yes	.	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	174
329.004.00014	SC	22NOV94	-7, .	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	116
329.004.00211	SC	24JAN96	-9, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	118
329.004.00215	SC	12MAR97	-8, .	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	76
329.005.00003	SC	12SEP94	-8, .	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	164
329.005.00006	SC	27OCT94	-8, -68	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	144
	8	03JAN95	61, 1	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	172
	24	28APR95	176, 116	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	172

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.005.00007	SC	02NOV94	-7, -70	Yes	Yes	No	No	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	85
	8	11JAN95	64, 1	Yes	Yes	No	No	No	No	No	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	85
	32	09AUG95	274, 211	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	No	Yes	No	No	Yes	No	No	No	No	No	146
329.005.00009	SC	07DEC94	-5, .	Yes	No	Yes	Yes	No	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	146
	8	07FEB95	58, .	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No	No	149
329.005.00110	SC	04JAN95	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	154
329.005.00113	SC	20JAN95	-10, .	Yes	No	No	No	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	130
329.005.00117	SC	06MAR95	-12, .	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	94
	8	15MAY95	59, .	No	No	Yes	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	106
329.005.00118	SC	09MAY95	-8, .	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	107
329.005.00153	SC	11JAN96	-14, -70	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	117
	8	21MAR96	57, 1	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	110
	32	04SEP96	224, 168	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	Yes	103
329.005.00255	SC	26FEB96	-7, .	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	139
	8	29APR96	57, .	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes	No	Yes	138
329.005.00256	SC	20FEB96	-14, -70	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	99
	8	30APR96	57, 1	Yes	Yes	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	118
329.005.00295	SC	21MAR96	-7, .	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	80
	8	22MAY96	56, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	Yes	No	No	79
329.005.00297	SC	28MAR96	-22, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	No	Yes	No	No	79

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.005.00332	SC	05DEC96	-7, .	Yes	No	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	101
	8	06FEB97	57, .	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	107
329.005.00335	SC	20FEB97	-8, .	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	No	No	127
329.006.00040	SC	10FEB95	-6, .	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	73
329.006.00041	SC	22MAR95	-14, -78	Yes	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	104
	8	31MAY95	57, -8	Yes	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	Yes	No	Yes	No	No	Yes	Yes	150
	32	21NOV95	231, 167	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	Yes	Yes	Yes	198
329.007.00139	SC	04MAY95	-4, .	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	Yes	No	Yes	No	No	No	84
329.007.00143	SC	26OCT95	-14, .	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	76
329.007.00146	SC	18JAN96	-7, -60	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	110
	8	18MAR96	54, 1	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	96
	32	09SEP96	229, 176	Yes	No	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	No	No	No	Yes	No	No	No	No	94
329.007.00269	SC	04APR96	-7, .	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	84
	3	02MAY96	22, .	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	72
329.007.00270	SC	02MAY96	-7, .	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	75
	7	27JUN96	50, .	No	No	No	No	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No	60
329.007.00307	SC	09MAY96	-7, .	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	56
	8	25JUL96	71, .	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	52
329.007.00308	SC	27JUN96	-5, .	Yes	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	No	46

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.008.00159	SC	06SEP95	-7, -69	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	No	Yes	Yes	No	No	No	125
329.008.00161	SC	31OCT95	-16, -71	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	82
329.008.00187	SC	15NOV95	-14, .	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	97
	8	26JAN96	59, .	Yes	Yes	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	No	Yes	100
329.008.00192	SC	14FEB96	-20, .	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	67
329.008.00272	SC	19MAR96	-15, -71	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	56
	8	29MAY96	57, 1	No	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	78
329.008.00273	SC	19APR96	-28, -91	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	114
	8	19JUL96	64, 1	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	Yes	135
329.009.00127	SC	03APR95	-7, .	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	71
329.009.00132	SC	17MAY95	-6, -63	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	Yes	124
	8	19JUL95	58, 1	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	131
329.009.00134	SC	28JUN95	-8, .	No	No	Yes	No	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Yes	70
	8	29AUG95	55, .	No	No	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	129
329.009.00137	SC	03OCT95	-7, .	Yes	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	63
	8	05DEC95	57, .	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	65
329.009.00171	SC	31OCT95	-7, .	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	Yes	Yes	No	No	Yes	No	No	No	No	131
329.009.00172	SC	06NOV95	-7, -64	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	No	121
	8	09JAN96	58, 1	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No	Yes	No	No	No	132

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.009.00172	32	08JUL96	239, 182	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	No	113
329.009.00194	SC	28NOV95	-7, -63	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	43
	8	30JAN96	57, 1	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	Yes	Yes	No	No	No	No	59
	24	04JUN96	183, 127	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	83
329.009.00195	SC	06DEC95	-9, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	104
329.009.00199	SC	10JAN96	-6, .	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	81
	8	13MAR96	58, .	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	149
329.009.00203	SC	28FEB96	-5, .	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	78
329.009.00236	SC	17DEC96	-13, .	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	84
	4	27JAN97	29, .	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	66
329.009.00239	SC	11NOV96	-8, -65	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	89
	8	15JAN97	58, 1	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	Yes	125
329.009.00262	SC	07FEB97	-10, .	No	No	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	Yes	No	No	No	Yes	99
	8	14APR97	57, .	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	113
329.009.00264	SC	25OCT96	-7, .	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	90
	7	23DEC96	53, .	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	Yes	Yes	No	No	No	No	Yes	No	No	No	64
329.009.00301	SC	06MAR96	-13, -69	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No	107
	8	14MAY96	57, 1	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	113
329.009.00305	SC	01MAY96	-6, -63	Yes	Yes	No	No	Yes	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	61
	8	03JUL96	58, 1	Yes	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	75

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.009.00305	32	10JAN97	249, 192	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	113
329.009.00325	SC	21AUG96	-6, -61	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	111
	8	21OCT96	56, 1	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes	117
	16	16DEC96	112, 57	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	86
329.009.00326	SC	26AUG96	-10, -63	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	84
	8	28OCT96	54, 1	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	130
	16	16DEC96	103, 50	No	No	No	No	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	101
329.010.00279	SC	08MAR96	-14, -70	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No	103
	8	17MAY96	57, 1	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	87
	32	06NOV96	230, 174	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	Yes	No	136
329.010.00281	SC	19JUL96	-7, -68	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	64
	8	25SEP96	62, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	Yes	Yes	No	No	No	58
	24	03JAN97	162, 101	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	69
329.011.00163	SC	18NOV95	-7, .	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	81
329.011.00208	SC	22AUG96	-15, -74	Yes	No	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	101
	8	03NOV96	59, -1	Yes	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	127
329.011.00209	SC	23AUG96	-19, -81	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	59
	8	11NOV96	62, -1	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	112
329.011.00284	SC	13MAR96	-9, -65	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	Yes	69
	8	16MAY96	56, -1	Yes	Yes	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	Yes	Yes	113
329.011.00286	SC	15MAY96	-22, -90	Yes	Yes	No	No	No	No	No	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	75

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.011.00286	8	09AUG96	65, -4	Yes	Yes	No	No	No	No	Yes	Yes	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	73
329.012.00026	SC	09NOV95	-19, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	67
329.012.00219	SC	24MAY96	-7, -67	Yes	Yes	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	Yes	No	Yes	Yes	80
	8	30JUL96	61, 1	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	101
	32	24JAN97	239, 179	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	No	Yes	Yes	No	Yes	Yes	80
329.012.00221	SC	18JUN96	-7, -70	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	120
	8	27AUG96	64, 1	Yes	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	119
329.012.00223	SC	23AUG96	-7, .	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No	Yes	68
329.012.00227	SC	12DEC96	-6, -75	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	135
	8	25FEB97	70, 1	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	No	No	No	Yes	Yes	No	No	No	Yes	Yes	122
	32	19AUG97	245, 176	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	132
329.012.00230	SC	20FEB97	-8, -77	No	No	No	No	Yes	No	Yes	No	Yes	No	No	Yes	No	No	No	Yes	Yes	Yes	No	No	60
	8	08MAY97	70, 1	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	53

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.001.00062	SC	06OCT94	-14, .	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	Yes	No	67
329.001.00064	SC	04NOV94	-6, -60	No	No	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	55
	8	03JAN95	55, 1	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	69
329.001.00069	SC	07FEB95	-9, .	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	No	85
	8	13APR95	57, .	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	Yes	No	Yes	No	Yes	112
329.001.00071	SC	02FEB95	-21, .	No	No	No	Yes	No	No	Yes	No	Yes	No	No	No	Yes	No	No	Yes	Yes	No	No	No	87
	8	20APR95	57, .	Yes	No	No	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	Yes	Yes	No	No	No	86
329.001.00123	SC	14DEC95	-21, .	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	52
329.001.00207	SC	19FEB96	-9, .	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	79
	8	24APR96	57, .	Yes	Yes	Yes	No	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	89
329.002.00049	SC	03MAR95	-6, .	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	75
	8	05MAY95	58, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	72
329.002.00059	SC	03NOV94	-7, .	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	Yes	63
	8	05JAN95	57, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	60
329.002.00060	SC	24JAN95	-7, -63	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	79
	8	28MAR95	57, 1	Yes	No	Yes	Yes	No	No	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	No	79
329.002.00097	SC	20DEC94	-14, -72	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No	No	101
	8	02MAR95	59, 1	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	118
	32	05SEP95	246, 188	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No	No	123
329.002.00101	SC	20MAR95	-8, -66	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	82

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.002.00101	8	25MAY95	59, 1	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	No	No	Yes	No	Yes	No	No	No	129
329.002.00107	SC	18JAN96	-7, -63	Yes	No	Yes	Yes	Yes	No	No	No	No	No	No	No	Yes	No	No	Yes	No	No	No	Yes	92
	8	21MAR96	57, 1	Yes	No	Yes	Yes	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No	Yes	127
	32	26SEP96	246, 190	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	No	Yes	No	No	Yes	144
329.002.00241	SC	25JAN96	-12, -68	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	110
	8	02APR96	57, 1	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	109
329.002.00246	SC	01APR96	-17, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	No	No	Yes	No	No	130
	8	18JUN96	62, .	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	Yes	No	Yes	No	No	Yes	No	128
329.002.00320	SC	09MAY96	-7, -68	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No	No	140
	8	16JUL96	62, 1	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	134
329.002.00323	SC	04NOV96	-8, -66	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	Yes	No	No	Yes	99
	8	09JAN97	59, 1	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	Yes	Yes	No	153
	32	12JUN97	213, 155	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	158
329.003.00074	SC	18JAN95	-7, -63	Yes	No	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	Yes	114
	8	22MAR95	57, 1	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	125
	32	11OCT95	260, 204	Yes	No	Yes	No	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	Yes	87
329.003.00078	SC	11APR95	-15, .	Yes	Yes	No	No	Yes	Yes	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No	No	86
	8	21JUN95	57, .	Yes	Yes	No	No	Yes	Yes	No	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	No	No	98
329.003.00080	SC	22NOV95	-5, .	No	No	No	No	Yes	Yes	No	No	.	Yes	Yes	Yes	No	No	No	No	No	No	No	No	68
329.003.00085	SC	26OCT94	-13, .	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	106
	8	03JAN95	57, .	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	108

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.003.00086	SC	09NOV94	-19, -76	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No	No	79
	8	23JAN95	57, -1	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No	No	89
	32	17AUG95	263, 206	Yes	No	Yes	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	102
329.003.00094	SC	20OCT95	-4, .	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	133
	8	19DEC95	57, .	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	83
329.003.00252	SC	19MAR96	-22, .	Yes	Yes	No	No	No	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	No	Yes	73
329.003.00315	SC	29OCT96	-14, .	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	74
	8	07JAN97	57, .	Yes	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	83
329.003.00316	SC	05DEC96	-12, .	Yes	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	78
	8	11FEB97	57, .	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No	No	83
329.004.00016	SC	01MAR95	-12, .	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	No	No	No	No	No	Yes	Yes	No	No	No	100
329.004.00018	SC	19APR95	-14, .	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	143
	8	29JUN95	58, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	107
329.004.00020	SC	02NOV95	-7, .	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	84
	2	24NOV95	16, .	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	No	90
329.004.00213	SC	18JUL96	-15, -69	Yes	No	Yes	No	Yes	Yes	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	96
	8	24SEP96	54, -1	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	85
	32	19MAR97	230, 176	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	115
329.005.00001	SC	11APR94	-9, .	No	No	No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	No	No	No	Yes	No	No	Yes	101
	8	15JUN94	57, .	No	No	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	Yes	108

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.005.00005	SC	24OCT94	-8, .	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	No	Yes	No	76
329.005.00010	SC	07DEC94	-6, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	No	111
	8	08FEB95	58, 1	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	No	147
	32	09AUG95	240, 183	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	175
329.005.00012	SC	12DEC94	-7, -66	Yes	No	Yes	No	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	109
	8	16FEB95	60, 1	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	129
329.005.00111	SC	05JAN95	-6, -62	Yes	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	156
	8	08MAR95	57, 1	Yes	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	No	Yes	No	No	Yes	No	Yes	No	Yes	138
	16	03MAY95	113, 57	Yes	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	167
329.005.00114	SC	23JAN95	-8, -65	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	No	114
	8	29MAR95	58, 1	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	128
	16	17MAY95	107, 50	No	Yes	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes	116
329.005.00115	SC	27JAN95	-10, -81	Yes	Yes	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes	80
	8	18APR95	72, 1	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	No	Yes	No	No	147
329.005.00120	SC	22AUG95	-8, .	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	43
	8	26OCT95	58, .	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	51
329.005.00253	SC	31JAN96	-8, .	Yes	No	No	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes	168
	8	03APR96	56, .	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	Yes	136
329.005.00254	SC	08FEB96	-7, -62	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No	Yes	104
	8	10APR96	56, 1	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	140
329.005.00293	SC	06MAR97	-6, .	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	Yes	No	No	No	No	No	83

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.005.00293	8	07MAY97	57, .	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	87
329.005.00298	SC	15MAY96	-7, -63	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	79
	8	17JUL96	57, 1	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	No	105
	32	13JAN97	237, 181	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	116
329.005.00331	SC	14NOV96	-7, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	140
	8	16JAN97	57, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	150
329.005.00334	SC	24JAN97	-7, .	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	93
	8	27MAR97	56, .	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	99
329.006.00037	SC	20JAN95	-8, .	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Yes	183
329.006.00042	SC	01DEC95	-6, -63	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	98
	8	02FEB96	58, 1	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	114
	32	16JUL96	223, 166	Yes	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No	No	120
329.006.00259	SC	22APR96	-32, .	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No	120
	8	17JUL96	55, .	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	123
329.007.00141	SC	14SEP95	-7, .	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	101
329.007.00144	SC	30NOV95	-7, -63	Yes	No	Yes	No	Yes	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	66
	8	01FEB96	57, 1	Yes	No	No	No	Yes	Yes	No	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No	No	73
329.007.00266	SC	29FEB96	-7, .	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	70
	8	02MAY96	57, .	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No	No	82
329.007.00267	SC	29FEB96	-7, .	Yes	No	No	No	Yes	No	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	No	No	No	86

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.007.00267	8	02MAY96	57, .	Yes	No	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	114
329.007.00311	SC	26SEP96	-7, -67	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	108
	8	02DEC96	61, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	126
329.008.00158	SC	06SEP95	-7, -69	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No	127
329.008.00162	SC	26OCT95	-6, -71	Yes	Yes	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	70
	32	02JUL96	245, 180	Yes	No	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	Yes	98
329.008.00191	SC	12JAN96	-20, -81	Yes	No	Yes	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	No	Yes	Yes	No	No	167
	8	02APR96	62, 1	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	No	No	Yes	Yes	No	185
329.009.00128	SC	05APR95	-6, .	No	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	No	84
329.009.00129	SC	22MAR95	-20, .	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	Yes	Yes	No	No	No	Yes	No	No	No	72
329.009.00135	SC	25SEP95	-7, .	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	65
329.009.00136	SC	26SEP95	-7, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	Yes	No	44
	8	28NOV95	57, .	No	No	No	No	Yes	No	No	No	No	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	79
329.009.00169	SC	25OCT95	-6, -71	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	124
	8	27DEC95	58, -8	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	119
329.009.00174	SC	14NOV95	-7, -64	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	70
	8	17JAN96	58, 1	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	76
329.009.00197	SC	20DEC95	-9, -63	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	49
	8	20FEB96	54, -1	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	66

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.009.00197	32	20AUG96	236, 182	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes	No	No	No	52
329.009.00198	SC	19DEC95	-14, .	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	Yes	Yes	No	Yes	71
	8	27FEB96	57, .	Yes	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	No	80
329.009.00200	SC	17JAN96	-6, .	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	80
329.009.00202	SC	14FEB96	-6, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	No	136
329.009.00237	SC	04NOV96	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	No	Yes	107
329.009.00238	SC	28OCT96	-15, .	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	Yes	No	No	No	Yes	Yes	No	No	No	102
	8	07JAN97	57, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	Yes	No	No	No	105
329.009.00276	SC	17JAN97	-4, .	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	69
	8	18MAR97	57, .	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	77
329.009.00302	SC	20MAR96	-7, .	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	No	Yes	No	No	No	No	74
329.009.00306	SC	03JUN96	-8, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	76
	8	06AUG96	57, .	No	No	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	55
329.009.00312	SC	30OCT96	-5, .	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes	No	Yes	118
329.009.00327	SC	09SEP96	-7, .	Yes	Yes	No	No	Yes	No	No	No	No	No	No	Yes	Yes	No	No	No	Yes	Yes	No	No	84
	5	21OCT96	36, .	Yes	No	No	No	No	No	No	No	Yes	No	No	Yes	Yes	No	No	No	Yes	Yes	No	No	78
329.009.00330	SC	15OCT96	-6, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	129
329.010.00183	SC	21NOV95	-12, .	No	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	64

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.010.00263	SC	24JUL96	-16, .	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	No	78
	8	09OCT96	62, .	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes	No	No	Yes	No	Yes	Yes	No	99
329.010.00277	SC	23FEB96	-7, -63	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	Yes	Yes	138
	8	26APR96	57, 1	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	148
	24	07AUG96	160, 104	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No	Yes	Yes	No	Yes	Yes	142
329.010.00282	SC	19JUL96	-7, .	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	85
	8	27SEP96	64, .	Yes	Yes	Yes	No	Yes	No	No	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	95
329.011.00164	SC	15DEC95	-7, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	120
329.011.00210	SC	13SEP96	-15, -81	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No	No	88
	8	02DEC96	66, -1	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	No	No	No	No	82
329.011.00285	SC	08MAY96	-10, .	No	No	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	No	Yes	107
	8	24JUL96	68, .	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	No	Yes	No	No	Yes	Yes	No	Yes	111
329.011.00287	SC	25JUN96	-8, .	Yes	Yes	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	67
	8	27AUG96	56, .	Yes	Yes	No	No	Yes	No	No	No	Yes	No	No	Yes	Yes	No	No	No	Yes	No	No	No	75
329.012.00027	SC	23NOV95	-13, .	Yes	Yes	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	Yes	Yes	No	No	No	138
329.012.00217	SC	14MAY96	-7, .	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	66
329.012.00218	SC	04JUN96	-12, -70	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	92
	8	13AUG96	59, 1	Yes	Yes	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	105
329.012.00224	SC	30AUG96	-17, -83	Yes	No	Yes	No	No	Yes	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	No	No	No	98
	8	20NOV96	66, -1	Yes	No	Yes	No	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	No	Yes	Yes	No	No	Yes	111

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Scores 59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	Total
329.012.00225	SC	19NOV96	-7, -71	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	Yes	64
	8	29JAN97	65, 1	Yes	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	No	No	No	No	No	Yes	No	No	Yes	79
	32	30JUL97	247, 183	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes	81

* days relative to start of acute phase, days relative to start of continuation phase
Total score was computed by converting yes/no answers to yes=1 and no=0, then summing all items (1-78).

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.001.00063	SC	02NOV94	-6, .	13	27	12	3
329.001.00065	SC	07NOV94	-10, .	28	38	22	9
329.001.00068	SC	01FEB95	-7, .	23	21	17	3
	8	05APR95	57, .	37	31	25	4
329.001.00072	SC	07MAR95	-13, .	11	24	20	8
329.001.00121	SC	22MAR95	-13, -69	32	35	29	9
	8	30MAY95	57, 1	31	44	30	10
329.001.00205	SC	29JAN96	-9, .	36	34	27	8
329.001.00206	SC	12FEB96	-9, .	15	28	24	10
	8	17APR96	57, .	15	38	27	9
329.002.00055	SC	09JUN94	-15, -70	15	21	11	3
	8	18AUG94	56, 1	19	25	20	4
	20	10NOV94	140, 85	33	46	14	9
329.002.00058	SC	08SEP94	-12, -70	33	21	14	5
	8	17NOV94	59, 1	35	47	22	9
329.002.00099	SC	23FEB95	-7, -62	31	33	27	9
	8	25APR95	55, -1	19	33	23	4
329.002.00102	SC	03APR95	-10, -64	26	38	17	4

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.002.00102	8	06JUN95	55, 1	19	44	20	7
	32	05DEC95	237, 183	33	57	18	9
329.002.00105	SC	20JUL95	-7, .	21	26	19	7
329.002.00106	SC	20JUL95	-7, .	22	32	11	3
329.002.00242	SC	26JAN96	-12, -70	20	39	16	6
	20	10JUL96	155, 97	15	30	14	6
329.002.00245	SC	21MAR96	-7, .	27	44	28	8
329.002.00319	SC	23APR96	-7, -63	28	47	30	10
	8	25JUN96	57, 1	47	58	36	10
	32	17DEC96	232, 176	40	58	40	11
329.003.00075	8	22MAR95	57, 1	68	66	44	18
	32	13SEP95	232, 176	42	60	44	12
329.003.00077	SC	01MAR95	-5, -64	35	23	25	6
329.003.00087	SC	23JAN95	-8, .	17	63	28	10
329.003.00089	SC	24FEB95	-11, .	11	38	35	6
	8	02MAY95	57, .	5	43	35	6
329.003.00091	SC	14MAR95	-10, -64	46	57	32	14
	8	16MAY95	54, -1	47	57	44	15

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.003.00091	32	07NOV95	229, 175	58	68	44	15
329.003.00248	SC	14FEB96	-16, .	20	25	13	2
	8	23APR96	54, .	27	43	25	6
329.003.00250	SC	05MAR96	-9, -66	37	44	24	8
329.003.00292	SC	02AUG96	-5, -63	35	40	24	8
	8	04OCT96	59, 1	39	40	30	15
329.003.00313	SC	08MAY96	-9, .	32	35	13	4
329.004.00015	SC	30NOV94	-8, -65	36	31	19	6
	8	03FEB95	58, 1	32	24	28	7
	28	14JUN95	189, 132	43	33	25	8
329.004.00017	SC	15MAR95	-7, -63	34	45	38	7
	8	17MAY95	57, 1	32	40	28	5
	32	01NOV95	225, 169	30	52	30	9
329.004.00019	SC	24MAY95	-7, .	33	39	24	14
329.004.00212	SC	24MAY96	-10, .	57	52	10	5
329.004.00214	SC	27SEP96	-7, -67	30	47	18	5
	8	03DEC96	61, 1	47	58	32	5
329.005.00002	SC	20MAY94	-5, -61	23	44	23	8

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Paroxetine - Protocol 329
Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.005.00004	SC	22SEP94	-18, -77	23	62	26	14
	8	08DEC94	60, 1	31	56	28	14
329.005.00008	SC	10NOV94	-6, -61	17	34	8	10
	8	10JAN95	56, 1	31	42	13	10
	24	10MAY95	176, 121	26	39	13	12
329.005.00011	SC	06DEC94	-7, -63	31	58	22	11
	8	07FEB95	57, 1	33	61	26	12
329.005.00109	SC	22DEC94	-8, -61	50	27	35	7
329.005.00112	SC	17JAN95	-9, -64	22	39	24	7
	8	22MAR95	56, 1	52	54	27	8
329.005.00116	SC	30JAN95	-8, -66	42	54	16	13
	8	06APR95	59, 1	33	47	19	10
	24	26JUL95	170, 112	44	62	33	10
329.005.00119	SC	27JUN95	-14, -73	33	53	28	8
	8	08SEP95	60, 1	30	45	29	8
	24	02JAN96	176, 117	37	54	31	9
329.005.00151	SC	29AUG95	-8, -65	31	71	23	10
	8	02NOV95	58, 1	35	63	25	11
	32	01MAY96	239, 182	25	65	26	7
329.005.00152	SC	12OCT95	-14, .	26	44	25	4

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Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.005.00257	SC	05MAR96	-6, -62	13	22	15	5
	8	06MAY96	57, 1	15	38	17	5
	32	21OCT96	225, 169	16	34	17	7
329.005.00258	SC	06FEB96	-35, .	34	26	26	6
	8	07MAY96	57, .	27	47	13	7
329.005.00299	SC	28MAY96	-11, -71	12	25	11	2
	8	07AUG96	61, 1	32	48	28	9
	20	05NOV96	151, 91	32	46	26	7
329.005.00300	SC	12SEP96	-7, .	14	19	9	4
	8	14NOV96	57, .	15	22	9	3
329.005.00333	SC	15JAN97	-8, .	32	40	21	14
329.005.00336	SC	26FEB97	-6, .	18	17	9	7
329.006.00038	SC	01FEB95	-14, .	54	55	30	10
329.006.00039	SC	03FEB95	-5, -66	15	46	21	5
	8	05APR95	57, -5	20	54	32	7
329.006.00260	SC	12JUL96	-6, -64	20	21	14	1
	8	18SEP96	63, 5	21	30	17	4
329.006.00261	SC	07NOV96	-19, -77	45	50	55	19

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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.007.00140	SC	07SEP95	-8, -63	21	41	27	9
	8	09NOV95	56, 1	20	41	36	11
329.007.00142	SC	12OCT95	-6, .	19	35	7	5
	8	21DEC95	65, .	22	33	7	3
329.007.00145	SC	04JAN96	-7, -63	16	31	23	6
	8	07MAR96	57, 1	19	26	31	12
	32	23AUG96	226, 170	36	43	42	15
329.007.00265	SC	25JAN96	-7, .	20	32	19	4
329.007.00268	SC	21MAR96	-11, -70	31	39	38	10
	8	30MAY96	60, 1	41	44	30	11
	32	05DEC96	249, 190	46	48	29	10
329.007.00294	SC	20FEB97	-8, .	20	27	22	8
329.007.00309	SC	02JUL96	-13, -65	29	35	10	6
	7	05SEP96	53, 1	28	36	10	6
	32	13MAR97	242, 190	40	48	14	8
329.007.00310	SC	19SEP96	-7, -67	15	30	15	11
	8	25NOV96	61, 1	19	35	20	9
	32	12JUN97	260, 200	24	42	20	12
329.007.00318	SC	22NOV96	-10, .	30	44	19	7

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.008.00157	SC	16AUG95	-14, -69	32	53	20	12
	8	24OCT95	56, 1	43	58	25	17
329.008.00160	SC	25OCT95	-7, -73	44	47	52	13
	8	05JAN96	66, -1	46	53	49	15
329.008.00188	SC	14DEC95	-21, .	30	27	16	11
	8	27FEB96	55, .	31	27	17	12
329.008.00271	SC	25JAN96	-46,-110	35	49	26	8
	8	14MAY96	65, 1	53	51	31	7
329.008.00275	SC	30APR96	-8, -63	25	35	11	2
	8	02JUL96	56, 1	30	51	23	9
	32	16DEC96	223, 168	30	60	20	11
329.009.00130	SC	12APR95	-6, -62	30	35	25	8
	8	13JUN95	57, 1	47	54	25	14
329.009.00131	SC	26APR95	-6, -62	14	16	14	2
	8	27JUN95	57, 1	23	47	19	3
329.009.00133	SC	07JUN95	-6, .	20	40	24	3
329.009.00138	SC	02OCT95	-8, .	14	28	19	6
329.009.00170	SC	26OCT95	-12, -69	11	22	15	0
	8	03JAN96	58, 1	27	38	26	4

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.009.00170	32	24JUN96	231, 174	28	42	25	3
329.009.00173	SC	08NOV95	-12, -75	27	33	21	5
	8	22JAN96	64, 1	22	24	17	4
329.009.00193	SC	21NOV95	-7, .	33	17	14	5
	8	24JAN96	58, .	37	13	11	6
329.009.00196	SC	11DEC95	-7, .	43	47	35	14
	8	12FEB96	57, .	52	68	44	15
329.009.00201	SC	31JAN96	-6, .	37	51	28	10
	8	02APR96	57, .	37	49	23	12
329.009.00204	SC	13MAR96	-6, -62	36	39	33	9
	8	14MAY96	57, 1	37	47	31	9
329.009.00235	SC	10DEC96	-8, -62	20	34	31	8
	8	10FEB97	55, 1	33	47	34	7
329.009.00240	SC	03JAN97	-11, .	27	28	24	5
	7	04MAR97	50, .	25	46	23	8
329.009.00303	SC	25MAR96	-8, -64	27	43	22	8
	8	28MAY96	57, 1	20	37	21	10
	32	10DEC96	253, 197	24	38	21	10
329.009.00304	SC	03APR96	-6, -62	26	38	15	6

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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.009.00304	8	04JUN96	57, 1	27	41	11	8
329.009.00324	SC	21OCT96	-7, .	46	62	38	9
	8	27DEC96	61, .	62	59	39	13
329.009.00328	SC	30SEP96	-7, .	17	37	16	5
329.009.00329	SC	01OCT96	-8, .	13	23	16	2
	8	03DEC96	56, .	10	22	19	3
329.010.00182	SC	05DEC95	-14, .	22	32	24	6
329.010.00278	SC	02FEB96	-7, -63	26	56	22	13
	8	05APR96	57, 1	35	64	33	15
	32	19SEP96	224, 168	34	68	42	17
329.010.00280	SC	10MAY96	-7, -62	25	22	22	4
	8	11JUL96	56, 1	20	25	25	6
	12	21AUG96	97, 42	30	25	28	5
329.011.00283	SC	30JAN96	-9, -66	14	24	9	7
	8	04APR96	57, -1	25	31	17	6
329.011.00288	SC	01JUL96	-24, .	51	33	15	9
329.012.00025	SC	17OCT95	-7, .	23	30	21	5
	8	19DEC95	57, .	18	41	19	2

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.012.00220	SC	04JUN96	-13, -73	28	41	26	5
	8	16AUG96	61, 1	36	40	25	8
329.012.00222	SC	18JUN96	-10, -73	27	27	23	6
	8	30AUG96	64, 1	23	35	20	7
329.012.00226	SC	26NOV96	-7, .	22	51	11	12
329.012.00228	SC	04MAR97	-15, .	8	20	17	4
329.012.00231	SC	26FEB97	-9, -70	31	36	28	5
	8	07MAY97	62, 1	38	34	36	14
	24	19AUG97	166, 105	30	49	33	7

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Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.001.00061	SC	19JUL94	-10, .	23	20	19	5
329.001.00066	SC	14NOV94	-8, .	35	73	32	9
329.001.00067	SC	15NOV94	-7, .	21	39	18	6
329.001.00070	SC	14FEB95	-8, .	11	24	19	7
329.001.00122	SC	13JUN95	-7, -64	25	48	21	5
	8	16AUG95	58, 1	35	54	28	9
329.002.00050	SC	10MAR95	-13, .	27	42	23	9
	5	28APR95	37, .	29	48	27	8
329.002.00056	SC	24JUN94	-25, .	45	50	19	5
329.002.00057	SC	11AUG94	-28, -85	14	16	13	4
	8	03NOV94	57, -1	20	33	20	5
	16	11JAN95	126, 69	17	33	12	6
329.002.00098	SC	20DEC94	-14, .	60	52	30	11
	8	02MAR95	59, .	45	43	29	10
329.002.00100	SC	16FEB95	-19, -77	38	49	34	8
	8	04MAY95	59, 1	55	52	36	9
	16	06JUL95	122, 64	45	63	30	9
329.002.00103	SC	11APR95	-9, -65	24	55	32	9

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.002.00103	8	15JUN95	57, 1	12	49	29	8
	16	10AUG95	113, 57	15	55	40	11
329.002.00104	SC	28APR95	-6, -62	30	34	25	10
	8	29JUN95	57, 1	30	35	25	12
	32	02JAN96	244, 188	33	40	29	9
329.002.00243	SC	27FEB96	-16, .	22	42	25	7
329.002.00244	SC	14MAR96	-7, -64	39	60	32	10
	8	16MAY96	57, -1	51	64	35	13
329.002.00321	SC	15MAY96	-8, .	24	27	12	5
329.002.00322	SC	06JAN97	-3, .	21	23	24	3
329.003.00073	SC	11JAN95	-8, .	25	33	20	11
329.003.00076	SC	24JAN95	-7, -62	41	59	55	10
	32	11OCT95	254, 199	30	60	46	7
329.003.00088	SC	06FEB95	-22, .	21	37	20	9
329.003.00090	SC	08MAR95	-6, .	40	48	18	8
	8	16MAY95	64, .	43	47	27	7
329.003.00092	SC	13APR95	-20, -78	28	16	18	3
	8	30JUN95	59, 1	29	30	28	7

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.003.00092	32	02JAN96	245, 187	22	30	18	6
329.003.00093	SC	08JUN95	-13, -76	20	55	16	12
	8	22AUG95	63, -1	34	69	37	13
	16	03OCT95	105, 42	30	57	32	13
329.003.00247	SC	05JAN96	-27, -81	21	36	29	7
	8	26MAR96	55, 1	30	49	23	6
329.003.00249	SC	01MAR96	-6, .	20	46	11	6
	8	30APR96	55, .	29	54	18	9
329.003.00289	SC	12FEB96	-16, -72	23	14	16	3
	8	24APR96	57, 1	19	7	12	2
	32	11OCT96	227, 171	27	9	23	9
329.003.00290	SC	06MAR96	-5, .	33	32	21	2
329.003.00317	SC	12DEC96	-7, .	.	43	16	0
	8	11FEB97	55, .	40	36	15	3
329.004.00013	SC	05JUL94	-14, -73	42	58	35	16
	8	16SEP94	60, 1	58	62	37	16
329.004.00014	SC	22NOV94	-7, .	40	53	9	14
329.004.00211	SC	24JAN96	-9, .	13	64	25	16

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.004.00215	SC	12MAR97	-8, .	12	40	23	1
329.005.00003	SC	12SEP94	-8, .	49	55	47	13
329.005.00006	SC	27OCT94	-8, -68	27	70	35	12
	8	03JAN95	61, 1	41	78	39	14
	24	28APR95	176, 116	35	74	50	14
329.005.00007	SC	02NOV94	-7, -70	28	28	22	7
	8	11JAN95	64, 1	31	28	21	5
	32	09AUG95	274, 211	42	61	36	7
329.005.00009	SC	07DEC94	-5, .	36	62	42	6
	8	07FEB95	58, .	42	62	37	8
329.005.00110	SC	04JAN95	-7, .	45	69	25	15
329.005.00113	SC	20JAN95	-10, .	34	58	27	11
329.005.00117	SC	06MAR95	-12, .	39	28	24	3
	8	15MAY95	59, .	39	32	32	3
329.005.00118	SC	09MAY95	-8, .	35	49	21	2
329.005.00153	SC	11JAN96	-14, -70	40	45	25	7
	8	21MAR96	57, 1	43	39	21	7
	32	04SEP96	224, 168	36	36	21	10

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.005.00255	SC	26FEB96	-7, .	32	52	43	12
	8	29APR96	57, .	37	54	37	10
329.005.00256	SC	20FEB96	-14, -70	35	41	22	1
	8	30APR96	57, 1	36	51	27	4
329.005.00295	SC	21MAR96	-7, .	21	32	22	5
	8	22MAY96	56, .	19	30	21	9
329.005.00297	SC	28MAR96	-22, .	26	29	14	10
329.005.00332	SC	05DEC96	-7, .	32	41	23	5
	8	06FEB97	57, .	30	48	23	6
329.005.00335	SC	20FEB97	-8, .	31	57	28	11
329.006.00040	SC	10FEB95	-6, .	23	33	17	1
329.006.00041	SC	22MAR95	-14, -78	18	48	33	6
	8	31MAY95	57, -8	24	77	42	8
	32	21NOV95	231, 167	56	80	51	11
329.007.00139	SC	04MAY95	-4, .	25	21	31	8
329.007.00143	SC	26OCT95	-14, .	25	25	25	1
329.007.00146	SC	18JAN96	-7, -60	44	39	20	7
	8	18MAR96	54, 1	40	31	19	6

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.007.00146	32	09SEP96	229, 176	39	29	19	7
329.007.00269	SC	04APR96	-7, .	27	36	16	5
	3	02MAY96	22, .	26	25	16	5
329.007.00270	SC	02MAY96	-7, .	20	35	14	6
	7	27JUN96	50, .	20	25	10	5
329.007.00307	SC	09MAY96	-7, .	22	23	10	1
	8	25JUL96	71, .	23	20	5	4
329.007.00308	SC	27JUN96	-5, .	15	8	17	6
329.008.00159	SC	06SEP95	-7, -69	29	53	33	10
329.008.00161	SC	31OCT95	-16, -71	31	31	17	4
329.008.00187	SC	15NOV95	-14, .	32	39	19	7
	8	26JAN96	59, .	32	37	23	8
329.008.00192	SC	14FEB96	-20, .	18	27	19	3
329.008.00272	SC	19MAR96	-15, -71	25	22	8	1
	8	29MAY96	57, 1	34	29	11	4
329.008.00273	SC	19APR96	-28, -91	27	48	32	8
	8	19JUL96	64, 1	39	47	39	10

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Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.009.00127	SC	03APR95	-7, .	22	24	21	4
329.009.00132	SC	17MAY95	-6, -63	46	44	25	9
	8	19JUL95	58, 1	37	61	22	11
329.009.00134	SC	28JUN95	-8, .	19	28	15	8
	8	29AUG95	55, .	35	52	31	11
329.009.00137	SC	03OCT95	-7, .	19	21	19	4
	8	05DEC95	57, .	22	19	20	4
329.009.00171	SC	31OCT95	-7, .	68	33	22	7
329.009.00172	SC	06NOV95	-7, -64	33	42	38	8
	8	09JAN96	58, 1	34	48	41	9
	32	08JUL96	239, 182	23	48	30	12
329.009.00194	SC	28NOV95	-7, -63	10	15	11	7
	8	30JAN96	57, 1	16	21	13	9
	24	04JUN96	183, 127	23	25	27	8
329.009.00195	SC	06DEC95	-9, .	21	47	25	11
329.009.00199	SC	10JAN96	-6, .	27	30	19	5
	8	13MAR96	58, .	51	48	43	7
329.009.00203	SC	28FEB96	-5, .	20	23	29	6

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
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Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.009.00236	SC	17DEC96	-13, .	19	32	28	5
	4	27JAN97	29, .	18	22	20	6
329.009.00239	SC	11NOV96	-8, -65	29	35	22	3
	8	15JAN97	58, 1	42	46	28	9
329.009.00262	SC	07FEB97	-10, .	28	42	25	4
	8	14APR97	57, .	39	45	22	7
329.009.00264	SC	25OCT96	-7, .	24	33	24	9
	7	23DEC96	53, .	20	22	14	8
329.009.00301	SC	06MAR96	-13, -69	41	42	15	9
	8	14MAY96	57, 1	37	53	17	6
329.009.00305	SC	01MAY96	-6, -63	18	23	15	5
	8	03JUL96	58, 1	21	24	25	6
	32	10JAN97	249, 192	33	42	30	9
329.009.00325	SC	21AUG96	-6, -61	37	41	30	3
	8	21OCT96	56, 1	37	50	22	8
	16	16DEC96	112, 57	34	31	18	3
329.009.00326	SC	26AUG96	-10, -63	36	22	23	3
	8	28OCT96	54, 1	61	41	25	3
	16	16DEC96	103, 50	44	30	22	5
329.010.00279	SC	08MAR96	-14, -70	23	38	35	7

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.010.00279	8	17MAY96	57, 1	14	34	31	9
	32	06NOV96	230, 174	40	45	39	12
329.010.00281	SC	19JUL96	-7, -68	28	16	13	7
	8	25SEP96	62, 1	13	15	19	11
	24	03JAN97	162, 101	28	16	19	6
329.011.00163	SC	18NOV95	-7, .	36	24	18	3
329.011.00208	SC	22AUG96	-15, -74	19	41	33	8
	8	03NOV96	59, -1	20	55	38	14
329.011.00209	SC	23AUG96	-19, -81	9	26	18	6
	8	11NOV96	62, -1	27	45	32	8
329.011.00284	SC	13MAR96	-9, -65	29	22	15	3
	8	16MAY96	56, -1	35	42	29	7
329.011.00286	SC	15MAY96	-22, -90	25	24	19	7
	8	09AUG96	65, -4	20	29	17	7
329.012.00026	SC	09NOV95	-19, .	31	24	12	0
329.012.00219	SC	24MAY96	-7, -67	11	35	26	8
	8	30JUL96	61, 1	23	46	24	8
	32	24JAN97	239, 179	18	37	16	9
329.012.00221	SC	18JUN96	-7, -70	41	48	25	6

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.012.00221	8	27AUG96	64, 1	41	40	31	7
329.012.00223	SC	23AUG96	-7, .	22	27	13	6
329.012.00227	SC	12DEC96	-6, -75	30	53	36	16
	8	25FEB97	70, 1	25	49	39	9
	32	19AUG97	245, 176	34	50	34	14
329.012.00230	SC	20FEB97	-8, -77	10	25	18	7
	8	08MAY97	70, 1	14	25	13	1

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.001.00062	SC	06OCT94	-14, .	18	26	17	6
329.001.00064	SC	04NOV94	-6, -60	13	21	15	6
	8	03JAN95	55, 1	15	28	19	7
329.001.00069	SC	07FEB95	-9, .	33	31	17	4
	8	13APR95	57, .	39	38	25	10
329.001.00071	SC	02FEB95	-21, .	17	36	28	6
	8	20APR95	57, .	15	35	30	6
329.001.00123	SC	14DEC95	-21, .	19	16	13	4
329.001.00207	SC	19FEB96	-9, .	17	42	16	4
	8	24APR96	57, .	15	47	21	6
329.002.00049	SC	03MAR95	-6, .	24	25	26	1
	8	05MAY95	58, .	19	25	28	0
329.002.00059	SC	03NOV94	-7, .	24	25	10	4
	8	05JAN95	57, .	25	18	16	1
329.002.00060	SC	24JAN95	-7, -63	24	34	15	6
	8	28MAR95	57, 1	22	33	17	7
329.002.00097	SC	20DEC94	-14, -72	36	37	20	8
	8	02MAR95	59, 1	38	43	26	11
	32	05SEP95	246, 188	44	42	29	8

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.002.00101	SC	20MAR95	-8, -66	24	25	23	10
	8	25MAY95	59, 1	35	53	32	9
329.002.00107	SC	18JAN96	-7, -63	28	35	22	7
	8	21MAR96	57, 1	46	42	31	8
	32	26SEP96	246, 190	47	50	35	12
329.002.00241	SC	25JAN96	-12, -68	27	48	24	11
	8	02APR96	57, 1	27	55	19	8
329.002.00246	SC	01APR96	-17, .	32	55	33	10
	8	18JUN96	62, .	42	45	32	9
329.002.00320	SC	09MAY96	-7, -68	41	67	23	9
	8	16JUL96	62, 1	42	61	23	8
329.002.00323	SC	04NOV96	-8, -66	34	45	13	7
	8	09JAN97	59, 1	43	65	37	8
	32	12JUN97	213, 155	49	70	25	14
329.003.00074	SC	18JAN95	-7, -63	30	58	20	6
	8	22MAR95	57, 1	38	46	27	14
	32	11OCT95	260, 204	20	49	13	5
329.003.00078	SC	11APR95	-15, .	25	35	19	7
	8	21JUN95	57, .	23	44	21	10
329.003.00080	SC	22NOV95	-5, .	46	12	4	5

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.003.00085	SC	26OCT94	-13, .	33	36	30	7
	8	03JAN95	57, .	36	40	26	7
329.003.00086	SC	09NOV94	-19, -76	18	34	21	6
	8	23JAN95	57, -1	27	34	22	6
	32	17AUG95	263, 206	35	40	21	6
329.003.00094	SC	20OCT95	-4, .	43	53	35	2
	8	19DEC95	57, .	16	40	24	3
329.003.00252	SC	19MAR96	-22, .	20	37	11	5
329.003.00315	SC	29OCT96	-14, .	23	31	18	2
	8	07JAN97	57, .	22	38	20	3
329.003.00316	SC	05DEC96	-12, .	32	30	12	4
	8	11FEB97	57, .	36	24	16	7
329.004.00016	SC	01MAR95	-12, .	26	47	20	7
329.004.00018	SC	19APR95	-14, .	65	46	21	11
	8	29JUN95	58, .	39	40	21	7
329.004.00020	SC	02NOV95	-7, .	14	45	18	7
	2	24NOV95	16, .	15	45	23	7
329.004.00213	SC	18JUL96	-15, -69	24	38	28	6
	8	24SEP96	54, -1	21	35	24	5

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.004.00213	32	19MAR97	230, 176	30	42	35	8
329.005.00001	SC	11APR94	-9, .	30	41	24	6
	8	15JUN94	57, .	28	53	23	4
329.005.00005	SC	24OCT94	-8, .	32	17	22	5
329.005.00010	SC	07DEC94	-6, -63	39	34	29	10
	8	08FEB95	58, 1	49	54	35	9
	32	09AUG95	240, 183	56	58	53	9
329.005.00012	SC	12DEC94	-7, -66	28	41	30	10
	8	16FEB95	60, 1	35	46	35	13
329.005.00111	SC	05JAN95	-6, -62	57	54	33	12
	8	08MAR95	57, 1	42	57	29	10
	16	03MAY95	113, 57	48	60	47	12
329.005.00114	SC	23JAN95	-8, -65	29	49	31	5
	8	29MAR95	58, 1	34	59	31	4
	16	17MAY95	107, 50	32	49	31	4
329.005.00115	SC	27JAN95	-10, -81	27	32	14	7
	8	18APR95	72, 1	49	52	35	11
329.005.00120	SC	22AUG95	-8, .	10	18	14	1
	8	26OCT95	58, .	11	23	15	2

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.005.00253	SC	31JAN96	-8, .	52	67	39	10
	8	03APR96	56, .	39	60	27	10
329.005.00254	SC	08FEB96	-7, -62	30	42	25	8
	8	10APR96	56, 1	37	61	32	10
329.005.00293	SC	06MAR97	-6, .	32	36	12	3
	8	07MAY97	57, .	39	36	11	1
329.005.00298	SC	15MAY96	-7, -63	26	28	19	6
	8	17JUL96	57, 1	35	34	29	7
	32	13JAN97	237, 181	35	40	33	8
329.005.00331	SC	14NOV96	-7, .	46	53	30	11
	8	16JAN97	57, .	58	48	32	12
329.005.00334	SC	24JAN97	-7, .	23	31	29	10
	8	27MAR97	56, .	26	40	27	7
329.006.00037	SC	20JAN95	-8, .	54	72	47	11
329.006.00042	SC	01DEC95	-6, -63	23	51	18	6
	8	02FEB96	58, 1	29	60	17	8
	32	16JUL96	223, 166	34	59	22	5
329.006.00259	SC	22APR96	-32, .	29	58	28	5
	8	17JUL96	55, .	28	57	33	5

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.007.00141	SC	14SEP95	-7, .	31	34	29	7
329.007.00144	SC	30NOV95	-7, -63	22	22	17	5
	8	01FEB96	57, 1	17	28	22	6
329.007.00266	SC	29FEB96	-7, .	16	29	17	8
	8	02MAY96	57, .	16	34	25	7
329.007.00267	SC	29FEB96	-7, .	27	36	17	6
	8	02MAY96	57, .	42	39	24	9
329.007.00311	SC	26SEP96	-7, -67	23	46	24	15
	8	02DEC96	61, 1	29	54	25	18
329.008.00158	SC	06SEP95	-7, -69	28	48	41	10
329.008.00162	SC	26OCT95	-6, -71	24	26	17	3
	32	02JUL96	245, 180	30	45	18	5
329.008.00191	SC	12JAN96	-20, -81	56	66	37	8
	8	02APR96	62, 1	56	73	47	9
329.009.00128	SC	05APR95	-6, .	14	32	31	7
329.009.00129	SC	22MAR95	-20, .	19	23	23	7
329.009.00135	SC	25SEP95	-7, .	14	32	13	6

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Appendix C.5
Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.009.00136	SC	26SEP95	-7, .	18	16	8	2
	8	28NOV95	57, .	30	24	18	7
329.009.00169	SC	25OCT95	-6, -71	40	41	33	10
	8	27DEC95	58, -8	27	42	39	11
329.009.00174	SC	14NOV95	-7, -64	22	33	13	2
	8	17JAN96	58, 1	29	32	10	5
329.009.00197	SC	20DEC95	-9, -63	21	10	13	5
	8	20FEB96	54, -1	21	22	18	5
	32	20AUG96	236, 182	14	16	16	6
329.009.00198	SC	19DEC95	-14, .	22	31	9	9
	8	27FEB96	57, .	23	41	10	6
329.009.00200	SC	17JAN96	-6, .	22	30	21	7
329.009.00202	SC	14FEB96	-6, .	36	55	32	13
329.009.00237	SC	04NOV96	-7, .	34	38	20	15
329.009.00238	SC	28OCT96	-15, .	21	43	29	9
	8	07JAN97	57, .	25	43	28	10
329.009.00276	SC	17JAN97	-4, .	17	26	21	5
	8	18MAR97	57, .	13	29	29	6

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.009.00302	SC	20MAR96	-7, .	12	40	13	9
329.009.00306	SC	03JUN96	-8, .	36	19	20	1
	8	06AUG96	57, .	10	15	24	6
329.009.00312	SC	30OCT96	-5, .	40	40	27	11
329.009.00327	SC	09SEP96	-7, .	19	40	18	7
	5	21OCT96	36, .	24	38	10	6
329.009.00330	SC	15OCT96	-6, .	51	38	30	10
329.010.00183	SC	21NOV95	-12, .	23	15	21	5
329.010.00263	SC	24JUL96	-16, .	30	20	19	9
	8	09OCT96	62, .	34	32	22	11
329.010.00277	SC	23FEB96	-7, -63	54	41	31	12
	8	26APR96	57, 1	56	51	31	10
	24	07AUG96	160, 104	47	53	28	14
329.010.00282	SC	19JUL96	-7, .	28	33	19	5
	8	27SEP96	64, .	30	38	21	6
329.011.00164	SC	15DEC95	-7, .	42	48	23	7
329.011.00210	SC	13SEP96	-15, -81	25	30	24	9
	8	02DEC96	66, -1	22	34	15	11

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Listing of Autonomous Function Checklist Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Autonomous Function Checklist Subscores: Self/Family Care	Management	Recreational Activity	Social/Vocational Activities
329.011.00285	SC	08MAY96	-10, .	30	41	28	8
	8	24JUL96	68, .	32	40	30	10
329.011.00287	SC	25JUN96	-8, .	20	25	18	4
	8	27AUG96	56, .	18	28	22	7
329.012.00027	SC	23NOV95	-13, .	46	57	26	9
329.012.00217	SC	14MAY96	-7, .	18	23	22	3
329.012.00218	SC	04JUN96	-12, -70	26	45	17	4
	8	13AUG96	59, 1	29	55	17	4
329.012.00224	SC	30AUG96	-17, -83	22	37	32	7
	8	20NOV96	66, -1	30	35	36	10
329.012.00225	SC	19NOV96	-7, -71	19	27	14	4
	8	29JAN97	65, 1	19	33	19	8
	32	30JUL97	247, 183	15	42	14	10

* days relative to start of acute phase, days relative to start of continuation phase
Self/Family Care = Items 1-22, Management = Items 23-42, Recreational Activity = Items 43-58,
Social/Vocational Activities = Items 59-78
Yes/No answers were converted to yes=1 and no=0 in order to sum items.

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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.001.00063	SC	02NOV94	-6, .	2	0	0	0	2	0	2	0	0	3	0	0	0	2	.	2	3	0	3	3	0	0	3	0	0	2	2	3	0
329.001.00065	SC	07NOV94	-10, .	1	1	1	1	2	1	2	2	1	0	1	1	2	2	2	1	2	1	0	2	1	2	2	1	2	2	1	0	2
329.001.00068	SC	01FEB95	-7, .	0	2	0	0	2	1	1	3	0	1	2	1	0	1	2	1	3	0	1	1	0	0	2	2	2	3	0	1	2
	8	05APR95	57, .	2	2	0	0	2	1	1	3	0	1	2	0	0	2	2	1	3	1	1	2	0	0	2	1	2	3	0	1	2
329.001.00072	SC	07MAR95	-13, .	3	3	2	2	3	2	2	3	2	3	3	3	2	3	3	2	3	1	3	3	2	2	1	2	3	3	3	3	2
329.001.00121	SC	22MAR95	-13, -69	1	2	2	1	3	1	1	2	1	1	2	2	0	2	1	1	1	2	2	1	2	1	1	1	1	3	1	1	1
	8	30MAY95	57, 1	1	2	2	1	3	2	1	1	1	2	2	2	1	3	1	2	2	2	1	1	2	0	2	1	1	2	1	2	2
329.001.00205	SC	29JAN96	-9, .	2	0	0	2	3	0	3	0	3	1	0	0	3	3	.	1	3	3	1	0	0	3	3	1	3	0	3	0	0
329.001.00206	SC	12FEB96	-9, .	1	0	2	1	2	1	1	0	1	0	1	2	1	2	1	1	2	2	0	0	1	1	1	1	2	1	1	0	0
	8	17APR96	57, .	1	0	3	2	2	0	1	1	1	1	0	1	0	2	.	2	.	2	2	0	2	1	2	0	2	1	1	2	1
329.002.00055	SC	09JUN94	-15, -70	1	1	2	3	1	2	2	1	2	0	1	1	3	1	1	1	3	0	0	0	1	0	0	2	0	3	0	0	0
	8	18AUG94	56, 1	3	2	2	3	3	2	1	2	3	0	1	0	0	2	0	0	3	2	1	2	0	3	3	3	1	0	2	1	3
	20	10NOV94	140, 85	2	3	3	0	2	2	2	3	3	0	3	3	3	1	0	1	3	1	1	1	1	3	1	3	0	3	2	1	2
329.002.00058	SC	08SEP94	-12, -70	1	2	2	1	2	0	1	1	0	3	3	1	0	2	3	0	3	1	2	2	2	1	3	0	1	2	1	2	1
	8	17NOV94	59, 1	3	2	2	2	3	2	1	3	2	3	3	1	1	3	2	2	3	2	3	3	2	1	3	2	2	3	2	1	2
329.002.00099	SC	23FEB95	-7, -62	1	2	1	1	3	2	2	2	1	1	1	1	0	3	1	1	1	2	1	1	0	1	2	1	2	2	2	2	1
	8	25APR95	55, -1	2	2	1	2	3	2	2	2	2	1	2	2	1	3	2	2	1	2	2	2	1	1	2	1	2	3	2	1	2
	32	26OCT95	239, 184	1	1	1	0	2	1	3	2	1	1	1	1	0	3	3	1	3	1	2	3	1	1	3	1	2	3	1	2	1

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.002.00102	SC	03APR95	-10, -64	0	0	0	0	2	0	1	3	1	0	2	0	0	1	2	1	3	1	0	2	0	0	2	0	0	3	0	0	1
	8	06JUN95	55, 1	1	2	0	0	3	1	3	3	2	1	2	1	0	3	3	3	3	2	2	2	0	0	3	1	2	3	2	1	2
	32	05DEC95	237, 183	1	1	1	1	3	2	2	2	2	1	3	1	1	3	3	1	3	3	3	2	1	0	3	1	2	3	2	1	2
329.002.00105	SC	20JUL95	-7, .	2	2	2	3	3	3	1	1	1	2	2	1	2	2	3	1	3	1	1	2	1	2	0	1	2	3	1	2	1
329.002.00106	SC	20JUL95	-7, .	3	0	2	0	3	1	0	0	0	0	1	2	0	2	0	1	3	1	0	0	2	0	2	0	1	2	0	2	0
329.002.00242	SC	26JAN96	-12, -70	2	3	2	2	2	3	0	3	0	0	3	2	0	3	3	0	3	0	0	3	3	0	2	2	3	3	1	0	3
	20	10JUL96	155, 97	3	3	3	3	3	3	3	3	3	3	3	1	3	3	3	3	3	3	0	3	1	3	2	3	3	3	3	1	3
329.002.00245	SC	21MAR96	-7, .	2	3	0	1	3	3	2	4	3	4	2	1	1	2	3	1	1	1	1	2	1	1	1	1	2	2	1	1	2
329.002.00319	SC	23APR96	-7, -63	3	1	1	1	2	2	3	0	2	3	1	2	1	2	2	0	2	2	3	3	1	1	3	1	1	2	1	3	0
	8	25JUN96	57, 1	3	0	2	2	3	2	2	0	3	3	0	1	1	3	.	0	3	3	3	2	2	2	3	2	2	2	2	3	0
	32	17DEC96	232, 176	2	1	2	2	2	3	2	1	2	2	1	2	1	3	2	3	1	3	2	2	2	2	2	1	2	3	2	3	0
329.003.00075	SC	18JAN95	-7, -63	2	3	2	0	3	0	2	3	0	1	3	2	0	1	2	1	3	1	0	2	1	0	2	0	1	2	0	2	3
	8	22MAR95	57, 1	0	3	2	2	3	0	3	3	0	1	3	2	0	0	2	0	2	1	0	3	2	0	1	0	0	0	0	0	3
	32	13SEP95	232, 176	0	3	2	0	3	1	2	2	0	2	3	2	0	3	2	0	3	1	0	2	2	0	3	0	3	2	1	1	3
329.003.00077	SC	01MAR95	-5, -64	3	1	3	2	3	1	1	1	1	2	1	3	2	3	0	1	2	1	1	3	3	2	3	2	2	2	1	3	1
329.003.00087	SC	23JAN95	-8, .	1	3	2	2	0	1	1	3	1	1	3	2	1	2	2	0	2	0	2	2	2	1	1	1	2	3	0	1	2
329.003.00089	8	02MAY95	57, .	1	0	3	2	3	3	2	3	1	2	2	3	2	3	2	1	3	3	2	2	1	3	3	0	2	3	2	1	1

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.003.00091	8	16MAY95	54, -1	2	0	1	0	3	3	2	3	2	2	2	2	1	3	1	2	3	3	3	2	1	1	3	2	2	3	2	3	2
	32	07NOV95	229, 175	3	3	2	2	3	3	3	2	2	3	2	2	1	3	3	3	2	2	2	3	1	2	3	3	3	3	2	2	3
329.003.00248	SC	14FEB96	-16, .	2	1	0	0	2	0	1	2	1	0	1	0	0	2	0	3	3	2	0	2	0	0	0	0	1	3	1	2	0
	8	23APR96	54, .	2	3	0	1	1	1	2	3	2	0	2	0	1	1	2	1	3	2	0	3	0	1	0	1	1	3	1	2	1
329.003.00250	SC	05MAR96	-9, -66	3	3	3	2	1	3	1	2	1	1	3	3	0	3	3	1	2	1	1	2	3	1	2	3	2	3	1	2	3
	8	09MAY96	57, -1	2	3	2	3	2	3	1	3	2	2	3	3	1	2	3	2	3	1	1	3	3	1	2	3	3	3	2	2	3
329.003.00292	SC	02AUG96	-5, -63	1	2	2	2	2	1	3	1	0	0	2	2	1	2	2	0	3	1	2	2	1	0	2	3	1	1	1	1	2
	8	04OCT96	59, 1	1	2	3	2	3	2	3	2	0	1	3	3	1	3	3	1	3	2	3	2	2	1	3	2	2	1	1	1	2
329.003.00313	SC	08MAY96	-9, .	0	1	2	0	3	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	2	0	0	0	0	1	0	1	0
329.004.00015	SC	30NOV94	-8, -65	3	1	1	1	1	2	1	0	2	0	1	1	2	1	2	3	3	1	0	3	1	2	3	2	3	3	2	0	.
	8	03FEB95	58, 1	2	2	1	2	3	1	1	2	2	1	1	1	2	2	2	2	3	1	1	2	1	2	2	2	3	2	3	1	2
	28	14JUN95	189, 132	3	2	1	3	1	2	2	1	3	1	3	1	3	1	1	2	3	1	2	3	1	3	3	3	3	3	3	1	3
329.004.00017	SC	15MAR95	-7, -63	0	0	0	0	2	0	0	0	0	2	0	0	0	2	2	0	3	0	2	2	0	0	1	0	0	0	0	1	0
	8	17MAY95	57, 1	0	1	1	2	2	1	1	1	1	2	0	2	1	1	2	2	3	1	2	1	1	1	1	1	1	1	1	1	0
	32	01NOV95	225, 169	0	1	1	1	2	1	1	0	1	1	0	1	0	2	1	3	3	0	0	1	1	1	2	1	1	0	1	2	0
329.004.00019	SC	24MAY95	-7, .	1	0	3	3	3	3	0	1	3	0	1	3	3	1	3	2	3	0	1	2	2	3	3	3	2	1	1	1	2
329.004.00212	SC	24MAY96	-10, .	2	0	2	1	2	0	1	0	0	1	2	2	1	1	2	0	3	1	2	2	2	1	2	0	1	3	1	2	2
329.004.00214	SC	27SEP96	-7, -67	1	1	2	0	1	0	3	2	1	1	2	1	0	0	0	2	3	1	1	0	0	0	1	0	2	2	1	2	2

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For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.004.00214	8	03DEC96	61, 1	1	2	2	0	2	0	3	3	0	1	2	2	0	0	0	0	3	0	2	0	1	0	2	0	1	2	0	2	2
329.005.00004	SC	22SEP94	-18, -77	2	2	3	2	2	2	2	3	2	1	3	2	2	2	1	2	3	1	1	3	2	2	1	3	2	3	2	2	2
	8	08DEC94	60, 1	3	3	3	3	4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	3
329.005.00008	SC	10NOV94	-6, -61	3	3	2	1	3	2	2	2	2	2	3	3	1	2	1	1	3	1	1	2	1	0	2	1	2	1	2	2	1
	8	10JAN95	56, 1	2	3	3	1	1	2	1	3	3	1	3	2	1	2	2	1	3	2	1	3	2	1	3	2	2	3	2	2	2
	24	10MAY95	176, 121	2	3	3	3	2	2	2	3	2	1	3	3	2	2	2	1	3	2	1	3	1	2	2	2	2	3	2	1	3
329.005.00011	SC	06DEC94	-7, -63	0	1	0	1	2	0	2	3	0	0	2	0	1	2	1	1	3	0	0	2	0	1	2	0	1	3	0	0	1
	8	07FEB95	57, 1	1	1	1	3	3	1	2	3	1	0	3	1	2	2	3	1	3	2	1	2	1	2	3	1	2	3	2	1	2
329.005.00109	SC	22DEC94	-8, -61	2	3	2	3	3	2	2	0	0	1	2	1	3	2	3	1	3	1	2	1	1	1	2	2	2	3	1	1	2
	8	21FEB95	54, 1	2	1	2	3	2	2	2	2	1	1	2	2	1	1	3	1	2	1	2	1	2	1	2	2	2	1	2	1	2
329.005.00112	SC	17JAN95	-9, -64	1	0	1	1	0	3	2	0	0	1	0	2	2	2	0	3	2	1	0	1	1	2	1	1	0	3	0	1	0
	8	22MAR95	56, 1	3	1	2	2	3	2	2	2	3	2	0	2	3	3	3	1	3	2	2	3	2	2	3	2	3	1	2	3	1
	20	21JUN95	147, 92	3	1	3	0	3	2	3	2	2	2	2	2	0	3	2	0	3	0	2	3	2	0	3	2	2	2	2	3	1
329.005.00116	SC	30JAN95	-8, -66	1	3	2	1	3	2	2	3	1	3	3	1	0	3	3	1	3	1	0	2	1	1	2	1	2	3	1	1	3
	8	06APR95	59, 1	2	3	2	2	3	2	2	3	2	2	3	2	0	3	3	1	3	2	1	3	1	1	3	2	2	3	2	1	3
	24	26JUL95	170, 112	2	3	2	2	3	1	2	3	2	2	3	2	1	3	2	1	3	1	2	3	2	1	3	2	3	3	3	2	3
329.005.00119	SC	27JUN95	-14, -73	2	2	0	1	2	1	0	3	1	1	2	0	0	2	2	2	3	2	3	2	0	1	0	2	2	3	2	3	2
	8	08SEP95	60, 1	3	3	1	2	3	2	1	3	3	3	3	1	1	3	3	3	2	3	3	3	1	2	1	2	3	3	3	3	3
	24	02JAN96	176, 117	2	3	0	2	3	2	2	2	2	2	2	1	2	3	3	2	2	3	2	2	0	2	0	3	2	2	2	3	3

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00151	SC	29AUG95	-8, -65	0	2	0	1	2	0	2	2	0	2	2	1	0	1	0	1	3	0	3	2	0	1	2	0	1	3	0	2	2
	8	02NOV95	58, 1	2	2	0	1	2	2	2	1	0	2	0	0	1	2	1	1	3	0	2	2	0	1	3	1	1	0	1	2	2
	32	01MAY96	239, 182	3	1	0	1	3	2	1	2	2	3	0	1	1	3	1	2	3	0	3	3	0	1	3	3	2	0	2	3	2
329.005.00152	SC	12OCT95	-14, .	0	2	0	0	1	0	2	1	0	2	1	1	2	2	1	1	0	1	2	2	1	1	1	1	1	3	0	2	1
329.005.00257	SC	05MAR96	-6, -62	3	3	0	2	2	2	3	2	2	2	3	1	2	2	2	0	2	2	2	3	0	2	3	2	2	3	2	2	1
	8	06MAY96	57, 1	3	3	0	3	3	2	2	3	2	2	3	0	3	2	2	2	3	3	2	3	0	3	3	1	3	3	3	2	1
	32	21OCT96	225, 169	3	3	0	3	3	3	3	3	3	3	3	1	3	3	2	3	3	3	2	3	1	3	3	2	3	3	3	3	2
329.005.00258	SC	06FEB96	-35, .	1	1	2	2	1	1	2	1	1	1	1	2	2	2	0	2	3	2	1	2	2	2	1	1	2	1	2	1	1
	8	07MAY96	57, .	2	2	2	2	2	1	1	2	2	2	2	2	2	1	1	2	2	1	1	1	2	2	2	2	1	1	1	1	1
329.005.00299	SC	28MAY96	-11, -71	1	3	2	3	3	2	1	3	2	1	2	2	3	1	3	0	2	1	1	2	1	2	2	2	2	3	2	1	2
	8	07AUG96	61, 1	2	3	2	2	2	3	2	3	2	1	2	2	2	2	2	2	2	1	1	2	1	2	2	2	2	3	2	1	2
	20	05NOV96	151, 91	1	3	1	2	2	1	1	2	2	0	2	2	2	2	1	1	3	2	2	2	1	2	3	2	2	2	2	1	1
329.005.00300	SC	12SEP96	-7, .	3	0	3	2	3	0	3	0	2	3	0	3	2	3	0	2	3	0	3	2	2	0	1	0	3	2	3	3	0
	8	14NOV96	57, .	1	0	1	0	2	1	1	0	0	0	1	1	1	1	1	2	3	0	3	0	1	0	2	1	1	2	1	2	1
329.005.00333	SC	15JAN97	-8, .	1	0	0	1	3	0	3	1	1	0	0	0	1	1	1	1	3	1	0	1	0	1	3	0	2	1	1	1	0
329.005.00336	SC	26FEB97	-6, .	1	2	2	2	2	2	3	3	2	1	2	2	3	1	3	1	2	1	1	3	2	2	2	2	1	3	1	1	2
	8	30APR97	58, .	2	2	2	1	1	2	3	2	1	2	2	2	2	1	3	0	1	1	1	3	2	2	2	2	2	3	1	2	2
329.006.00038	SC	01FEB95	-14, .	0	3	2	0	2	1	3	2	0	1	3	1	0	1	3	0	3	1	1	2	1	0	1	1	2	1	1	2	3

* days relative to start of acute phase, days relative to start of continuation phase
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.006.00039	SC	03FEB95	-5, -66	3	1	0	0	0	0	2	0	0	3	1	0	0	3	1	0	3	0	3	1	0	0	2	0	0	1	0	3	1
	8	05APR95	57, -5	3	0	0	0	1	0	3	0	0	3	0	0	0	2	0	0	3	0	3	0	0	0	0	0	0	1	0	3	1
329.006.00260	SC	12JUL96	-6, -64	1	1	2	2	2	1	2	2	2	1	1	1	2	2	1	2	2	2	1	1	1	2	1	2	2	2	2	1	1
	8	18SEP96	63, 5	2	1	2	2	2	1	2	2	1	2	2	2	2	2	2	1	2	1	1	2	2	2	1	2	2	3	2	1	1
329.006.00261	SC	07NOV96	-19, -77	0	3	0	1	0	0	0	3	0	0	3	0	0	0	0	0	0	0	0	3	0	0	2	0	0	3	0	0	3
	8	23JAN97	59, 1	2	3	0	1	1	2	0	3	1	0	3	0	1	0	3	0	3	1	2	2	0	1	2	0	0	3	2	0	2
329.007.00140	SC	07SEP95	-8, -63	3	3	3	1	2	1	3	3	1	3	3	3	0	2	1	1	3	2	3	1	3	0	3	3	3	3	2	3	3
	8	09NOV95	56, 1	3	3	3	1	2	3	2	3	1	3	3	3	3	1	0	1	3	0	3	1	3	3	2	1	1	1	3	0	2
329.007.00142	SC	12OCT95	-6, .	1	1	0	0	2	1	1	1	0	0	1	0	0	1	1	1	2	1	0	2	0	0	2	0	2	1	3	1	1
	8	21DEC95	65, .	1	1	0	0	2	1	2	1	0	0	1	0	0	2	0	3	2	0	0	2	0	0	2	1	2	0	0	0	0
329.007.00145	SC	04JAN96	-7, -63	3	3	2	0	3	0	1	1	1	0	2	2	1	3	0	0	3	2	0	2	1	2	3	1	1	3	2	1	2
	8	07MAR96	57, 1	3	3	3	3	3	3	3	1	1	0	3	3	3	3	3	0	3	3	1	3	3	3	0	3	3	0	1	1	3
	32	23AUG96	226, 170	3	3	3	3	3	1	3	3	3	2	3	3	3	3	3	3	3	3	3	3	3	3	3	1	3	3	3	2	3
329.007.00265	SC	25JAN96	-7, .	0	3	3	0	2	0	1	3	1	1	2	1	0	1	2	2	3	1	0	1	1	0	1	1	2	2	2	1	3
329.007.00268	SC	21MAR96	-11, -70	3	0	0	0	3	0	2	2	0	2	0	0	0	3	0	0	3	0	0	0	0	0	1	0	3	3	0	2	0
	8	30MAY96	60, 1	3	1	0	0	3	1	3	3	2	3	1	0	0	3	0	2	3	0	2	2	0	0	3	0	2	3	2	2	0
	32	05DEC96	249, 190	2	2	2	0	2	0	2	2	2	3	2	2	1	2	1	1	2	2	3	2	1	1	2	1	2	2	2	2	2
329.007.00294	SC	20FEB97	-8, .	1	3	0	0	3	1	0	1	0	1	3	1	0	2	0	0	2	1	0	3	1	0	0	0	1	1	1	0	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.007.00309	SC	02JUL96	-13, -65	3	3	3	1	0	1	3	0	0	3	3	3	2	1	2	0	3	0	0	3	3	2	1	1	3	1	0	3	3
	7	05SEP96	53, 1	3	3	3	2	3	2	2	0	1	3	3	3	1	3	3	2	3	2	3	3	3	1	3	2	3	1	2	3	3
	32	13MAR97	242, 190	1	3	3	2	3	2	3	2	1	3	3	3	1	1	3	1	3	0	3	3	3	1	3	2	3	2	2	2	3
329.007.00310	SC	19SEP96	-7, -67	2	3	3	3	0	1	1	2	2	0	3	3	0	1	2	0	1	1	1	3	3	3	2	1	1	3	3	0	2
	8	25NOV96	61, 1	2	3	2	2	1	2	2	2	2	1	3	2	3	1	2	1	3	2	2	2	2	2	3	1	2	3	2	1	2
	32	12JUN97	260, 200	3	3	3	3	3	2	3	3	2	2	3	3	3	3	2	1	3	3	2	3	2	2	3	3	2	3	3	2	2
329.007.00318	SC	22NOV96	-10, .	3	3	3	3	3	2	3	3	3	3	3	3	3	3	0	3	3	3	3	3	2	3	3	2	2	0	3	1	3
329.008.00157	SC	16AUG95	-14, -69	3	0	2	0	3	0	1	1	1	1	2	2	0	3	0	1	3	0	2	1	3	0	0	0	2	1	1	3	1
	8	24OCT95	56, 1	2	1	3	1	3	0	2	0	1	3	0	2	0	2	0	1	3	1	2	2	3	0	3	0	2	1	2	2	2
329.008.00160	SC	25OCT95	-7, -73	1	0	0	0	2	0	2	2	0	2	0	0	0	2	1	0	2	0	1	1	0	0	2	0	1	2	0	1	0
	8	05JAN96	66, -1	0	1	0	1	3	1	2	1	2	1	2	1	1	2	1	0	2	1	1	2	1	1	3	1	2	1	1	1	1
	32	23JUL96	266, 200	2	2	1	2	3	1	2	2	2	2	2	1	2	3	3	1	3	3	3	3	1	2	3	2	2	3	3	2	1
329.008.00188	SC	14DEC95	-21, .	1	1	0	0	1	0	1	1	0	1	1	1	0	2	2	1	3	1	2	1	1	0	1	0	2	2	1	1	1
	8	27FEB96	55, .	1	1	0	0	1	1	1	1	0	1	1	1	0	3	2	1	3	1	1	1	0	0	1	0	1	2	1	1	1
329.008.00271	SC	25JAN96	-46,-110	0	0	1	0	1	0	1	1	0	0	2	0	0	1	1	1	3	1	0	1	0	0	0	0	1	3	0	0	2
	8	14MAY96	65, 1	0	2	0	0	0	0	1	2	1	0	1	0	0	0	0	0	3	1	0	1	0	0	1	0	1	3	0	0	0
	32	05NOV96	240, 176	0	2	0	0	2	0	1	1	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	1	1	0	0	0
329.008.00275	SC	30APR96	-8, -63	2	0	0	0	3	0	2	0	0	0	2	0	0	1	0	0	3	1	2	.	0	0	2	0	2	3	0	1	0
	8	02JUL96	56, 1	2	2	1	0	3	1	1	2	1	0	2	1	0	2	2	1	3	1	1	3	0	0	2	2	2	3	2	2	1
	32	16DEC96	223, 168	3	2	0	0	2	1	2	2	1	1	2	0	1	2	0	0	2	3	1	2	0	1	2	0	2	3	2	2	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00130	SC	12APR95	-6, -62	3	2	2	2	2	2	1	2	2	2	3	2	0	3	1	1	2	0	2	2	2	2	2	2	0	3	2	1	2
329.009.00131	SC	26APR95	-6, -62	3	1	3	1	2	3	2	2	1	1	2	3	0	1	0	0	2	0	2	1	2	0	3	2	3	0	2	1	3
	8	27JUN95	57, 1	3	3	1	3	3	2	3	1	3	3	3	2	2	3	1	0	3	3	3	3	1	2	3	3	3	1	3	3	2
329.009.00133	SC	07JUN95	-6, .	3	1	0	0	3	0	3	0	1	0	0	0	0	3	0	2	1	0	3	3	0	0	0	0	2	3	0	2	0
329.009.00138	SC	02OCT95	-8, .	0	3	2	0	2	2	0	2	1	0	3	1	1	1	3	2	2	1	0	1	0	1	0	1	1	1	0	0	2
329.009.00170	SC	26OCT95	-12, -69	2	0	2	2	2	2	2	0	2	3	0	2	3	2	0	2	0	3	0	0	2	2	2	1	2	3	2	1	0
	8	03JAN96	58, 1	2	1	2	2	3	0	3	0	2	3	0	0	2	2	0	3	1	3	1	0	1	2	1	0	2	3	2	0	0
	32	24JUN96	231, 174	3	0	1	1	2	0	3	2	1	3	1	1	2	2	0	2	1	1	1	1	0	1	2	0	3	1	1	2	0
329.009.00173	SC	08NOV95	-12, -75	1	3	3	0	3	0	1	3	0	0	3	3	1	1	0	0	3	0	0	2	1	2	3	0	2	2	3	0	3
	8	22JAN96	64, 1	3	2	2	2	1	3	3	1	3	2	1	1	1	1	.	1	3	0	0	2	1	0	1	1	3	2	2	1	1
329.009.00193	SC	21NOV95	-7, .	2	3	2	0	3	1	0	3	1	1	0	2	0	3	3	1	3	3	3	3	0	0	3	0	3	3	0	3	3
	8	24JAN96	58, .	3	3	2	0	2	1	0	3	0	2	3	2	0	1	3	3	3	1	2	3	1	0	2	1	1	3	0	2	3
329.009.00196	SC	11DEC95	-7, .	3	2	1	3	3	0	1	1	1	2	2	1	0	1	3	0	2	1	3	3	1	0	2	0	3	0	2	2	0
	8	12FEB96	57, .	3	3	1	2	3	2	3	1	3	3	2	1	0	3	3	1	3	3	3	3	1	0	3	1	3	1	2	3	3
329.009.00201	SC	31JAN96	-6, .	3	3	3	2	3	3	1	3	2	3	3	3	1	2	3	2	3	1	3	2	3	1	3	2	3	2	2	2	3
	8	02APR96	57, .	3	3	3	2	3	3	2	3	1	3	3	3	1	3	3	0	3	0	2	3	3	1	3	3	2	3	3	2	3
329.009.00204	SC	13MAR96	-6, -62	2	1	2	1	2	2	1	2	2	1	2	2	2	3	.	1	3	2	2	2	2	2	2	.	2	1	2	1	2
	8	14MAY96	57, 1	2	2	2	2	2	.	2	1	2	2	2	3	2	3	.	2	3	2	2	2	2	2	2	.	2	1	2	2	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00235	SC	10DEC96	-8, -62	3	3	2	3	2	2	3	3	3	2	3	2	1	2	3	0	3	3	3	3	1	2	3	2	2	3	3	1	3
	8	10FEB97	55, 1	3	3	1	2	0	2	1	3	3	2	3	1	1	2	3	1	3	3	2	3	1	1	2	2	3	3	3	1	2
329.009.00240	SC	03JAN97	-11, .	2	1	1	2	2	1	2	1	1	1	1	1	2	2	2	1	2	1	2	2	1	2	3	0	2	2	2	2	0
329.009.00303	SC	25MAR96	-8, -64	2	0	2	3	3	2	1	1	1	0	1	2	2	2	1	1	3	1	2	1	2	3	2	1	1	1	1	2	1
	8	28MAY96	57, 1	2	2	2	3	3	3	2	2	2	1	2	2	3	3	3	1	2	2	2	2	2	3	2	2	2	2	2	2	2
	32	10DEC96	253, 197	3	3	2	3	3	2	2	3	3	0	3	2	2	3	3	1	2	2	2	3	2	3	1	2	2	3	2	2	2
329.009.00304	SC	03APR96	-6, -62	1	3	3	2	2	2	2	3	1	0	3	2	1	2	2	1	2	0	1	2	2	1	2	2	1	2	0	2	2
	8	04JUN96	57, 1	2	3	2	2	2	2	2	2	2	2	3	3	2	2	2	1	2	0	1	2	2	2	2	2	1	3	2	2	2
329.009.00324	SC	21OCT96	-7, .	2	2	0	1	0	0	1	2	1	1	2	0	1	3	3	3	3	2	1	3	1	0	3	0	3	3	3	1	3
	8	27DEC96	61, .	3	3	2	3	1	1	3	2	2	2	3	1	2	2	2	1	3	3	2	3	2	3	3	2	2	3	2	1	3
329.009.00328	SC	30SEP96	-7, .	1	3	3	2	3	1	1	3	2	0	3	2	1	2	2	0	3	1	1	2	2	1	2	1	2	2	2	0	2
329.009.00329	SC	01OCT96	-8, .	2	2	2	2	3	1	2	2	2	1	3	1	3	1	2	1	3	2	2	2	2	2	2	1	2	3	2	0	1
	8	03DEC96	56, .	3	0	2	3	3	2	2	3	1	1	3	2	3	1	2	0	3	2	2	2	2	2	3	2	2	3	3	1	2
329.010.00182	SC	05DEC95	-14, .	2	1	1	2	1	1	0	3	0	1	1	1	2	1	1	2	3	1	1	1	1	2	1	1	1	3	0	1	1
329.010.00278	SC	02FEB96	-7, -63	0	2	0	0	2	0	1	3	0	2	2	0	0	2	0	0	3	1	2	2	0	0	2	0	1	2	0	1	2
	8	05APR96	57, 1	0	2	0	1	3	2	2	2	1	2	1	0	0	3	1	2	3	0	1	3	0	0	2	1	2	3	1	2	2
	32	19SEP96	224, 168	1	3	2	0	3	3	3	3	1	1	3	1	0	3	3	1	3	1	1	3	1	0	3	2	3	3	1	2	3
329.010.00280	SC	10MAY96	-7, -62	1	3	0	1	3	3	1	3	1	1	2	1	0	1	2	1	3	0	2	1	1	0	2	3	1	3	1	2	3

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.010.00280	8	11JUL96	56, 1	2	3	2	2	3	3	0	3	2	2	3	3	1	3	2	0	3	0	2	3	2	2	2	3	1	3	1	1	3
	12	21AUG96	97, 42	2	2	2	2	3	2	2	3	2	2	3	2	1	2	2	1	2	1	2	2	2	2	2	2	1	3	2	2	2
329.011.00283	SC	30JAN96	-9, -66	1	3	2	3	1	3	3	2	1	1	3	2	0	2	3	2	3	0	0	3	1	3	3	3	2	3	1	1	2
	8	04APR96	57, -1	1	3	3	3	3	1	3	3	2	1	3	3	1	3	0	0	3	0	1	3	3	3	3	3	2	3	2	1	3
329.011.00288	SC	01JUL96	-24, .	3	1	0	3	3	1	0	2	2	3	2	1	3	3	1	3	3	1	3	1	0	2	3	2	1	3	3	3	1
329.012.00025	SC	17OCT95	-7, .	1	3	1	1	2	1	2	2	1	1	2	1	1	2	1	2	3	1	1	1	1	1	1	1	2	3	1	0	2
	8	19DEC95	57, .	1	2	0	0	1	1	1	2	1	1	2	1	1	1	1	2	2	0	1	0	1	1	2	1	1	2	0	1	2
329.012.00220	SC	04JUN96	-13, -73	3	1	1	2	2	1	3	1	1	1	1	3	2	3	0	1	3	1	2	1	1	1	2	2	2	4	1	2	1
	8	16AUG96	61, 1	3	2	2	3	3	3	3	3	3	2	2	2	3	3	0	2	3	3	2	2	2	3	3	3	3	3	3	2	2
329.012.00222	SC	18JUN96	-10, -73	1	2	0	1	2	0	2	3	1	1	2	1	0	2	1	0	3	1	1	2	0	1	1	1	1	3	1	0	1
	8	30AUG96	64, 1	1	2	0	0	2	2	1	2	0	1	1	0	0	2	2	0	2	1	1	2	0	0	2	1	1	3	2	1	1
329.012.00226	SC	26NOV96	-7, .	2	2	3	2	2	1	2	2	1	0	2	1	2	1	1	2	3	1	1	2	2	2	1	1	2	3	1	3	2
329.012.00228	SC	04MAR97	-15, .	0	3	1	3	0	3	1	3	1	0	3	0	3	3	3	1	3	0	0	3	0	2	2	3	3	3	1	0	2
329.012.00231	SC	26FEB97	-9, -70	0	1	0	0	2	1	2	3	0	0	3	0	0	1	2	0	3	0	0	3	0	1	0	0	3	3	1	0	3
	8	07MAY97	62, 1	1	2	2	1	2	2	3	2	1	1	3	2	0	2	3	1	3	2	1	2	2	0	2	1	2	3	2	1	2
	24	19AUG97	166, 105	0	2	0	3	2	2	2	3	0	0	2	0	0	2	2	1	3	1	.	2	0	0	2	2	2	3	0	1	1

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.001.00061	SC	19JUL94	-10, .	2	2	1	3	3	3	1	3	3	0	3	1	3	0	2	0	3	3	0	3	1	3	3	1	2	3	3	0	2
329.001.00066	SC	14NOV94	-8, .	0	1	0	1	2	0	3	3	0	0	1	0	1	1	0	0	2	1	2	1	0	1	2	1	2	2	1	1	1
329.001.00067	SC	15NOV94	-7, .	1	0	1	1	1	1	1	2	1	0	1	1	2	1	.	1	2	2	0	1	1	2	0	1	2	3	1	1	0
329.001.00070	SC	14FEB95	-8, .	1	2	1	1	2	1	2	1	1	1	2	1	0	2	2	1	3	1	0	1	1	0	2	1	1	0	1	1	2
329.001.00122	SC	13JUN95	-7, -64	1	3	1	1	3	1	2	1	1	1	2	1	0	3	1	0	1	1	1	2	1	1	3	1	2	1	1	1	2
	8	16AUG95	58, 1	0	1	0	2	3	2	2	2	2	1	1	1	2	3	2	1	0	2	0	2	0	2	3	1	2	1	2	0	3
329.002.00050	SC	10MAR95	-13, .	3	1	2	1	3	3	0	3	2	2	2	2	1	3	3	0	3	1	2	3	1	0	0	2	3	3	3	3	2
	5	28APR95	37, .	3	1	2	2	3	2	2	3	2	2	2	2	1	2	1	2	2	1	2	2	1	1	2	1	2	3	2	2	2
329.002.00056	SC	24JUN94	-25, .	0	3	0	2	3	2	0	3	0	3	3	0	0	3	2	0	3	3	0	3	0	3	3	1	0	3	0	3	3
329.002.00057	SC	11AUG94	-28, -85	2	1	2	1	3	2	2	3	1	1	3	2	1	1	1	1	3	1	2	0	2	1	3	3	2	0	2	1	2
	8	03NOV94	57, -1	3	3	3	3	0	3	3	.	3	3	3	3	2	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3
	16	11JAN95	126, 69	3	1	3	1	3	3	3	3	1	1	3	3	1	1	1	1	3	1	2	1	2	1	3	3	3	1	2	1	3
329.002.00098	SC	20DEC94	-14, .	1	1	0	0	0	2	3	3	1	0	0	0	0	1	1	0	3	0	0	1	0	0	1	1	1	3	0	1	1
	8	02MAR95	59, .	1	1	0	0	1	1	3	2	1	0	0	0	0	2	3	2	3	0	2	2	0	0	2	2	1	3	1	1	0
329.002.00100	SC	16FEB95	-19, -77	0	0	1	0	3	3	2	3	0	2	1	2	1	3	3	3	3	0	2	2	1	2	3	3	1	3	0	1	1
	8	04MAY95	59, 1	2	1	2	2	3	3	2	3	1	2	1	1	2	3	3	3	2	2	2	2	1	2	3	3	2	3	2	1	2
	16	06JUL95	122, 64	2	1	2	2	3	2	2	2	2	2	1	2	2	2	3	2	2	2	2	1	1	2	3	3	2	3	2	2	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.002.00103	SC	11APR95	-9, -65	1	3	1	2	2	2	1	3	1	0	3	1	1	2	2	2	2	1	0	2	1	1	1	2	2	3	1	0	3
	8	15JUN95	57, 1	1	3	1	3	2	2	2	3	1	1	3	1	1	2	2	1	2	2	2	1	3	0	2	2	2	2	2	1	2
	16	10AUG95	113, 57	2	2	1	2	2	2	2	3	2	1	2	1	1	2	2	0	3	2	2	2	1	3	3	2	2	2	2	1	2
329.002.00104	SC	28APR95	-6, -62	1	0	2	2	3	1	1	2	1	0	1	1	2	2	1	2	3	1	1	2	2	1	2	1	2	2	1	0	2
	8	29JUN95	57, 1	1	1	2	2	2	1	1	2	1	2	1	2	2	2	1	1	3	2	1	2	2	1	3	1	2	1	1	1	2
	32	02JAN96	244, 188	2	1	2	2	3	1	1	2	2	2	2	2	2	2	2	1	2	2	2	2	2	2	2	1	2	2	2	2	2
329.002.00243	SC	27FEB96	-16, .	2	2	3	1	1	1	2	3	0	0	2	3	0	0	1	1	3	0	1	2	2	0	1	1	2	2	1	1	2
329.002.00244	SC	14MAR96	-7, -64	2	2	0	0	1	1	2	2	0	2	2	1	0	1	3	0	3	0	2	1	0	0	2	1	0	2	0	2	1
	8	16MAY96	57, -1	3	2	1	1	2	2	2	3	1	2	2	1	1	2	3	1	2	1	2	1	1	1	2	2	2	1	2	2	1
329.002.00321	SC	15MAY96	-8, .	2	2	3	2	3	2	1	0	1	1	2	2	2	2	1	1	3	1	2	2	2	2	3	2	2	0	1	3	2
329.002.00322	SC	06JAN97	-3, .	3	2	3	0	3	0	1	2	1	3	2	2	1	3	2	1	1	2	3	1	2	0	1	1	2	2	1	2	2
329.003.00073	SC	11JAN95	-8, .	0	2	1	0	2	1	1	2	0	1	2	1	1	1	2	1	2	1	2	2	1	0	1	1	1	2	1	1	2
329.003.00076	SC	24JAN95	-7, -62	1	3	0	1	2	0	1	3	0	0	3	0	0	2	3	2	3	0	0	1	0	0	3	0	3	3	0	0	2
	32	11OCT95	254, 199	3	3	2	3	3	3	2	3	3	3	3	2	2	3	2	3	3	3	2	3	1	2	3	3	3	3	0	3	3
329.003.00082	SC	11DEC95	1, .	2	0	2	0	2	1	1	0	0	1	0	0	0	1	3	2	1	0	0	0	1	0	2	0	0	0	0	0	0
329.003.00088	SC	06FEB95	-22, .	2	1	3	2	1	2	2	1	2	2	1	3	2	1	2	0	3	1	2	2	2	2	2	2	1	2	2	1	1
329.003.00090	SC	08MAR95	-6, .	0	1	2	0	2	0	2	2	1	0	1	1	0	1	.	0	2	1	0	2	2	1	2	1	1	3	1	0	0

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.003.00090	8	16MAY95	64, .	2	1	1	0	2	1	2	2	1	1	1	1	1	1	.	1	2	1	1	2	1	1	2	1	2	1	1	1	1
329.003.00092	SC	13APR95	-20, -78	2	2	1	1	1	2	3	0	1	2	1	1	1	1	1	3	3	3	3	3	3	3	3	1	3	0	3	2	0
	8	30JUN95	59, 1	3	3	3	3	2	1	3	3	3	2	3	3	3	2	1	3	3	3	2	3	3	3	2	2	3	3	3	3	2
	32	02JAN96	245, 187	0	3	3	3	2	2	3	3	3	0	3	3	3	1	1	3	3	3	0	3	3	3	2	2	3	3	3	1	3
329.003.00093	SC	08JUN95	-13, -76	1	3	1	2	1	1	3	3	1	0	3	0	1	2	3	0	3	0	1	3	0	1	3	2	3	3	2	1	3
	8	22AUG95	63, -1	1	3	1	3	3	3	3	3	3	1	3	0	1	3	3	1	3	3	2	3	0	1	3	3	3	3	3	1	3
	16	03OCT95	105, 42	2	3	0	1	3	1	3	3	2	1	3	0	0	3	3	0	2	2	2	3	0	1	3	3	3	3	2	1	3
329.003.00247	SC	05JAN96	-27, -81	1	2	0	0	1	1	1	1	2	2	3	1	0	0	2	0	3	1	2	2	2	2	2	1	1	2	2	2	1
	8	26MAR96	55, 1	1	2	1	1	1	1	1	1	2	2	2	1	1	1	2	2	1	2	2	1	1	2	2	2	1	1	1	2	1
329.003.00249	SC	01MAR96	-6, .	3	2	1	1	0	1	1	0	1	0	2	1	1	2	2	2	1	0	2	2	1	1	0	2	2	1	1	3	2
	8	30APR96	55, .	1	2	1	1	0	1	2	0	0	1	2	1	0	2	1	2	1	0	2	1	1	0	1	1	1	1	0	2	2
329.003.00289	SC	12FEB96	-16, -72	1	1	3	0	3	1	2	0	0	2	1	3	0	3	1	1	3	0	2	1	2	0	2	1	0	0	0	.	0
	8	24APR96	57, 1	1	1	3	1	3	2	2	1	2	2	1	3	2	3	1	2	3	2	2	2	2	2	2	2	2	1	2	2	1
	32	11OCT96	227, 171	3	2	3	1	3	2	2	3	3	3	2	3	2	3	3	3	3	2	3	3	3	2	3	3	3	2	2	3	2
329.003.00290	SC	06MAR96	-5, .	1	1	0	1	0	0	1	0	0	1	0	0	1	0	1	1	2	0	2	0	0	1	2	1	1	0	0	0	0
329.003.00314	SC	15OCT96	-7, .	0	1	0	1	3	1	0	3	0	0	3	0	0	3	2	0	1	0	0	2	0	0	3	2	0	1	0	3	2
329.003.00317	SC	12DEC96	-7, .	0	0	0	0	0	0	3	0	0	0	0	0	0	0	2	0	2	0	0	2	0	0	2	0	1	0	0	0	0
	8	11FEB97	55, .	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	3	0	2	0	0	0	3	1	1	2	0	1	0

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
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Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.004.00013	SC	05JUL94	-14, -73	2	1	1	1	3	0	2	2	0	1	0	0	1	2	0	0	3	1	2	2	1	1	2	0	2	3	2	2	1
	8	16SEP94	60, 1	2	1	0	2	3	2	2	1	2	2	1	1	2	3	1	2	2	2	2	2	1	2	2	2	2	1	2	2	1
329.004.00014	SC	22NOV94	-7, .	2	2	3	2	1	1	3	3	1	1	3	3	2	2	2	2	3	0	0	1	2	2	2	1	1	3	1	1	2
329.004.00211	SC	24JAN96	-9, .	2	3	3	2	3	2	3	3	2	1	3	3	3	3	3	1	3	1	3	3	2	3	3	2	2	3	2	1	3
329.004.00215	SC	12MAR97	-8, .	1	2	3	1	2	1	2	3	1	2	3	2	2	2	2	1	2	2	1	2	2	1	2	2	2	3	2	2	2
329.005.00003	SC	12SEP94	-8, .	.	0	3	0	3	.	3	2	1	0	3	1	0	2	1	0	3	1	.	2	2	0	2	1	2	0	2	0	3
329.005.00006	SC	27OCT94	-8, -68	3	2	1	3	3	0	3	2	3	0	3	1	3	3	1	0	3	3	3	2	1	3	2	1	3	1	3	3	2
	8	03JAN95	61, 1	3	3	2	3	3	1	2	3	3	1	3	2	1	3	2	0	3	2	3	3	2	3	3	1	3	2	3	2	2
	24	28APR95	176, 116	3	1	1	3	3	1	2	1	1	1	2	1	2	3	3	0	3	2	3	2	1	3	3	1	2	0	2	3	2
329.005.00007	SC	02NOV94	-7, -70	1	3	0	0	1	0	1	2	0	0	2	1	0	0	1	2	2	0	0	1	0	0	1	1	1	2	0	0	2
	8	11JAN95	64, 1	0	3	1	1	1	2	3	1	2	0	2	1	2	1	3	2	3	2	1	0	0	1	2	0	2	3	1	0	3
	32	09AUG95	274, 211	0	3	1	2	2	1	3	1	2	1	1	1	1	2	3	1	3	2	1	2	1	2	3	1	2	3	2	1	2
329.005.00009	SC	07DEC94	-5, .	0	1	0	0	2	0	2	2	0	2	0	0	0	0	0	1	3	0	0	1	0	0	0	0	1	1	0	1	1
	8	07FEB95	58, .	1	2	0	1	3	1	2	2	1	2	1	0	0	2	2	2	3	0	2	2	0	1	1	0	2	3	1	1	2
329.005.00110	SC	04JAN95	-7, .	1	3	0	2	3	2	2	3	1	1	1	0	2	3	2	0	3	1	3	3	0	2	3	2	2	3	1	2	1
329.005.00113	SC	20JAN95	-10, .	3	2	3	2	3	1	2	3	1	1	1	2	1	2	1	2	3	1	2	3	2	2	2	1	2	2	1	1	2
329.005.00117	SC	06MAR95	-12, .	1	3	1	1	2	1	3	2	1	1	2	1	1	2	0	1	2	1	1	1	1	1	2	1	0	1	1	1	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00117	8	15MAY95	59, .	3	3	3	1	3	2	3	3	2	2	3	2	0	3	1	1	1	2	2	3	2	0	2	2	2	3	3	1	3
329.005.00118	SC	09MAY95	-8, .	3	0	1	0	1	0	2	0	1	0	1	2	1	2	1	2	3	0	2	1	2	0	1	1	0	2	0	.	2
329.005.00153	SC	11JAN96	-14, -70	1	2	0	1	2	1	2	2	2	0	2	0	0	1	1	2	3	2	0	2	0	1	1	1	3	3	1	0	2
	8	21MAR96	57, 1	2	3	1	1	1	1	2	3	2	1	3	1	1	2	2	2	3	2	2	2	0	2	2	2	2	3	2	1	2
	32	04SEP96	224, 168	1	2	1	2	2	2	1	2	2	1	2	1	0	1	2	2	3	2	2	1	0	1	2	2	2	2	2	1	3
329.005.00255	SC	26FEB96	-7, .	0	3	2	2	3	1	2	3	1	1	2	2	0	1	2	0	2	2	1	2	2	1	2	1	2	3	2	2	1
	8	29APR96	57, .	2	2	2	0	3	0	2	3	1	1	2	2	0	2	1	1	3	1	2	3	1	0	2	0	2	3	0	2	2
329.005.00256	SC	20FEB96	-14, -70	2	1	0	1	2	0	2	3	1	0	1	0	2	2	3	2	3	2	2	2	1	0	2	1	3	3	2	1	2
	8	30APR96	57, 1	3	2	1	1	0	1	3	3	2	0	2	1	1	1	3	1	3	1	1	2	1	1	2	1	2	3	3	1	2
	16	02JUL96	120, 64	2	1	1	1	3	1	2	3	1	1	2	0	2	2	3	1	3	2	2	2	1	1	2	1	2	3	2	1	2
329.005.00295	SC	21MAR96	-7, .	2	3	3	1	1	1	2	3	1	2	3	2	1	1	3	1	3	1	1	3	2	1	2	2	2	3	1	1	3
	8	22MAY96	56, .	1	3	3	1	1	2	1	3	1	1	3	2	1	1	2	1	2	1	1	2	2	1	2	2	1	3	2	2	3
329.005.00297	SC	28MAR96	-22, .	0	3	2	2	3	3	2	3	1	2	3	1	2	1	3	1	1	0	1	3	1	1	2	2	2	3	1	1	2
329.005.00332	SC	05DEC96	-7, .	0	2	2	0	1	0	2	1	0	1	2	2	0	2	1	0	3	0	1	2	1	1	1	0	1	3	0	1	2
	8	06FEB97	57, .	1	2	2	1	1	1	1	1	1	1	2	2	1	2	1	1	2	2	1	1	2	1	1	1	1	2	1	1	2
329.005.00335	SC	20FEB97	-8, .	3	3	1	3	3	1	3	3	2	2	2	1	3	2	2	1	3	1	2	3	0	3	3	1	2	3	1	2	2
	8	24APR97	56, .	3	1	0	3	3	2	2	3	2	2	2	1	2	3	0	1	3	1	2	2	1	2	3	1	2	3	3	2	2
329.006.00040	SC	10FEB95	-6, .	2	0	2	2	0	0	2	1	1	3	1	1	2	1	1	1	2	1	3	2	1	2	1	1	1	1	0	2	1

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.006.00041	SC	22MAR95	-14, -78	0	0	2	0	2	1	3	0	0	0	1	1	0	2	3	1	2	2	2	1	2	0	2	1	0	3	0	1	1
	8	31MAY95	57, -8	2	3	2	3	3	0	3	0	2	2	0	1	0	3	3	1	2	2	2	0	2	0	3	1	0	3	0	1	0
	32	21NOV95	231, 167	2	1	2	3	3	1	3	2	2	1	2	2	0	3	2	1	3	2	2	2	2	0	3	2	3	1	2	1	2
329.007.00139	SC	04MAY95	-4, .	0	2	2	0	2	2	2	1	2	1	2	2	0	2	2	1	1	0	2	2	1	0	3	1	2	3	1	2	2
329.007.00143	SC	26OCT95	-14, .	3	2	1	2	2	1	2	1	2	2	2	1	2	2	2	2	2	2	1	2	1	2	0	1	2	1	2	1	2
329.007.00146	SC	18JAN96	-7, -60	1	1	1	1	2	0	2	0	1	2	1	1	0	2	0	1	2	2	2	2	1	0	2	1	2	0	1	2	0
	8	18MAR96	54, 1	1	2	0	1	2	0	3	2	2	2	2	0	0	2	0	1	3	2	1	3	1	0	2	1	2	2	2	2	2
	32	09SEP96	229, 176	2	3	0	1	2	1	3	3	2	2	3	1	1	3	1	2	3	2	2	3	0	1	3	1	2	3	2	2	1
329.007.00269	SC	04APR96	-7, .	3	3	3	2	1	2	2	3	2	2	3	2	1	1	2	1	2	2	1	2	2	1	2	2	2	2	1	1	3
	3	02MAY96	22, .	3	3	3	2	2	2	3	2	2	1	3	2	2	3	2	3	3	2	1	3	2	2	2	2	2	2	2	2	2
329.007.00270	SC	02MAY96	-7, .	3	0	3	2	1	1	2	2	1	3	2	3	2	2	2	1	3	1	2	3	2	1	2	1	2	2	1	2	3
	7	27JUN96	50, .	2	0	2	3	3	1	2	2	2	2	1	3	2	2	2	1	2	2	1	2	2	2	3	0	2	1	2	1	2
329.007.00307	SC	09MAY96	-7, .	2	2	1	0	3	1	2	3	0	1	1	0	1	3	3	0	3	0	1	3	0	1	3	1	0	3	1	0	1
	8	25JUL96	71, .	1	1	1	0	2	1	2	2	0	0	2	0	0	2	1	1	3	1	1	2	0	0	3	0	2	3	0	1	0
329.007.00308	SC	27JUN96	-5, .	3	3	1	2	2	2	1	2	2	1	2	1	1	2	2	3	2	2	0	2	1	1	2	2	2	3	2	1	2
329.008.00159	SC	06SEP95	-7, -69	0	3	1	0	3	0	3	3	1	0	2	0	1	2	3	0	3	2	3	3	1	1	3	1	3	3	3	1	2
	8	14NOV95	63, 1	0	2	3	0	3	1	0	3	2	1	3	1	1	1	3	2	3	2	2	2	3	0	0	1	1	3	2	2	3
329.008.00161	SC	31OCT95	-16, -71	1	1	2	0	1	0	2	1	1	0	0	1	0	0	0	0	3	0	0	2	1	0	3	0	2	3	1	1	1

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.008.00161	8	10JAN96	56, 1	2	1	2	1	2	1	2	2	1	0	1	2	1	1	0	1	3	1	0	2	1	1	3	1	2	2	2	1	1
329.008.00187	SC	15NOV95	-14, .	2	0	0	1	1	1	2	1	0	1	0	0	1	0	3	1	3	0	3	2	0	1	1	2	1	2	0	3	1
	8	26JAN96	59, .	2	0	0	1	2	2	2	1	1	0	0	0	2	1	3	3	3	1	2	1	0	1	2	2	0	2	0	3	1
329.008.00192	SC	14FEB96	-20, .	1	1	3	2	0	2	3	2	2	2	1	3	2	2	1	1	3	2	2	2	2	2	2	1	2	2	2	3	1
329.008.00272	SC	19MAR96	-15, -71	1	0	0	3	0	3	2	0	1	0	0	2	3	1	1	0	3	0	0	0	0	1	2	2	2	3	2	1	1
	8	29MAY96	57, 1	2	0	0	3	2	3	2	0	3	0	0	2	2	1	3	0	2	1	0	1	1	2	3	3	2	2	3	0	2
329.008.00273	SC	19APR96	-28, -91	1	2	1	1	1	1	1	3	1	0	1	1	1	2	0	1	3	2	1	1	1	1	2	1	2	3	1	0	1
	8	19JUL96	64, 1	2	1	2	2	2	1	3	3	3	2	2	1	1	3	3	1	3	3	2	3	1	1	2	1	3	3	3	2	2
329.009.00127	SC	03APR95	-7, .	2	0	2	3	2	0	1	0	2	1	2	2	2	1	1	0	1	1	3	3	1	2	0	0	3	3	2	1	3
329.009.00132	SC	17MAY95	-6, -63	3	2	2	0	2	1	2	3	1	2	2	3	0	3	1	2	3	0	3	1	2	0	1	0	1	2	2	3	1
	8	19JUL95	58, 1	3	2	2	2	2	1	3	2	2	1	3	3	3	3	1	2	3	2	3	2	3	3	2	2	2	2	3	3	2
329.009.00134	SC	28JUN95	-8, .	1	2	0	1	0	2	1	0	0	2	2	1	1	3	1	0	1	0	1	2	1	2	1	2	0	1	0	2	2
	8	29AUG95	55, .	2	2	1	2	1	1	2	2	1	2	1	1	1	2	2	0	1	1	1	1	1	1	1	1	2	0	1	2	2
329.009.00137	SC	03OCT95	-7, .	1	1	1	2	2	1	1	2	1	0	1	1	2	1	1	2	2	0	0	1	1	2	1	1	1	2	1	0	1
	8	05DEC95	57, .	1	2	1	2	0	1	1	2	1	0	2	1	2	0	2	1	1	2	0	1	0	2	1	1	2	2	1	0	1
329.009.00171	SC	31OCT95	-7, .	2	1	0	0	3	3	1	0	0	2	0	0	0	1	3	2	0	1	2	2	0	0	1	1	0	3	0	1	0
329.009.00172	SC	06NOV95	-7, -64	0	0	2	2	2	2	2	2	0	1	1	2	2	2	1	2	3	1	1	2	1	2	3	1	1	3	1	1	1

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00172	8	09JAN96	58, 1	1	2	3	2	1	.	3	3	1	1	1	2	3	2	3	1	3	2	1	2	2	3	3	1	2	1	2	1	1
	32	08JUL96	239, 182	2	2	2	2	2	2	3	3	1	1	2	2	2	2	2	1	2	3	1	2	1	2	3	2	2	3	1	1	2
329.009.00194	SC	28NOV95	-7, -63	3	1	2	1	2	0	1	1	3	0	2	2	1	2	0	1	3	1	1	1	1	1	2	1	2	0	1	0	0
	8	30JAN96	57, 1	2	2	3	1	2	1	0	1	2	3	3	2	1	2	3	0	3	1	2	0	2	0	2	1	1	3	1	3	2
	24	04JUN96	183, 127	3	1	2	2	3	1	2	0	1	2	2	2	1	3	0	1	3	3	2	2	1	1	2	3	2	2	2	3	1
329.009.00195	SC	06DEC95	-9, .	1	3	0	2	0	1	1	2	0	1	3	3	1	1	3	0	3	0	0	1	3	1	2	1	1	3	0	1	3
329.009.00199	SC	10JAN96	-6, .	0	1	0	0	1	0	2	2	0	0	1	0	0	0	3	0	3	1	0	2	0	0	1	0	1	2	1	0	0
	8	13MAR96	58, .	0	2	0	0	1	0	1	1	0	0	2	0	0	0	2	2	3	0	1	1	0	0	2	0	1	2	1	1	0
329.009.00203	SC	28FEB96	-5, .	1	2	2	2	0	1	3	2	1	1	2	2	1	2	3	0	3	2	0	3	2	1	3	1	2	1	2	0	1
329.009.00236	SC	17DEC96	-13, .	1	0	1	0	2	2	3	3	0	0	2	0	0	2	3	1	3	1	0	0	1	0	0	1	3	3	1	0	3
	4	27JAN97	29, .	1	1	0	2	3	1	1	2	1	0	2	1	2	2	2	1	3	1	0	1	1	2	3	2	1	3	2	0	3
329.009.00239	SC	11NOV96	-8, -65	1	1	1	0	2	1	2	1	0	0	2	1	0	1	3	1	2	1	0	2	1	0	1	1	2	1	1	0	0
	8	15JAN97	58, 1	1	1	1	0	2	2	2	2	1	1	1	1	0	1	3	1	2	1	1	2	1	0	1	1	2	2	0	1	1
329.009.00262	SC	07FEB97	-10, .	2	2	0	0	3	1	0	0	0	1	0	0	0	1	.	1	3	0	2	1	0	0	2	0	1	0	0	1	0
	8	14APR97	57, .	2	1	0	1	2	0	2	0	0	2	1	0	0	2	.	1	2	1	2	2	0	0	2	0	2	0	0	2	1
329.009.00264	SC	25OCT96	-7, .	1	3	2	2	3	2	3	3	2	0	3	2	0	1	1	2	3	2	0	3	1	1	0	2	3	3	3	0	2
	7	23DEC96	53, .	.	3	.	.	3	.	2	3	3	2	3	2	.	2	.	3	3	3	.	.	.	2	3	1	.	3	3	1	.
329.009.00301	SC	06MAR96	-13, -69	3	1	2	2	0	2	2	1	1	2	3	2	2	2	3	0	3	2	3	2	2	1	0	2	2	2	3	2	3

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00301	8	14MAY96	57, 1	3	2	2	3	2	3	3	3	2	3	3	2	2	3	3	3	1	2	2	2	2	3	2	3	3	3	3	3	3
329.009.00305	SC	01MAY96	-6, -63	3	2	2	2	3	1	1	2	3	1	2	2	1	3	2	2	3	2	1	2	2	1	2	2	2	3	2	2	2
	8	03JUL96	58, 1	3	2	3	3	3	3	1	2	2	1	1	3	2	3	3	1	3	3	1	2	3	2	2	2	2	2	2	2	2
	32	10JAN97	249, 192	3	3	3	3	3	2	2	2	3	1	2	3	1	3	3	2	3	3	2	3	3	2	3	3	2	3	3	3	2
329.009.00325	SC	21AUG96	-6, -61	0	2	2	1	2	2	2	3	1	1	2	1	1	1	3	1	3	1	2	2	1	1	1	2	2	2	1	1	2
	8	21OCT96	56, 1	1	1	1	1	3	1	3	1	1	2	0	1	0	3	1	1	3	1	2	3	1	1	2	1	2	2	1	2	1
	16	16DEC96	112, 57	1	1	1	1	3	1	3	2	1	2	0	1	0	2	1	1	3	1	1	2	1	1	1	1	2	2	1	1	1
329.009.00326	SC	26AUG96	-10, -63	1	1	1	2	2	0	2	0	2	3	0	1	2	3	.	0	3	1	0	1	1	0	1	0	2	0	2	2	0
	8	28OCT96	54, 1	2	1	0	2	2	.	2	1	2	2	1	1	1	2	.	1	3	1	1	1	1	1	2	.	2	2	2	3	0
	16	16DEC96	103, 50	1	1	1	2	2	.	2	1	2	2	1	1	1	2	2	1	2	1	1	1	1	1	2	0	2	1	1	2	2
329.010.00279	SC	08MAR96	-14, -70	2	1	1	2	3	1	1	3	3	3	3	2	3	3	1	0	3	2	2	2	1	3	2	1	3	1	0	3	2
	8	17MAY96	57, 1	2	0	0	2	2	1	3	0	0	3	2	2	0	3	1	0	2	1	3	0	1	0	.	0	3	3	1	3	1
	32	06NOV96	230, 174	3	1	1	2	3	1	2	0	2	2	0	1	2	3	.	3	2	2	3	0	1	2	2	1	3	2	2	3	0
329.010.00281	SC	19JUL96	-7, -68	3	3	3	3	3	1	2	3	2	1	3	3	3	3	3	1	3	2	1	3	2	2	3	2	1	3	2	2	0
	8	25SEP96	62, 1	3	3	3	3	2	1	1	3	2	2	3	3	3	3	1	1	2	2	1	3	3	2	1	2	1	1	2	0	3
	24	03JAN97	162, 101	2	3	3	3	2	2	1	3	2	0	3	2	3	2	2	2	2	2	1	2	2	2	1	1	2	2	2	2	2
329.011.00163	SC	18NOV95	-7, .	1	1	1	1	3	3	2	1	0	2	1	2	0	1	3	0	3	1	0	3	2	0	0	3	3	0	0	0	0
329.011.00208	SC	22AUG96	-15, -74	3	1	0	0	2	1	2	0	1	2	0	1	2	3	1	0	2	1	3	1	0	1	3	1	2	0	1	3	0
	8	03NOV96	59, -1	2	1	0	2	2	2	3	2	2	3	1	1	2	2	1	1	2	2	3	1	0	2	2	2	3	1	3	3	1

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.011.00209	SC	23AUG96	-19, -81	2	2	3	1	2	1	2	2	2	2	2	2	3	2	2	0	2	1	2	2	2	2	3	2	2	3	2	2	2
	8	11NOV96	62, -1	3	2	3	2	2	2	2	3	2	2	3	2	2	1	2	2	2	1	3	2	2	2	2	2	2	3	2	3	3
329.011.00284	SC	13MAR96	-9, -65	2	0	0	1	3	0	2	3	2	0	2	1	1	3	0	2	3	1	0	3	0	1	3	1	3	2	1	1	0
	8	16MAY96	56, -1	3	2	2	3	3	2	3	3	3	2	3	2	2	3	3	3	3	3	3	3	1	2	3	2	3	3	2	2	2
329.011.00286	SC	15MAY96	-22, -90	1	2	0	1	2	1	1	3	1	1	3	0	1	1	1	2	3	2	1	2	0	1	2	1	2	3	1	2	2
	8	09AUG96	65, -4	2	2	0	1	2	2	2	3	1	2	2	0	1	1	2	1	3	2	1	2	0	2	2	1	2	3	2	2	2
329.012.00026	SC	09NOV95	-19, .	2	2	3	1	3	0	3	3	1	3	3	3	0	2	2	0	3	2	3	3	3	0	3	1	2	3	2	3	3
329.012.00219	SC	24MAY96	-7, -67	3	2	2	3	2	2	2	2	2	2	3	2	3	2	3	1	3	1	2	2	2	3	2	2	2	2	3	2	2
	8	30JUL96	61, 1	3	3	2	3	3	3	3	3	3	3	3	2	3	3	3	1	3	3	3	3	2	3	3	2	0	3	0	3	2
	32	24JAN97	239, 179	3	2	2	3	2	2	2	2	3	2	3	2	3	2	2	1	3	3	2	2	2	3	2	2	2	2	3	2	2
329.012.00221	SC	18JUN96	-7, -70	1	1	2	1	0	2	1	1	1	1	1	1	2	1	2	0	2	0	1	2	1	0	2	1	1	0	1	0	1
	8	27AUG96	64, 1	2	1	2	2	2	2	3	1	2	1	1	2	2	1	2	1	2	2	2	2	2	2	2	2	2	1	2	2	1
329.012.00223	SC	23AUG96	-7, .	0	0	1	0	2	0	3	2	1	2	0	0	0	0	0	0	3	1	1	2	0	0	2	0	3	2	0	0	0
329.012.00227	SC	12DEC96	-6, -75	1	0	1	1	1	0	0	1	0	1	2	0	0	1	0	0	3	0	0	0	0	0	3	1	0	2	0	1	1
	8	25FEB97	70, 1	2	2	2	1	0	0	2	1	0	0	2	1	1	1	0	0	3	0	0	0	1	1	2	1	1	1	1	1	2
	32	19AUG97	245, 176	2	2	1	2	3	2	1	1	1	0	2	2	1	1	2	1	3	0	0	1	0	1	3	2	0	0	1	1	2
329.012.00230	SC	20FEB97	-8, -77	2	1	2	1	3	2	2	0	2	2	2	0	3	0	1	1	3	0	0	3	0	3	2	0	0	0	2	0	1
	8	08MAY97	70, 1	2	2	0	2	2	1	2	2	1	0	2	0	2	2	1	2	3	2	1	2	1	2	1	1	2	1	2	0	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.001.00062	SC	06OCT94	-14, .	1	3	2	2	3	1	3	3	3	2	3	2	3	3	3	2	3	2	2	2	2	3	2	1	3	3	2	1	2
329.001.00064	SC	04NOV94	-6, -60	1	3	3	2	3	2	1	3	2	1	3	3	2	3	2	1	1	2	1	3	3	3	1	2	2	3	2	1	3
	8	03JAN95	55, 1	2	3	3	2	2	2	2	2	2	1	3	3	2	3	2	2	2	2	1	2	3	3	1	2	2	3	2	1	3
329.001.00069	SC	07FEB95	-9, .	1	0	0	2	1	0	2	1	1	0	1	0	2	1	0	1	3	0	0	2	0	2	0	1	2	3	1	1	1
	8	13APR95	57, .	1	3	0	1	2	1	2	2	1	1	2	1	1	2	3	2	3	1	2	3	1	1	1	2	2	3	1	1	2
329.001.00071	SC	02FEB95	-21, .	2	1	0	2	2	0	3	3	1	1	2	0	2	2	1	1	3	1	2	1	0	1	2	0	2	2	2	1	0
	8	20APR95	57, .	2	1	0	2	2	0	2	3	2	2	1	0	2	2	1	2	3	2	1	1	0	2	2	0	2	1	2	1	0
329.001.00123	SC	14DEC95	-21, .	0	1	0	0	3	0	2	2	0	0	2	0	0	2	2	1	1	0	0	0	0	0	2	1	2	3	0	2	2
329.001.00207	SC	19FEB96	-9, .	1	3	3	0	3	0	2	3	1	1	2	2	0	1	0	1	1	1	0	3	2	0	3	0	1	3	1	1	3
	8	24APR96	57, .	0	3	3	0	3	0	2	3	1	1	2	2	0	3	1	1	2	1	0	3	2	0	3	0	2	3	1	0	2
329.002.00049	SC	03MAR95	-6, .	3	0	0	1	1	1	1	0	1	2	0	1	1	.	1	3	3	3	1	1	1	1	1	1	3	0	3	3	1
	8	05MAY95	58, .	3	0	1	2	2	.	2	0	2	1	0	2	2	2	0	3	3	3	1	0	1	2	0	1	2	0	2	2	0
329.002.00059	SC	03NOV94	-7, .	3	2	1	0	0	1	3	0	2	1	1	1	0	1	1	3	3	3	0	2	2	0	0	1	2	1	0	0	2
	8	05JAN95	57, .	1	2	1	3	1	1	3	1	0	1	1	1	0	3	3	2	0	0	1	3	1	0	0	1	3	1	1	1	3
329.002.00060	SC	24JAN95	-7, -63	1	2	1	0	1	0	1	1	0	1	2	1	0	1	2	0	3	1	0	1	1	0	1	1	1	2	0	1	1
	8	28MAR95	57, 1	1	2	0	0	2	0	1	0	0	0	2	0	0	1	2	0	2	1	0	2	0	0	2	1	1	1	0	0	1
329.002.00097	.	.	., .	.	.	.	.	.	.	.	.	.	.	2	0	0	3	1	2	2	2	0	2	1	0	.	.	.	.	.	.	.
	SC	20DEC94	-14, -72	0	2	0	0	0	0	0	2	1	2	2	1	0	1	1	2	1	0	1	2	1	0	0	1	2	3	1	0	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.002.00097	8	02MAR95	59, 1	0	2	1	0	0	0	2	2	0	0	.	.	.	.	.	.	.	.	.	.	.	.	0	0	1	3	1	1	2
	32	05SEP95	246, 188	1	2	1	0	0	0	2	2	2	1	2	1	1	2	2	2	2	2	1	2	1	1	1	2	2	3	2	2	2
329.002.00101	SC	20MAR95	-8, -66	1	3	3	1	3	3	2	3	1	0	3	1	0	3	1	1	3	0	0	1	3	0	2	2	2	3	2	0	3
	8	25MAY95	59, 1	0	3	3	3	3	3	1	3	0	0	3	3	0	3	3	0	3	0	0	3	3	0	3	3	2	3	2	0	3
329.002.00107	SC	18JAN96	-7, -63	3	0	0	1	1	1	3	3	1	1	0	0	1	1	2	0	2	2	0	3	0	1	2	1	1	1	1	1	0
	8	21MAR96	57, 1	3	1	0	2	1	1	3	1	1	1	1	0	1	1	1	1	1	1	1	2	0	1	2	1	2	1	2	1	1
	32	26SEP96	246, 190	3	1	0	2	1	1	2	2	1	3	1	0	2	0	1	0	2	1	2	1	0	2	2	0	2	0	1	3	0
329.002.00241	SC	25JAN96	-12, -68	2	0	1	1	1	0	1	2	2	1	2	1	0	2	1	3	3	3	0	3	3	1	1	0	3	3	0	2	2
	8	02APR96	57, 1	3	3	1	1	3	3	2	3	2	0	3	2	1	3	3	3	0	3	0	3	3	1	3	3	3	3	2	3	3
329.002.00246	SC	01APR96	-17, .	0	2	3	0	2	0	2	0	1	0	2	1	2	1	1	1	3	0	0	3	2	0	3	1	2	1	1	0	2
	8	18JUN96	62, .	0	2	3	1	2	1	3	0	1	0	2	2	1	2	1	1	3	2	0	2	2	0	3	1	2	0	2	0	2
329.002.00320	SC	09MAY96	-7, -68	3	2	0	1	3	0	2	2	1	3	1	0	1	3	2	1	3	1	3	3	0	1	.	0	2	3	0	3	1
	8	16JUL96	62, 1	2	2	0	0	3	0	3	2	0	3	2	0	0	3	3	1	3	1	2	2	0	0	2	0	2	3	0	3	1
329.002.00323	SC	04NOV96	-8, -66	2	0	0	2	3	2	2	2	1	1	1	1	1	2	1	0	3	1	1	0	1	1	3	1	1	3	0	1	1
	8	09JAN97	59, 1	3	2	0	2	3	3	2	2	2	1	2	1	2	3	3	2	3	2	1	2	1	2	3	2	2	3	2	1	1
	32	12JUN97	213, 155	3	1	0	2	3	2	2	2	2	2	2	1	2	3	3	1	3	3	1	2	1	2	3	2	2	3	2	2	1
329.003.00074	32	11OCT95	260, 204	.	3	2	2	0	2	2	3	2	0	3	3	2	2	2	2	2	3	3	3	2	2	2	2	2	2	1	2	2
329.003.00078	8	21JUN95	57, .	3	2	1	0	2	0	1	3	1	1	2	2	0	2	1	1	3	1	0	2	1	0	2	0	2	3	2	1	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.003.00080	SC	22NOV95	-5, .	0	0	0	0	3	1	2	0	1	0	0	2	0	3	2	1	3	0	0	2	1	1	3	1	0	0	3	0	0
329.003.00085	SC	26OCT94	-13, .	1	1	0	0	0	0	0	0	1	2	2	1	1	1	1	3	1	1	0	3	0	0	0	1	1	3	0	1	1
	8	03JAN95	57, .	3	3	1	3	3	1	1	1	2	2	0	0	2	3	3	1	3	1	0	3	0	2	0	2	1	3	2	3	0
329.003.00086	SC	09NOV94	-19, -76	0	3	1	0	3	1	0	2	1	1	2	0	0	3	3	3	3	1	0	3	1	0	0	0	.	3	0	0	1
	8	23JAN95	57, -1	2	2	2	0	3	2	1	3	2	0	3	2	0	2	2	1	3	2	2	2	2	0	0	2	2	3	2	1	2
	32	17AUG95	263, 206	2	3	2	1	3	3	1	3	1	1	3	2	1	3	2	1	3	1	2	3	2	1	0	3	2	3	2	1	2
329.003.00094	8	19DEC95	57, .	0	3	0	0	2	1	2	3	0	0	2	0	0	1	0	1	3	0	2	1	0	0	2	1	1	3	0	1	2
329.003.00251	SC	19MAR96	-9, .	0	0	0	0	3	0	0	0	0	2	0	1	0	0	0	0	3	0	2	2	0	0	0	0	1	0	0	1	0
329.003.00252	SC	19MAR96	-22, .	3	2	0	2	2	0	1	3	2	1	2	0	3	3	3	1	3	1	3	3	0	2	3	2	2	3	0	3	2
	8	04JUN96	56, .	3	2	0	2	0	0	0	3	1	0	2	0	2	2	3	1	3	2	2	2	0	2	2	1	3	3	1	3	2
329.003.00291	SC	01JUL96	-2, -67	0	0	0	0	1	0	0	0	0	1	1	0	1	1	1	0	3	1	1	1	0	1	1	0	1	1	0	1	2
329.003.00315	SC	29OCT96	-14, .	2	2	0	1	2	0	2	3	1	1	0	1	0	2	1	1	3	0	2	2	1	0	0	1	2	3	1	2	0
	8	07JAN97	57, .	3	1	1	1	2	1	2	3	2	2	2	1	1	2	2	1	3	1	2	2	1	1	0	1	2	3	2	2	1
329.003.00316	SC	05DEC96	-12, .	2	3	0	1	3	2	1	3	0	1	3	1	1	2	2	0	3	0	1	3	0	1	2	2	1	3	0	2	3
	8	11FEB97	57, .	2	3	0	2	3	1	1	3	0	2	3	0	2	1	1	0	3	1	3	2	0	2	2	1	1	3	1	2	3
329.004.00016	SC	01MAR95	-12, .	3	3	0	3	3	3	3	3	2	2	3	1	3	3	3	3	3	1	0	3	0	3	3	3	3	3	0	2	2
	5	19APR95	38, .	3	2	0	3	3	2	2	3	2	2	2	0	2	3	3	2	2	2	1	2	0	3	3	3	2	3	1	1	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.004.00018	SC	19APR95	-14, .	0	2	1	1	2	1	1	1	0	0	0	0	1	1	3	2	2	0	0	0	0	1	3	0	2	3	0	0	1
	8	29JUN95	58, .	0	3	2	2	3	1	2	0	1	0	0	1	1	2	3	3	3	0	0	3	1	1	3	2	3	3	2	0	2
329.004.00020	SC	02NOV95	-7, .	1	2	1	1	3	0	1	0	0	2	2	1	0	3	2	0	3	0	1	2	1	1	1	2	1	3	0	1	3
	2	24NOV95	16, .	1	2	1	1	2	1	1	1	3	2	2	1	1	2	2	0	3	1	1	1	1	1	2	1	1	3	0	1	2
329.004.00213	SC	18JUL96	-15, -69	2	2	0	0	2	0	2	2	0	0	3	0	0	1	.	3	2	0	2	2	0	1	0	0	2	1	1	1	1
	8	24SEP96	54, -1	2	2	0	0	2	0	2	1	1	1	1	0	0	2	0	3	2	1	2	2	0	1	.	0	2	2	0	2	2
	32	19MAR97	230, 176	3	2	0	1	2	0	2	3	1	0	2	0	1	2	1	1	3	1	2	2	0	1	2	0	2	3	2	1	2
329.005.00001	SC	11APR94	-9, .	0	1	1	.	2	0	3	0	0	0	0	0	1	1	.	2	3	0	0	.	1	.	2	1	1	1	0	.	.
	8	15JUN94	57, .	0	1	0	2	2	.	3	1	1	0	0	0	3	1	.	3	3	0	1	2	1	2	2	0	0	0	0	0	1
329.005.00005	SC	24OCT94	-8, .	0	0	2	0	1	0	0	0	2	0	0	2	3	0	1	3	2	2	0	2	1	3	1	0	1	0	2	0	0
329.005.00010	SC	07DEC94	-6, -63	1	0	2	0	2	0	3	3	2	1	0	0	0	2	0	2	3	1	2	1	2	0	1	0	2	3	1	1	0
	8	08FEB95	58, 1	2	2	3	2	3	2	3	3	2	2	2	3	1	3	1	2	3	2	2	3	2	1	2	1	3	3	2	2	2
	32	09AUG95	240, 183	3	2	3	2	3	3	3	3	2	2	3	3	2	3	2	0	3	2	3	3	3	2	2	1	3	3	2	1	2
329.005.00012	SC	12DEC94	-7, -66	3	0	1	2	3	2	2	0	1	0	0	2	2	3	2	1	3	1	1	1	1	2	3	2	2	3	1	0	1
	8	16FEB95	60, 1	3	1	0	3	3	2	2	1	2	1	1	3	3	3	2	1	1	0	2	0	1	2	3	1	2	3	2	1	1
329.005.00111	SC	05JAN95	-6, -62	2	2	1	1	2	2	2	1	1	2	2	2	.	2	2	2	3	.	2	0	1	.	.	2	2	3	.	2	3
	8	08MAR95	57, 1	2	2	2	.	3	3	3	2	2	2	2	2	.	3	2	2	3	.	2	2	1	2	.	2	3	2	2	2	2
	16	03MAY95	113, 57	3	2	1	1	3	2	3	2	2	2	2	.	.	3	3	3	3	2	2	2	1	.	.	3	3	2	3	.	3
329.005.00114	SC	23JAN95	-8, -65	1	2	2	2	2	3	3	3	0	1	2	2	2	2	3	1	3	1	1	1	2	2	2	1	2	3	0	2	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.005.00114	8	29MAR95	58, 1	2	1	2	2	2	0	1	1	0	2	2	2	2	2	0	1	2	1	1	1	1	2	2	0	1	1	1	2	2
	16	17MAY95	107, 50	2	1	2	2	2	0	2	1	1	2	2	2	2	2	0	2	2	1	0	2	2	2	2	0	1	1	1	1	2
329.005.00115	8	18APR95	72, 1	2	1	2	1	3	2	2	2	1	1	2	2	2	2	2	2	1	2	2	2	1	1	1	2	2	2	2	1	2
329.005.00120	SC	22AUG95	-8, .	2	1	2	1	1	1	2	1	1	2	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	2
	8	26OCT95	58, .	3	1	1	1	1	1	2	1	2	2	0	1	1	2	0	2	3	0	2	2	1	1	1	1	2	2	2	1	1
329.005.00253	SC	31JAN96	-8, .	2	1	0	0	2	0	2	1	0	2	2	1	0	2	0	1	2	1	1	2	0	0	1	0	0	1	0	1	1
	8	03APR96	56, .	1	2	0	0	2	0	1	1	0	1	2	0	0	1	2	1	1	1	1	1	0	0	1	0	1	0	0	2	0
329.005.00254	SC	08FEB96	-7, -62	0	0	1	0	1	0	1	2	0	1	1	1	0	1	1	1	1	0	2	2	0	0	1	0	1	2	1	1	1
	8	10APR96	56, 1	2	1	2	0	1	1	2	3	1	1	2	1	0	1	1	1	1	1	2	1	1	0	2	1	2	3	2	1	2
	32	16OCT96	245, 190	2	1	1	1	1	0	1	2	2	0	2	1	0	1	2	1	3	2	2	2	1	0	2	1	2	2	2	2	2
329.005.00293	SC	06MAR97	-6, .	2	1	0	2	3	1	1	0	1	0	0	0	1	3	3	1	2	2	1	0	0	1	1	1	1	0	1	1	0
	8	07MAY97	57, .	2	1	0	1	3	1	2	1	1	2	0	0	0	3	3	1	2	2	1	0	0	1	2	1	0	1	1	1	1
329.005.00298	SC	15MAY96	-7, -63	1	2	0	0	1	0	1	2	0	1	3	0	0	2	3	1	3	0	2	3	2	0	1	0	2	3	0	2	3
	8	17JUL96	57, 1	1	2	1	0	2	1	2	3	0	1	3	0	0	3	2	1	2	0	2	3	1	0	1	0	2	2	1	2	2
	32	13JAN97	237, 181	2	2	2	0	2	0	2	2	0	1	2	0	0	1	2	1	2	1	2	3	2	0	2	1	1	3	1	2	2
329.005.00331	SC	14NOV96	-7, .	3	1	0	1	0	0	2	3	0	3	2	0	0	1	0	1	2	1	3	2	0	0	1	0	1	3	0	3	1
	8	16JAN97	57, .	3	2	0	.	2	2	2	3	0	2	2	0	0	2	3	0	2	1	2	2	0	0	1	1	1	3	1	3	2
329.005.00334	SC	24JAN97	-7, .	3	3	3	1	2	1	3	3	2	3	3	3	1	2	1	0	3	3	2	3	2	0	2	0	2	3	1	2	2
	8	27MAR97	56, .	2	3	3	2	3	3	3	3	2	2	3	2	1	2	3	1	3	3	3	3	3	0	3	3	3	3	3	3	3

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.006.00037	SC	20JAN95	-8, .	3	1	0	2	3	1	3	3	0	3	0	0	2	3	3	3	3	3	3	2	0	3	3	2	2	3	1	3	0
329.006.00042	SC	01DEC95	-6, -63	2	0	0	0	2	0	1	1	1	3	0	0	0	2	0	1	1	1	1	0	0	0	1	0	1	2	1	3	0
	8	02FEB96	58, 1	3	1	1	1	2	1	1	0	0	2	1	0	0	1	0	0	1	2	1	1	1	1	2	1	2	1	1	3	0
	32	16JUL96	223, 166	2	1	1	1	3	1	1	2	1	2	1	0	0	1	0	0	1	2	1	1	0	0	1	0	2	1	1	3	1
329.006.00259	SC	22APR96	-32, .	3	1	1	2	2	2	3	3	3	3	0	2	3	3	0	3	2	0	3	3	1	2	3	2	3	3	3	3	1
	8	17JUL96	55, .	3	2	1	2	2	2	3	3	3	3	1	2	3	3	1	3	3	2	3	3	1	2	3	3	3	3	3	3	2
329.007.00141	SC	14SEP95	-7, .	3	1	1	3	0	0	1	2	1	2	2	2	1	0	.	1	3	2	3	0	2	0	2	1	3	1	2	3	1
329.007.00144	SC	30NOV95	-7, -63	1	3	0	1	2	1	1	2	1	0	3	0	0	1	1	3	3	2	1	2	0	0	1	1	2	3	1	1	2
	8	01FEB96	57, 1	2	3	0	1	2	1	2	2	1	1	2	2	1	1	1	2	3	2	1	1	0	1	2	1	2	2	0	1	3
329.007.00266	SC	29FEB96	-7, .	1	3	3	3	1	1	1	3	1	1	3	3	2	2	1	0	3	1	1	1	1	2	0	1	2	3	3	2	2
	8	02MAY96	57, .	2	2	1	2	1	1	1	3	2	2	3	1	2	2	0	2	3	2	2	2	1	2	2	2	2	3	3	2	2
329.007.00267	SC	29FEB96	-7, .	2	2	0	2	3	1	1	0	2	1	2	0	0	2	0	2	2	1	0	2	1	2	2	1	2	1	1	1	2
	8	02MAY96	57, .	2	1	1	2	2	1	1	1	2	1	2	1	0	2	1	2	2	1	1	2	1	1	1	1	2	1	2	1	1
329.007.00311	SC	26SEP96	-7, -67	1	3	2	3	2	3	2	3	3	0	2	3	3	3	3	1	3	2	2	3	0	3	3	3	2	3	3	0	2
	8	02DEC96	61, 1	3	3	3	3	3	2	3	3	3	1	3	2	3	0	3	0	3	3	3	3	1	3	3	2	3	3	3	1	0
329.008.00158	SC	06SEP95	-7, -69	1	0	0	2	3	3	3	3	3	0	0	0	1	3	3	3	3	2	0	2	0	1	3	3	3	3	3	0	2
	8	14NOV95	63, 1	3	0	0	3	3	2	3	0	3	0	2	1	2	3	3	1	3	2	1	2	1	3	3	3	3	3	3	0	1
329.008.00162	SC	26OCT95	-6, -71	1	1	0	0	3	0	1	1	0	0	1	0	0	1	1	0	3	0	0	2	1	0	0	0	1	3	0	0	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.008.00162	8	05JAN96	66, 1	3	2	1	1	3	2	1	0	1	0	2	1	1	2	2	0	3	0	0	2	1	1	0	0	2	3	1	0	1
	32	02JUL96	245, 180	3	1	2	1	3	2	2	2	2	2	2	2	1	2	2	2	3	3	3	2	2	1	3	2	2	3	2	2	2
329.008.00191	SC	12JAN96	-20, -81	1	1	0	0	1	0	2	0	0	1	2	0	0	1	0	0	2	1	1	2	0	0	2	0	1	0	0	0	1
	8	02APR96	62, 1	1	0	0	1	3	0	1	0	1	2	0	1	1	2	0	2	3	3	1	0	1	0	0	0	1	2	1	2	0
329.009.00128	SC	05APR95	-6, .	3	0	0	0	1	0	3	0	3	1	0	0	1	2	0	3	3	3	1	0	0	0	0	0	3	3	3	1	0
329.009.00129	SC	22MAR95	-20, .	0	2	2	0	2	0	1	1	0	0	2	2	0	0	0	0	3	1	0	2	2	0	3	0	0	2	0	0	2
329.009.00135	SC	25SEP95	-7, .	0	2	0	2	1	1	2	2	0	1	1	1	1	1	2	1	2	1	2	2	1	2	2	2	2	2	1	2	1
329.009.00136	SC	26SEP95	-7, .	0	1	0	0	0	1	1	0	0	0	0	0	0	1	1	0	3	1	0	1	0	0	0	2	2	1	0	0	1
	8	28NOV95	57, .	1	1	2	1	2	1	2	2	2	1	2	2	0	2	3	1	3	1	1	2	2	0	2	1	2	2	2	1	2
329.009.00169	SC	25OCT95	-6, -71	2	3	3	2	3	3	2	3	0	3	3	2	0	3	3	0	2	0	0	3	2	1	2	3	0	0	1	2	3
	8	27DEC95	58, -8	2	3	2	3	3	3	2	2	3	3	3	3	1	2	3	0	2	3	1	3	0	3	2	3	2	3	0	1	3
329.009.00174	SC	14NOV95	-7, -64	1	2	2	1	0	1	1	2	3	1	2	0	0	2	3	2	3	1	2	3	2	1	2	2	3	3	2	1	2
	8	17JAN96	58, 1	1	2	2	1	1	1	2	3	2	1	2	2	1	1	3	1	3	2	2	3	2	1	2	1	3	3	2	1	2
329.009.00197	SC	20DEC95	-9, -63	2	1	1	2	0	1	3	1	2	1	2	2	3	0	2	2	2	2	2	1	2	2	3	2	2	2	3	1	1
	8	20FEB96	54, -1	3	2	2	3	0	2	3	1	3	1	2	2	3	3	2	0	3	3	2	2	1	3	3	2	2	0	0	1	1
	32	20AUG96	236, 182	3	2	1	3	1	2	3	1	3	1	2	2	3	2	1	1	2	3	2	2	2	3	3	2	2	1	3	1	1
329.009.00198	SC	19DEC95	-14, .	3	1	2	1	3	2	2	3	1	2	3	1	1	3	3	2	3	2	3	2	2	1	3	2	2	3	2	3	3
	8	27FEB96	57, .	3	2	2	1	3	1	2	3	1	1	2	2	0	3	3	2	3	1	2	2	2	0	3	0	3	3	1	2	3

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.009.00200	SC	17JAN96	-6, .	1	2	0	1	3	2	2	2	1	1	2	1	0	1	0	1	3	0	0	1	1	1	1	2	2	1	0	1	2
329.009.00202	SC	14FEB96	-6, .	1	1	0	1	2	0	1	3	1	1	2	0	1	1	2	0	3	1	1	2	0	1	0	1	1	3	1	1	1
329.009.00238	SC	28OCT96	-15, .	0	3	1	2	2	2	2	2	1	0	2	1	2	2	3	0	2	2	1	3	1	2	1	2	2	3	1	1	2
	8	07JAN97	57, .	1	2	1	2	1	2	2	2	1	0	2	1	1	2	2	1	2	1	1	3	1	1	2	2	2	2	1	2	2
329.009.00276	SC	17JAN97	-4, .	3	1	0	0	3	1	1	0	0	1	0	1	1	2	3	3	3	1	0	0	0	1	1	0	2	1	0	2	2
	8	18MAR97	57, .	3	2	1	2	2	2	2	1	1	2	2	0	1	2	2	0	2	2	1	1	1	1	2	2	1	2	2	2	2
329.009.00302	SC	20MAR96	-7, .	2	3	3	1	3	3	1	3	1	0	3	3	1	3	0	1	3	1	1	3	3	2	3	3	2	3	1	2	3
329.009.00306	SC	03JUN96	-8, .	2	3	3	1	3	2	3	0	2	0	0	0	0	2	2	2	3	0	1	3	1	0	2	1	3	3	0	0	3
	8	06AUG96	57, .	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	3	2	.	.	.	.	.	.	.	.	.	.	.
329.009.00312	SC	30OCT96	-5, .	0	3	0	1	3	1	3	0	1	3	3	0	1	3	3	3	1	2	3	1	0	1	3	3	3	0	1	1	3
	8	06JAN97	64, .	3	3	0	1	3	2	3	3	1	1	3	0	1	3	3	1	3	1	2	3	0	1	3	3	3	2	1	1	3
329.009.00327	SC	09SEP96	-7, .	0	2	1	1	3	1	0	2	1	1	2	1	1	3	3	2	3	1	1	2	1	1	1	1	1	3	1	1	2
	5	21OCT96	36, .	0	1	1	0	2	0	0	1	0	0	0	1	0	1	1	2	2	0	0	1	1	0	0	0	0	1	0	0	0
329.009.00330	SC	15OCT96	-6, .	0	3	3	3	3	2	1	3	0	2	3	3	3	3	3	1	3	1	2	3	2	2	3	2	3	3	2	1	3
329.010.00183	SC	21NOV95	-12, .	2	3	2	3	3	3	2	3	1	3	3	1	3	3	3	1	3	3	3	1	0	3	3	3	3	3	2	3	3
329.010.00263	SC	24JUL96	-16, .	2	0	0	1	2	2	3	0	2	0	0	0	3	0	3	0	3	3	0	3	0	0	3	3	0	0	3	0	3
	8	09OCT96	62, .	2	1	0	3	0	1	.	2	1	2	2	1	1	1	1	1	2	3	3	2	1	0	1	2	2	2	2	1	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.010.00277	SC	23FEB96	-7, -63	1	1	1	1	2	1	2	2	1	1	2	1	1	2	1	1	1	1	1	2	1	1	2	1	1	2	2	2	2
	8	26APR96	57, 1	3	3	2	3	2	2	3	3	3	3	3	3	3	3	3	0	2	3	3	3	3	3	3	3	3	3	3	3	3
	24	07AUG96	160, 104	3	3	1	3	3	3	3	3	3	3	1	2	1	1	3	0	3	3	3	3	1	0	3	3	3	0	3	3	3
329.010.00282	SC	19JUL96	-7, .	1	1	2	1	3	2	2	2	1	1	1	2	0	2	3	1	1	2	1	2	2	0	2	1	2	3	2	2	1
	8	27SEP96	64, .	2	2	2	2	3	2	2	3	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	3	2	2	2
329.011.00164	SC	15DEC95	-7, .	1	2	3	2	3	2	0	3	3	0	3	3	3	2	3	1	3	0	1	0	3	2	2	2	3	3	2	1	3
329.011.00210	SC	13SEP96	-15, -81	1	3	0	2	0	1	1	1	1	2	3	0	1	0	3	2	3	1	0	3	0	1	1	1	2	0	1	3	3
	8	02DEC96	66, -1	2	3	0	2	1	1	2	3	2	0	3	0	0	1	3	0	3	3	0	3	0	0	0	1	1	3	2	0	3
329.011.00285	SC	08MAY96	-10, .	0	0	0	0	1	0	2	1	0	1	1	1	1	3	0	0	2	0	1	0	1	1	3	0	1	1	0	1	0
	8	24JUL96	68, .	1	1	1	1	1	1	2	1	1	2	1	0	2	2	0	1	2	1	1	1	0	1	3	1	2	2	1	1	1
329.011.00287	SC	25JUN96	-8, .	1	2	0	0	2	0	1	3	0	0	3	0	0	0	1	0	3	0	0	0	0	0	2	0	0	3	0	0	2
	8	27AUG96	56, .	1	3	0	1	2	2	1	3	1	1	2	1	1	1	3	1	3	2	1	2	1	1	2	1	1	3	1	1	2
329.012.00027	SC	23NOV95	-13, .	0	0	0	1	0	2	2	2	0	2	2	1	1	2	2	1	3	1	2	3	0	0	3	1	2	2	1	1	1
329.012.00217	SC	14MAY96	-7, .	0	1	0	0	2	0	1	2	0	0	1	0	0	1	1	3	3	0	0	0	0	0	1	0	2	2	1	0	0
329.012.00218	SC	04JUN96	-12, -70	1	2	1	0	2	1	1	3	0	1	2	1	2	2	3	1	0	0	1	2	1	0	0	1	2	3	0	1	2
	8	13AUG96	59, 1	1	2	1	2	3	2	2	3	2	1	2	1	3	2	3	1	2	2	1	2	1	2	0	2	2	3	2	1	2
329.012.00224	SC	30AUG96	-17, -83	0	0	0	1	2	1	3	0	1	2	1	0	1	2	.	0	2	3	2	2	0	1	2	0	1	1	3	1	1
	8	20NOV96	66, -1	2	1	0	2	1	1	3	2	1	2	1	0	2	2	.	1	2	3	2	2	0	1	2	1	2	1	2	1	1

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
329.012.00225	SC	19NOV96	-7, -71	2	1	2	1	2	1	2	2	1	2	1	1	1	2	2	2	2	1	2	2	2	1	2	1	1	3	2	2	1
	8	29JAN97	65, 1	2	1	2	1	1	1	3	2	2	2	1	1	1	2	1	2	3	1	2	2	1	1	2	1	2	3	2	2	1
	32	30JUL97	247, 183	3	1	2	1	2	1	2	2	2	2	2	1	1	2	2	2	3	1	2	1	2	1	2	2	2	2	2	2	2

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.001.00063	SC	02NOV94	-6, .	0	0	.	0	1	0	0	2	0	0	0	0	0	1	1	0	39
329.001.00065	SC	07NOV94	-10, .	1	2	1	2	1	1	2	1	1	1	2	2	2	2	1	1	62
329.001.00068	SC	01FEB95	-7, .	0	0	1	1	0	3	0	1	1	0	0	2	2	1	3	0	49
	8	05APR95	57, .	0	0	1	1	1	3	1	1	2	0	0	1	1	1	3	2	55
329.001.00072	SC	07MAR95	-13, .	3	2	2	3	1	3	3	3	3	2	2	1	2	3	3	3	111
329.001.00121	SC	22MAR95	-13, -69	3	1	1	1	1	1	1	1	2	2	1	1	1	1	2	0	61
	8	30MAY95	57, 1	3	1	2	1	1	1	1	1	2	2	1	2	1	1	3	1	70
329.001.00205	SC	29JAN96	-9, .	0	2	2	.	3	0	2	3	0	0	3	0	.	3	0	3	66
329.001.00206	SC	12FEB96	-9, .	2	1	1	1	1	1	1	2	1	1	2	1	1	1	1	1	48
	8	17APR96	57, .	2	1	1	1	1	0	2	2	1	1	1	1	1	1	1	1	53
329.002.00055	SC	09JUN94	-15, -70	0	0	1	2	0	0	0	0	0	1	0	3	2	3	3	0	47
	8	18AUG94	56, 1	0	3	1	3	0	1	3	2	2	1	3	0	0	0	3	3	73
	20	10NOV94	140, 85	1	3	3	3	1	0	3	1	3	1	3	0	3	0	3	3	84
329.002.00058	SC	08SEP94	-12, -70	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	59
	8	17NOV94	59, 1	1	1	2	2	2	2	2	2	2	0	1	1	2	1	3	2	90
329.002.00099	SC	23FEB95	-7, -62	2	1	3	0	1	1	2	1	2	0	2	2	0	3	3	2	66
	8	25APR95	55, -1	2	2	2	2	2	1	2	2	2	2	2	2	1	2	3	2	84
	32	26OCT95	239, 184	2	2	3	2	2	2	1	2	.	1	1	3	1	3	2	1	76

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.002.00102	SC	03APR95	-10, -64	0	0	1	0	1	2	0	1	0	0	0	0	1	2	3	0	36
	8	06JUN95	55, 1	1	0	3	2	1	2	2	1	2	0	0	3	2	3	3	2	78
	32	05DEC95	237, 183	1	1	2	1	2	2	1	1	2	1	1	3	2	3	2	1	80
329.002.00105	SC	20JUL95	-7, .	1	2	1	1	1	1	1	1	2	1	2	1	2	1	3	1	73
329.002.00106	SC	20JUL95	-7, .	2	0	2	1	0	0	1	3	1	1	0	2	0	0	2	0	43
329.002.00242	SC	26JAN96	-12, -70	2	1	1	3	0	3	2	1	3	2	2	3	2	0	3	1	80
	20	10JUL96	155, 97	3	3	1	3	0	0	3	3	3	2	3	3	3	0	3	3	113
329.002.00245	SC	21MAR96	-7, .	1	2	1	1	1	2	1	1	2	1	1	0	0	1	3	1	71
329.002.00319	SC	23APR96	-7, -63	1	0	1	1	2	0	1	3	1	1	1	3	1	3	2	1	71
	8	25JUN96	57, 1	2	2	2	1	3	0	2	3	0	2	2	3	1	3	2	3	87
	32	17DEC96	232, 176	2	1	2	1	2	1	2	3	0	2	2	3	0	2	3	2	84
329.003.00075	SC	18JAN95	-7, -63	1	0	0	0	0	3	0	1	3	2	0	2	0	3	3	0	60
	8	22MAR95	57, 1	2	0	1	0	3	3	0	0	2	2	0	1	1	2	3	0	56
	32	13SEP95	232, 176	2	0	3	0	3	2	1	0	2	2	0	3	1	1	2	0	68
329.003.00077	SC	01MAR95	-5, -64	3	2	1	1	2	1	2	2	1	3	2	3	0	2	2	1	82
329.003.00087	SC	23JAN95	-8, .	2	1	1	1	1	0	1	1	1	2	1	0	1	1	2	1	61
329.003.00089	8	02MAY95	57, .	3	2	3	3	1	2	2	2	2	3	2	2	0	2	2	2	92

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.003.00091	8	16MAY95	54, -1	2	2	2	3	1	3	1	2	2	1	2	3	2	3	3	2	93
	32	07NOV95	229, 175	2	2	0	3	2	2	3	3	3	2	2	3	2	3	3	3	109
329.003.00248	SC	14FEB96	-16, .	0	0	3	1	1	1	1	2	0	0	0	1	0	2	3	0	44
	8	23APR96	54, .	0	1	3	1	1	3	2	2	1	0	1	0	1	1	3	2	62
329.003.00250	SC	05MAR96	-9, -66	3	2	1	2	1	2	2	3	3	2	2	1	3	1	3	2	92
	8	09MAY96	57, -1	3	3	2	3	0	2	3	3	3	2	3	1	3	1	3	2	104
329.003.00292	SC	02AUG96	-5, -63	1	1	2	1	0	1	1	1	1	2	2	2	0	3	0	1	62
	8	04OCT96	59, 1	1	1	3	3	3	3	3	1	2	3	2	0	2	3	2	2	92
329.003.00313	SC	08MAY96	-9, .	3	0	1	1	1	1	0	0	0	2	0	2	1	0	1	3	29
329.004.00015	SC	30NOV94	-8, -65	0	2	3	1	0	0	3	2	0	0	2	3	0	1	3	2	69
	8	03FEB95	58, 1	1	2	1	2	1	1	3	2	1	1	2	2	2	1	2	2	78
	28	14JUN95	189, 132	1	3	3	3	0	0	3	3	1	1	3	3	3	0	3	3	95
329.004.00017	SC	15MAR95	-7, -63	1	0	1	1	1	0	0	0	0	0	0	1	0	1	0	0	23
	8	17MAY95	57, 1	2	2	1	1	1	1	0	0	0	1	2	1	0	1	1	1	50
	32	01NOV95	225, 169	2	0	1	1	2	0	1	0	0	1	1	2	0	0	1	1	42
329.004.00019	SC	24MAY95	-7, .	3	3	3	3	1	0	3	2	2	3	3	3	2	2	1	1	89
329.004.00212	SC	24MAY96	-10, .	2	2	1	1	0	0	1	1	0	2	1	2	1	1	3	1	58
329.004.00214	SC	27SEP96	-7, -67	1	0	2	1	3	2	2	2	2	1	0	0	0	3	2	0	53

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.004.00214	8	03DEC96	61, 1	2	0	2	0	1	1	2	0	1	1	0	2	0	2	1	0	48
329.005.00004	SC	22SEP94	-18, -77	2	2	2	2	2	3	3	2	2	3	2	1	0	2	3	2	93
	8	08DEC94	60, 1	4	3	3	4	3	3	3	4	4	4	3	2	2	3	3	3	140
329.005.00008	SC	10NOV94	-6, -61	1	2	1	1	1	3	2	2	2	2	1	2	2	1	2	2	79
	8	10JAN95	56, 1	2	2	2	2	1	3	2	2	2	2	1	1	1	1	3	2	88
	24	10MAY95	176, 121	3	2	1	2	1	1	2	2	3	2	1	1	2	1	1	1	89
329.005.00011	SC	06DEC94	-7, -63	0	1	2	0	1	3	1	0	0	0	1	3	1	2	3	1	48
	8	07FEB95	57, 1	1	2	2	1	1	2	3	1	3	1	2	3	1	1	3	2	82
329.005.00109	SC	22DEC94	-8, -61	1	2	1	2	1	1	2	2	2	1	2	2	1	2	2	1	77
	8	21FEB95	54, 1	1	2	1	2	1	1	2	2	1	2	3	1	.	2	1	2	75
329.005.00112	SC	17JAN95	-9, -64	2	3	1	.	1	0	3	1	0	1	3	0	0	0	1	0	48
	8	22MAR95	56, 1	2	3	3	.	3	1	3	3	2	2	3	3	1	3	1	3	101
	20	21JUN95	147, 92	0	1	3	2	2	2	0	3	2	2	0	3	2	3	2	0	82
329.005.00116	SC	30JAN95	-8, -66	1	2	1	2	.	3	0	1	2	1	1	3	2	1	3	1	79
	8	06APR95	59, 1	2	2	2	3	1	3	2	2	3	2	1	3	2	1	3	2	96
	24	26JUL95	170, 112	2	2	1	3	1	3	2	2	3	2	2	3	2	2	3	3	101
329.005.00119	SC	27JUN95	-14, -73	2	2	1	2	0	2	2	2	2	0	1	2	2	1	3	2	72
	8	08SEP95	60, 1	2	2	2	3	1	3	3	3	2	1	2	2	2	1	3	3	105
	24	02JAN96	176, 117	2	2	2	2	2	2	3	3	3	0	3	2	3	2	2	3	95

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.005.00151	SC	29AUG95	-8, -65	1	2	1	.	1	2	1	1	2	0	1	2	1	1	3	0	55
	8	02NOV95	58, 1	0	2	.	.	1	1	1	2	1	0	1	3	0	2	1	1	55
	32	01MAY96	239, 182	1	2	3	.	1	2	1	3	2	0	2	3	1	2	1	1	78
329.005.00152	SC	12OCT95	-14, .	1	0	1	1	1	1	1	1	1	1	1	1	1	1	2	1	48
329.005.00257	SC	05MAR96	-6, -62	1	2	2	2	2	3	3	2	2	1	2	3	1	2	3	2	90
	8	06MAY96	57, 1	1	2	2	2	2	2	2	3	3	0	2	0	2	3	3	3	97
	32	21OCT96	225, 169	1	2	3	2	3	3	3	2	3	1	3	0	2	3	3	3	113
329.005.00258	SC	06FEB96	-35, .	3	1	2	1	2	2	2	2	2	2	1	1	0	2	2	2	70
	8	07MAY96	57, .	2	2	1	1	1	.	.	.	.	.	.	.	.	.	.	.	70
329.005.00299	SC	28MAY96	-11, -71	1	2	2	2	1	2	2	2	1	2	2	3	1	2	2	2	84
	8	07AUG96	61, 1	1	2	2	2	1	2	2	2	2	2	2	2	1	2	2	2	86
	20	05NOV96	151, 91	2	2	2	2	2	1	2	2	2	2	2	2	1	1	2	2	79
329.005.00300	SC	12SEP96	-7, .	3	3	2	0	1	0	0	3	0	3	1	3	0	3	2	0	75
	8	14NOV96	57, .	1	1	1	1	1	0	0	3	0	2	0	0	1	1	2	0	44
329.005.00333	SC	15JAN97	-8, .	0	1	3	0	2	0	2	1	0	0	1	3	0	2	0	1	44
329.005.00336	SC	26FEB97	-6, .	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	85
	8	30APR97	58, .	2	2	1	1	3	1	2	2	2	2	2	2	3	0	2	0	79
329.006.00038	SC	01FEB95	-14, .	1	0	0	0	3	0	0	0	3	1	0	2	1	2	0	0	54

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.006.00039	SC	03FEB95	-5, -66	0	0	3	0	3	1	0	3	0	0	0	3	1	3	1	0	46
	8	05APR95	57, -5	0	0	1	0	3	0	0	3	1	0	0	3	0	3	2	0	39
329.006.00260	SC	12JUL96	-6, -64	2	2	2	2	1	2	2	2	2	2	2	1	2	2	3	2	76
	8	18SEP96	63, 5	2	2	1	2	1	3	2	2	2	1	2	2	2	2	3	1	80
329.006.00261	SC	07NOV96	-19, -77	0	0	2	0	0	0	0	0	2	0	0	2	0	0	0	0	27
	8	23JAN97	59, 1	0	1	1	1	0	3	2	2	2	0	1	2	1	1	3	1	59
329.007.00140	SC	07SEP95	-8, -63	3	2	3	3	2	3	0	3	3	3	1	0	3	3	3	1	101
	8	09NOV95	56, 1	1	2	1	3	0	1	3	3	2	0	2	3	0	3	0	3	85
329.007.00142	SC	12OCT95	-6, .	0	0	1	1	1	1	0	1	1	0	0	2	1	1	1	0	37
	8	21DEC95	65, .	0	0	1	1	1	0	0	1	0	0	0	1	0	1	0	0	29
329.007.00145	SC	04JAN96	-7, -63	3	3	0	2	1	2	3	3	1	3	3	3	1	1	1	2	77
	8	07MAR96	57, 1	3	3	3	0	0	1	3	3	0	3	3	3	3	0	0	3	96
	32	23AUG96	226, 170	3	3	3	3	3	3	3	3	3	3	3	3	1	3	3	3	127
329.007.00265	SC	25JAN96	-7, .	2	0	1	0	0	1	3	1	1	2	0	3	1	1	3	0	59
329.007.00268	SC	21MAR96	-11, -70	0	0	0	1	1	0	0	3	0	0	0	1	1	3	3	0	40
	8	30MAY96	60, 1	1	0	2	1	0	1	1	3	2	1	0	2	0	2	3	0	63
	32	05DEC96	249, 190	1	1	1	1	1	2	2	2	1	0	0	0	0	0	0	0	62
329.007.00294	SC	20FEB97	-8, .	1	0	1	0	0	0	1	1	2	0	0	2	1	0	1	1	39

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.007.00309	SC	02JUL96	-13, -65	3	2	0	3	1	1	2	3	3	3	1	3	2	2	0	1	81
	7	05SEP96	53, 1	3	2	3	3	1	1	3	3	3	3	2	3	2	2	1	3	107
	32	13MAR97	242, 190	3	2	1	3	3	1	3	3	3	3	2	3	2	3	2	1	103
329.007.00310	SC	19SEP96	-7, -67	2	3	1	3	0	1	2	2	2	3	2	1	1	1	3	2	79
	8	25NOV96	61, 1	2	2	2	3	1	2	3	2	2	3	3	3	1	1	3	3	94
	32	12JUN97	260, 200	2	3	2	3	1	3	3	2	2	3	3	3	2	3	3	3	116
329.007.00318	SC	22NOV96	-10, .	3	3	3	0	1	3	3	3	3	3	3	3	0	3	3	3	115
329.008.00157	SC	16AUG95	-14, -69	3	0	2	1	1	0	1	3	0	3	0	2	0	1	0	0	54
	8	24OCT95	56, 1	1	1	2	0	1	1	1	2	0	3	1	1	0	1	0	1	60
329.008.00160	SC	25OCT95	-7, -73	0	0	2	1	1	0	0	2	1	0	0	2	1	2	2	0	36
	8	05JAN96	66, -1	2	1	2	1	1	1	3	2	2	1	1	3	1	2	1	1	62
	32	23JUL96	266, 200	3	2	2	2	2	2	2	3	2	1	2	2	2	2	2	2	95
329.008.00188	SC	14DEC95	-21, .	0	1	1	0	0	1	1	1	1	0	1	1	0	1	2	1	41
	8	27FEB96	55, .	0	0	1	0	0	1	1	1	0	0	1	1	0	0	2	0	36
329.008.00271	SC	25JAN96	-46,-110	0	0	0	0	0	0	0	0	2	0	0	2	1	0	2	0	27
	8	14MAY96	65, 1	0	0	1	0	1	1	0	0	1	0	0	1	0	1	3	0	26
	32	05NOV96	240, 176	1	0	1	0	0	0	1	0	1	0	0	2	0	0	1	0	20
329.008.00275	SC	30APR96	-8, -63	1	0	1	1	.	0	2	2	2	0	0	2	0	1	2	0	40
	8	02JUL96	56, 1	1	1	2	1	1	2	2	2	2	1	1	1	2	1	3	1	67
	32	16DEC96	223, 168	0	1	1	0	2	3	2	2	2	0	1	1	0	2	3	2	63

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.009.00130	SC	12APR95	-6, -62	2	2	2	2	0	1	3	2	2	3	2	3	1	0	3	2	82
329.009.00131	SC	26APR95	-6, -62	1	2	0	2	1	0	2	2	3	1	2	3	0	3	0	2	70
	8	27JUN95	57, 1	1	3	3	3	3	1	3	3	3	1	3	3	1	3	0	3	106
329.009.00133	SC	07JUN95	-6, .	0	0	1	0	3	0	0	3	0	0	0	0	0	1	3	0	41
329.009.00138	SC	02OCT95	-8, .	0	0	1	0	3	0	0	0	0	0	0	3	1	0	1	0	42
329.009.00170	SC	26OCT95	-12, -69	2	2	2	2	3	1	2	2	0	2	2	0	0	3	2	2	71
	8	03JAN96	58, 1	1	2	1	2	3	0	2	2	0	1	2	0	0	3	3	2	65
	32	24JUN96	231, 174	2	1	2	1	3	0	1	1	0	1	1	1	0	3	2	0	57
329.009.00173	SC	08NOV95	-12, -75	3	0	2	3	0	3	2	1	2	2	1	1	.	3	3	2	73
	8	22JAN96	64, 1	0	0	1	1	3	2	0	1	.	3	3	2	1	3	1	3	71
329.009.00193	SC	21NOV95	-7, .	3	0	1	3	0	3	3	3	3	2	0	3	3	2	3	2	86
	8	24JAN96	58, .	2	0	1	2	1	3	0	1	3	2	0	2	2	1	3	0	73
329.009.00196	SC	11DEC95	-7, .	2	1	2	0	0	0	3	3	0	1	2	3	3	2	0	2	67
	8	12FEB96	57, .	1	3	0	3	1	0	3	3	2	1	3	0	1	2	0	1	87
329.009.00201	SC	31JAN96	-6, .	2	2	0	3	0	2	2	2	3	3	2	3	3	1	3	2	103
	8	02APR96	57, .	3	2	0	3	0	3	3	3	0	3	3	3	3	2	3	2	106
329.009.00204	SC	13MAR96	-6, -62	2	2	2	.	1	1	2	2	2	2	2	2	.	1	1	2	80
	8	14MAY96	57, 1	2	2	2	.	2	1	2	2	2	1	2	2	.	2	1	2	88

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.009.00235	SC	10DEC96	-8, -62	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3	2	102
	8	10FEB97	55, 1	1	2	2	2	2	2	2	2	2	1	1	2	2	2	2	2	89
329.009.00240	SC	03JAN97	-11, .	1	2	2	0	1	1	2	3	0	2	2	3	0	1	2	1	67
329.009.00303	SC	25MAR96	-8, -64	3	3	1	1	1	2	2	2	1	2	3	1	0	1	1	1	70
	8	28MAY96	57, 1	2	3	2	1	1	2	2	2	2	3	3	2	1	2	2	2	95
	32	10DEC96	253, 197	2	3	1	2	1	2	3	2	2	2	3	2	2	2	3	3	101
329.009.00304	SC	03APR96	-6, -62	2	2	1	2	3	2	0	2	2	2	1	1	2	1	3	0	75
	8	04JUN96	57, 1	2	2	1	3	1	1	2	3	2	2	2	2	2	1	3	2	88
329.009.00324	SC	21OCT96	-7, .	1	1	3	2	1	1	2	2	3	1	0	0	2	1	0	1	69
	8	27DEC96	61, .	2	2	3	3	3	2	3	3	3	2	3	3	2	3	3	3	108
329.009.00328	SC	30SEP96	-7, .	2	2	1	2	1	2	2	1	2	3	2	2	2	1	2	1	78
329.009.00329	SC	01OCT96	-8, .	1	1	2	1	1	1	2	2	3	3	2	3	1	2	2	2	83
	8	03DEC96	56, .	2	1	2	1	1	1	2	3	2	3	3	3	1	2	3	3	93
329.010.00182	SC	05DEC95	-14, .	1	2	1	1	0	1	1	2	2	1	1	1	1	1	3	1	57
329.010.00278	SC	02FEB96	-7, -63	1	0	1	1	2	1	1	1	1	0	0	3	0	2	3	0	47
	8	05APR96	57, 1	1	1	2	1	1	3	2	1	1	0	1	1	1	2	3	1	64
	32	19SEP96	224, 168	2	1	3	3	1	3	3	1	3	1	0	3	3	3	3	1	91
329.010.00280	SC	10MAY96	-7, -62	3	3	0	3	1	1	2	2	2	1	2	2	1	3	3	0	75

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.010.00280	8	11JUL96	56, 1	2	3	1	3	1	3	2	2	2	0	3	2	1	1	1	2	89
	12	21AUG96	97, 42	1	2	1	2	1	2	2	2	2	1	2	2	1	2	2	1	84
329.011.00283	SC	30JAN96	-9, -66	2	3	2	2	1	2	1	2	2	1	2	2	2	2	2	2	87
	8	04APR96	57, -1	2	3	2	3	1	1	3	3	3	3	3	3	3	3	3	3	105
329.011.00288	SC	01JUL96	-24, .	0	1	1	1	0	2	1	3	1	0	2	1	2	0	3	1	76
329.012.00025	SC	17OCT95	-7, .	1	0	1	2	1	2	2	1	3	0	1	2	1	1	2	2	64
	8	19DEC95	57, .	1	0	1	1	1	1	1	1	2	0	0	2	1	1	2	0	47
329.012.00220	SC	04JUN96	-13, -73	1	2	1	1	2	1	1	3	1	1	2	2	0	2	2	1	72
	8	16AUG96	61, 1	2	3	0	3	3	3	3	3	2	2	3	1	2	3	3	3	112
329.012.00222	SC	18JUN96	-10, -73	1	1	1	1	2	1	1	1	1	1	1	2	1	2	3	1	56
	8	30AUG96	64, 1	1	1	3	2	1	1	1	1	2	0	0	3	2	1	3	1	56
329.012.00226	SC	26NOV96	-7, .	2	1	1	1	1	1	1	3	1	3	2	1	1	2	3	1	75
329.012.00228	SC	04MAR97	-15, .	1	2	2	0	1	2	2	0	2	0	2	1	3	0	3	2	73
329.012.00231	SC	26FEB97	-9, -70	1	1	0	3	1	3	1	0	1	0	1	1	1	1	3	1	51
	8	07MAY97	62, 1	3	1	2	2	2	2	1	1	2	2	1	2	2	2	3	1	80
	24	19AUG97	166, 105	2	1	1	1	2	2	1	1	2	2	1	2	2	1	2	1	63

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.001.00061	SC	19JUL94	-10, .	1	3	2	2	3	3	3	1	0	1	3	0	0	3	3	3	88
329.001.00066	SC	14NOV94	-8, .	0	1	1	0	1	1	2	1	2	0	1	1	0	3	2	1	47
329.001.00067	SC	15NOV94	-7, .	1	2	1	.	0	2	1	1	1	1	1	2	0	0	3	1	50
329.001.00070	SC	14FEB95	-8, .	1	0	1	1	2	1	0	1	1	1	1	1	1	1	0	1	49
329.001.00122	SC	13JUN95	-7, -64	1	1	1	1	1	1	1	1	2	0	1	2	0	2	0	1	56
	8	16AUG95	58, 1	0	2	2	1	1	1	2	1	2	1	2	1	0	2	2	1	64
329.002.00050	SC	10MAR95	-13, .	2	2	2	3	0	1	2	3	3	2	0	2	0	1	3	2	85
	5	28APR95	37, .	1	2	2	2	1	2	2	3	2	2	1	2	1	1	2	2	83
329.002.00056	SC	24JUN94	-25, .	3	0	2	0	0	0	0	0	3	0	0	3	3	0	2	0	65
329.002.00057	SC	11AUG94	-28, -85	0	3	1	2	1	1	2	3	3	1	2	2	1	2	0	2	75
	8	03NOV94	57, -1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	130
	16	11JAN95	126, 69	1	3	0	3	1	1	3	3	3	0	3	3	1	3	1	3	90
329.002.00098	SC	20DEC94	-14, .	1	0	1	0	3	0	0	1	0	0	0	2	1	3	3	0	40
	8	02MAR95	59, .	0	0	1	0	3	1	0	1	0	0	0	3	2	3	3	0	51
329.002.00100	SC	16FEB95	-19, -77	2	1	3	3	0	2	.	1	1	2	1	3	2	1	2	1	76
	8	04MAY95	59, 1	1	2	3	2	1	2	2	2	1	1	2	3	3	1	3	2	92
	16	06JUL95	122, 64	2	2	3	2	1	2	2	2	1	2	2	3	3	2	3	2	93

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.002.00103	SC	11APR95	-9, -65	1	2	2	1	0	0	2	3	2	2	2	0	2	2	3	2	72
	8	15JUN95	57, 1	1	2	2	1	1	1	2	2	2	1	2	1	1	1	2	2	76
	16	10AUG95	113, 57	1	2	2	2	1	2	2	2	2	1	2	3	2	2	3	2	85
329.002.00104	SC	28APR95	-6, -62	1	1	1	1	1	1	1	1	2	2	1	2	1	1	2	1	62
	8	29JUN95	57, 1	1	1	2	1	1	2	1	1	2	2	1	2	1	1	1	1	67
	32	02JAN96	244, 188	2	2	0	2	1	2	2	2	2	2	2	3	1	1	2	2	82
329.002.00243	SC	27FEB96	-16, .	2	1	1	1	1	1	1	1	1	3	0	1	0	2	3	0	59
329.002.00244	SC	14MAR96	-7, -64	1	0	.	1	3	2	2	2	1	0	0	0	2	3	2	0	53
	8	16MAY96	57, -1	1	1	2	2	2	1	2	2	2	1	1	2	2	2	2	1	75
329.002.00321	SC	15MAY96	-8, .	2	2	2	1	1	0	2	2	2	3	2	3	1	2	1	2	80
329.002.00322	SC	06JAN97	-3, .	2	1	1	1	1	1	1	2	2	3	0	1	0	1	2	1	69
329.003.00073	SC	11JAN95	-8, .	1	1	1	1	1	1	1	1	1	1	1	1	2	1	2	1	53
329.003.00076	SC	24JAN95	-7, -62	0	0	3	1	1	2	1	1	0	0	1	1	2	0	3	1	53
	32	11OCT95	254, 199	1	3	3	3	2	3	3	3	3	2	3	3	3	3	3	3	119
329.003.00082	SC	11DEC95	1, .	1	0	1	0	1	0	1	1	1	1	0	1	2	0	1	0	30
329.003.00088	SC	06FEB95	-22, .	3	2	1	1	2	1	2	2	2	3	2	1	1	2	2	1	78
329.003.00090	SC	08MAR95	-6, .	1	2	1	1	2	0	1	0	0	2	1	2	0	2	2	1	48

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.003.00090	8	16MAY95	64, .	0	1	1	1	2	1	2	1	1	2	2	1	1	2	1	1	56
329.003.00092	SC	13APR95	-20, -78	0	1	2	3	0	1	3	0	0	0	2	2	1	0	1	1	70
	8	30JUN95	59, 1	3	2	2	2	3	0	0	3	0	0	0	3	3	3	3	3	106
	32	02JAN96	245, 187	2	3	1	2	0	3	3	0	3	0	2	2	1	0	3	3	96
329.003.00093	SC	08JUN95	-13, -76	0	2	2	3	1	2	2	2	3	0	2	3	1	2	3	2	80
	8	22AUG95	63, -1	0	3	3	3	2	0	3	2	3	1	3	3	1	3	3	3	102
	16	03OCT95	105, 42	0	1	3	3	3	1	3	3	3	0	0	3	0	3	3	2	87
329.003.00247	SC	05JAN96	-27, -81	0	2	1	1	2	0	2	1	1	3	3	2	1	2	1	2	64
	8	26MAR96	55, 1	1	2	1	1	2	1	1	1	1	1	2	1	2	1	1	2	62
329.003.00249	SC	01MAR96	-6, .	1	2	1	1	1	0	1	2	2	1	1	1	2	2	0	1	57
	8	30APR96	55, .	1	1	1	1	3	0	1	1	2	1	1	1	2	3	0	1	50
329.003.00289	SC	12FEB96	-16, -72	2	0	2	0	2	0	0	0	0	3	0	3	0	1	0	0	47
	8	24APR96	57, 1	2	2	3	2	2	1	2	2	2	2	2	3	2	2	1	2	87
	32	11OCT96	227, 171	3	2	3	2	2	2	2	2	3	3	2	3	3	2	3	3	115
329.003.00290	SC	06MAR96	-5, .	0	0	1	1	1	0	1	0	0	0	1	3	0	3	0	0	28
329.003.00314	SC	15OCT96	-7, .	0	2	3	0	0	1	0	1	2	0	1	3	2	1	0	0	47
329.003.00317	SC	12DEC96	-7, .	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	14
	8	11FEB97	55, .	0	0	1	1	1	1	0	1	1	0	0	2	0	1	1	0	25

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.004.00013	SC	05JUL94	-14, -73	1	1	2	0	1	0	1	2	2	1	1	3	0	2	3	1	59
	8	16SEP94	60, 1	1	2	2	1	2	1	2	2	2	1	2	3	1	2	1	2	77
329.004.00014	SC	22NOV94	-7, .	2	2	2	1	2	3	3	3	3	3	2	2	1	2	3	1	87
329.004.00211	SC	24JAN96	-9, .	3	2	3	2	2	2	2	2	3	3	1	3	2	3	3	2	109
329.004.00215	SC	12MAR97	-8, .	3	1	1	1	2	3	1	1	2	3	1	3	1	2	3	2	85
329.005.00003	SC	12SEP94	-8, .	2	0	0	2	3	1	2	0	1	2	0	3	0	3	3	1	64
329.005.00006	SC	27OCT94	-8, -68	1	3	2	0	2	0	3	2	0	1	3	2	0	2	0	3	85
	8	03JAN95	61, 1	2	3	3	1	2	2	2	3	0	2	3	3	2	2	0	3	100
	24	28APR95	176, 116	2	3	3	2	2	0	3	2	2	1	3	3	2	2	0	2	87
329.005.00007	SC	02NOV94	-7, -70	0	0	1	0	0	0	1	0	1	0	0	1	0	1	2	0	31
	8	11JAN95	64, 1	1	1	1	1	1	0	2	0	1	1	1	1	1	1	3	2	61
	32	09AUG95	274, 211	1	1	2	2	2	2	2	1	2	1	2	2	2	2	2	2	78
329.005.00009	SC	07DEC94	-5, .	1	0	1	0	1	0	0	1	1	1	0	1	1	1	2	0	29
	8	07FEB95	58, .	1	1	1	1	2	2	1	1	2	1	1	2	2	2	2	1	63
329.005.00110	SC	04JAN95	-7, .	0	2	1	3	1	1	2	2	2	0	2	3	3	2	3	1	80
329.005.00113	SC	20JAN95	-10, .	1	2	1	0	1	1	1	1	2	2	1	2	1	1	3	0	74
329.005.00117	SC	06MAR95	-12, .	1	1	1	1	2	2	1	1	1	1	1	2	1	1	1	1	57

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.005.00117	8	15MAY95	59, .	3	2	2	2	2	3	2	2	2	2	2	1	2	3	3	2	96
329.005.00118	SC	09MAY95	-8, .	2	1	2	1	0	0	0	2	1	1	1	2	0	0	2	0	47
329.005.00153	SC	11JAN96	-14, -70	0	1	1	3	0	2	2	1	2	0	1	2	0	1	3	2	59
	8	21MAR96	57, 1	1	1	1	2	2	3	2	2	2	2	1	2	2	2	3	2	83
	32	04SEP96	224, 168	0	1	2	2	2	3	3	2	2	1	2	2	2	2	2	2	77
329.005.00255	SC	26FEB96	-7, .	2	2	1	1	1	0	2	2	2	2	2	2	1	2	3	2	75
	8	29APR96	57, .	1	0	1	1	1	1	2	2	1	1	0	2	0	3	3	1	65
329.005.00256	SC	20FEB96	-14, -70	1	0	2	1	1	1	2	3	0	0	1	3	1	2	3	2	69
	8	30APR96	57, 1	1	2	.	.	0	3	2	3	0	1	1	3	1	3	3	2	76
	16	02JUL96	120, 64	1	1	2	1	1	1	2	3	0	1	1	3	1	2	3	2	75
329.005.00295	SC	21MAR96	-7, .	3	1	2	2	2	3	1	0	3	3	1	2	3	2	3	1	87
	8	22MAY96	56, .	3	2	1	2	1	2	2	1	3	3	2	2	2	2	3	1	83
329.005.00297	SC	28MAR96	-22, .	2	1	1	1	1	3	2	1	3	2	1	3	2	2	3	1	81
329.005.00332	SC	05DEC96	-7, .	2	1	2	1	1	1	1	0	2	2	1	1	1	1	3	1	53
	8	06FEB97	57, .	2	1	2	1	1	1	1	1	2	1	1	1	1	1	2	1	59
329.005.00335	SC	20FEB97	-8, .	1	2	3	1	3	3	1	2	1	0	3	3	1	3	3	2	93
	8	24APR97	56, .	1	2	1	2	2	2	2	2	2	1	2	3	1	2	3	2	87
329.006.00040	SC	10FEB95	-6, .	2	2	1	1	1	1	1	2	1	2	2	1	1	2	1	1	60

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.006.00041	SC	22MAR95	-14, -78	1	0	.	1	1	0	0	1	0	1	0	3	1	3	3	0	49
	8	31MAY95	57, -8	2	0	2	2	2	0	1	2	0	2	0	2	0	3	3	1	66
	32	21NOV95	231, 167	2	2	2	3	3	1	2	2	2	1	2	3	2	2	1	1	86
329.007.00139	SC	04MAY95	-4, .	2	0	1	2	1	1	3	2	1	2	0	3	2	2	3	1	69
329.007.00143	SC	26OCT95	-14, .	1	2	1	2	2	1	2	2	2	1	2	1	2	2	1	2	74
329.007.00146	SC	18JAN96	-7, -60	1	0	1	1	2	1	1	2	1	0	0	1	0	2	2	0	48
	8	18MAR96	54, 1	1	0	2	0	2	2	2	1	2	1	1	2	0	2	2	2	65
	32	09SEP96	229, 176	1	1	2	2	1	3	2	2	2	1	1	2	1	2	2	1	81
329.007.00269	SC	04APR96	-7, .	2	2	2	2	2	0	2	3	2	2	2	2	1	2	0	2	84
	3	02MAY96	22, .	2	2	2	2	2	2	2	3	2	3	2	2	2	2	2	2	99
329.007.00270	SC	02MAY96	-7, .	3	2	1	2	1	1	2	2	3	3	1	3	2	2	3	2	88
	7	27JUN96	50, .	3	2	2	2	2	1	2	2	2	3	2	2	1	2	2	2	84
329.007.00307	SC	09MAY96	-7, .	0	0	2	1	2	3	2	2	1	1	1	3	2	2	3	1	66
	8	25JUL96	71, .	1	0	3	1	2	1	2	1	1	0	0	3	0	2	3	0	52
329.007.00308	SC	27JUN96	-5, .	1	2	2	2	1	2	2	2	2	1	2	2	2	2	2	2	81
329.008.00159	SC	06SEP95	-7, -69	2	1	2	0	3	3	1	1	1	2	1	3	1	3	3	1	79
	8	14NOV95	63, 1	2	1	1	2	0	1	1	1	1	2	1	2	2	2	3	1	73
329.008.00161	SC	31OCT95	-16, -71	1	0	1	1	1	1	0	1	1	2	0	2	0	3	2	0	43

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.008.00161	8	10JAN96	56, 1	1	1	1	2	1	2	1	1	2	2	1	2	0	2	2	1	62
329.008.00187	SC	15NOV95	-14, .	1	2	2	1	1	0	1	2	0	0	1	2	1	2	2	1	52
	8	26JAN96	59, .	1	2	2	0	3	0	0	2	1	0	1	2	1	1	2	0	56
329.008.00192	SC	14FEB96	-20, .	3	1	2	1	1	1	2	3	2	3	1	1	1	2	3	1	82
329.008.00272	SC	19MAR96	-15, -71	2	3	1	1	1	0	2	2	0	1	2	3	1	1	3	3	60
	8	29MAY96	57, 1	2	3	0	3	1	0	3	3	3	1	3	3	2	2	3	3	80
329.008.00273	SC	19APR96	-28, -91	1	1	1	1	1	3	1	1	1	1	1	3	1	1	3	2	60
	8	19JUL96	64, 1	2	1	2	1	2	3	2	2	3	2	1	3	0	2	3	1	91
329.009.00127	SC	03APR95	-7, .	1	2	1	3	1	3	1	2	2	3	3	2	2	1	1	0	72
329.009.00132	SC	17MAY95	-6, -63	0	1	1	1	1	3	2	3	1	3	0	0	0	1	2	1	68
	8	19JUL95	58, 1	3	2	2	2	2	1	2	3	2	2	2	2	2	2	1	2	99
329.009.00134	SC	28JUN95	-8, .	2	2	1	1	1	0	1	1	2	0	2	2	1	2	0	0	50
	8	29AUG95	55, .	0	2	.	1	2	0	1	2	1	1	2	1	1	2	0	1	56
329.009.00137	SC	03OCT95	-7, .	1	2	1	1	1	1	2	1	1	1	1	2	0	1	2	1	52
	8	05DEC95	57, .	1	1	1	1	1	1	2	1	2	1	2	2	1	1	2	2	55
329.009.00171	SC	31OCT95	-7, .	1	0	1	2	2	0	0	1	1	0	0	3	1	1	0	0	42
329.009.00172	SC	06NOV95	-7, -64	2	2	3	0	2	0	2	0	0	2	2	3	1	3	2	1	69

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.009.00172	8	09JAN96	58, 1	2	2	2	2	2	2	2	1	1	2	2	3	2	2	2	2	86
	32	08JUL96	239, 182	2	2	1	2	3	3	3	2	2	2	2	3	2	3	3	2	93
329.009.00194	SC	28NOV95	-7, -63	1	1	1	2	1	0	3	3	2	2	0	3	0	1	0	0	56
	8	30JAN96	57, 1	1	3	3	1	1	1	0	1	2	3	1	2	0	1	3	2	74
	24	04JUN96	183, 127	2	2	2	0	2	1	2	3	0	2	1	3	1	3	2	2	81
329.009.00195	SC	06DEC95	-9, .	3	1	2	1	0	3	1	0	2	3	1	2	1	2	3	0	66
329.009.00199	SC	10JAN96	-6, .	0	0	1	0	2	1	0	0	0	0	0	0	0	2	2	0	29
	8	13MAR96	58, .	0	0	1	0	1	1	0	0	0	0	0	1	1	1	1	0	30
329.009.00203	SC	28FEB96	-5, .	2	2	1	2	3	1	2	1	2	2	1	3	1	3	1	2	75
329.009.00236	SC	17DEC96	-13, .	2	2	2	3	1	1	2	1	0	0	1	3	0	1	3	3	61
	4	27JAN97	29, .	2	1	2	2	1	1	2	1	1	0	2	1	1	1	3	1	66
329.009.00239	SC	11NOV96	-8, -65	1	0	2	1	1	0	0	1	0	1	0	1	1	1	1	0	40
	8	15JAN97	58, 1	2	0	1	1	1	1	1	1	0	1	0	1	1	1	1	0	48
329.009.00262	SC	07FEB97	-10, .	0	0	1	.	1	0	0	2	0	0	0	3	.	1	0	0	31
	8	14APR97	57, .	0	0	1	.	3	0	1	2	1	0	0	2	0	2	0	1	43
329.009.00264	SC	25OCT96	-7, .	2	2	3	3	2	3	2	2	1	1	1	2	1	2	3	1	84
	7	23DEC96	53, .	.	.	2	2	2	3	3	.	3	.	.	3	.	3	3	.	115
329.009.00301	SC	06MAR96	-13, -69	2	2	1	2	1	1	2	3	3	2	2	1	2	2	3	2	86

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.009.00301	8	14MAY96	57, 1	3	3	3	3	2	2	3	3	3	2	2	1	3	2	3	2	114
329.009.00305	SC	01MAY96	-6, -63	2	2	1	2	0	1	3	3	2	2	2	1	1	1	3	3	87
	8	03JUL96	58, 1	3	2	2	2	1	1	2	3	2	3	3	2	2	1	2	3	98
	32	10JAN97	249, 192	3	2	2	2	2	2	3	3	2	2	2	3	2	2	3	3	112
329.009.00325	SC	21AUG96	-6, -61	1	1	1	1	1	0	1	1	2	1	1	2	2	2	2	1	66
	8	21OCT96	56, 1	1	1	2	2	2	0	2	1	1	1	1	2	1	2	1	1	64
	16	16DEC96	112, 57	2	1	1	1	2	0	1	1	2	1	1	2	1	3	3	1	62
329.009.00326	SC	26AUG96	-10, -63	1	0	3	.	2	0	2	2	0	1	0	2	.	2	0	0	51
	8	28OCT96	54, 1	0	1	2	.	2	1	2	2	1	1	2	3	.	2	1	2	69
	16	16DEC96	103, 50	1	1	2	3	2	1	2	2	1	1	1	2	2	2	1	1	65
329.010.00279	SC	08MAR96	-14, -70	1	2	1	.	3	3	3	3	2	2	3	3	1	3	1	3	93
	8	17MAY96	57, 1	1	1	.	.	3	0	3	3	2	0	1	2	0	2	2	3	66
	32	06NOV96	230, 174	1	2	1	.	2	0	2	3	2	1	2	3	1	2	1	2	77
329.010.00281	SC	19JUL96	-7, -68	0	2	1	0	1	2	0	2	3	2	0	1	0	1	1	0	82
	8	25SEP96	62, 1	3	2	2	1	0	2	2	1	2	3	2	1	1	2	2	3	89
	24	03JAN97	162, 101	2	2	2	.	1	1	2	2	3	3	2	2	2	2	2	2	90
329.011.00163	SC	18NOV95	-7, .	1	0	1	3	0	0	0	0	0	0	0	0	3	2	1	0	48
329.011.00208	SC	22AUG96	-15, -74	0	0	2	1	2	0	2	3	1	1	0	2	1	2	0	2	56
	8	03NOV96	59, -1	0	2	2	2	3	1	2	3	2	0	2	3	2	3	1	3	83

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.011.00209	SC	23AUG96	-19, -81	1	2	3	2	2	1	2	2	2	3	2	3	2	2	2	1	89
	8	11NOV96	62, -1	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	95
329.011.00284	SC	13MAR96	-9, -65	2	1	3	0	2	0	2	2	1	1	1	3	0	3	2	1	65
	8	16MAY96	56, -1	2	2	3	2	3	2	3	3	2	0	2	3	2	3	3	3	112
329.011.00286	SC	15MAY96	-22, -90	1	1	1	2	0	3	1	1	2	0	1	1	2	1	3	2	65
	8	09AUG96	65, -4	1	1	2	1	1	3	2	2	2	0	1	2	2	1	3	2	74
329.012.00026	SC	09NOV95	-19, .	3	2	3	3	1	3	2	3	3	3	2	0	2	3	3	1	99
329.012.00219	SC	24MAY96	-7, -67	2	3	2	3	1	2	3	3	2	2	3	3	2	1	2	3	101
	8	30JUL96	61, 1	2	3	3	2	2	3	3	3	3	3	2	3	3	2	3	3	117
	32	24JAN97	239, 179	2	3	2	2	1	2	3	2	3	2	3	2	2	2	2	3	102
329.012.00221	SC	18JUN96	-7, -70	1	1	2	1	1	0	1	1	2	2	1	2	2	2	0	1	50
	8	27AUG96	64, 1	2	2	2	2	3	1	2	1	1	2	2	2	1	3	1	2	80
329.012.00223	SC	23AUG96	-7, .	0	0	1	0	2	0	2	0	1	0	0	3	0	3	2	0	39
329.012.00227	SC	12DEC96	-6, -75	1	0	0	0	0	0	0	1	1	2	0	2	0	0	0	0	27
	8	25FEB97	70, 1	1	1	1	1	0	0	0	1	2	2	1	2	0	1	0	0	42
	32	19AUG97	245, 176	.	1	2	1	0	0	1	2	3	0	1	3	1	2	0	0	56
329.012.00230	SC	20FEB97	-8, -77	2	1	1	2	1	1	1	0	1	0	2	1	0	2	2	2	57
	8	08MAY97	70, 1	0	2	1	1	2	2	2	2	3	0	2	2	1	2	1	3	69

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.001.00062	SC	06OCT94	-14, .	2	2	1	2	1	3	3	1	3	2	2	1	2	2	3	3	100
329.001.00064	SC	04NOV94	-6, -60	3	2	2	2	1	3	3	1	3	3	2	2	2	1	3	2	97
	8	03JAN95	55, 1	3	2	1	2	1	3	2	1	3	3	2	2	2	1	3	2	96
329.001.00069	SC	07FEB95	-9, .	1	1	2	0	1	0	0	1	0	0	1	1	0	2	3	0	42
	8	13APR95	57, .	1	1	2	1	1	1	0	1	2	0	1	1	2	2	3	1	68
329.001.00071	SC	02FEB95	-21, .	0	2	2	1	2	2	3	2	1	0	2	3	0	2	2	2	66
	8	20APR95	57, .	0	2	2	1	2	1	2	2	1	0	2	3	0	2	1	2	64
329.001.00123	SC	14DEC95	-21, .	0	1	1	1	1	1	0	0	2	0	0	1	1	1	3	0	41
329.001.00207	SC	19FEB96	-9, .	0	0	0	3	1	3	2	3	2	3	0	3	1	1	3	0	67
	8	24APR96	57, .	3	0	3	3	1	1	1	2	2	3	0	3	0	2	3	0	71
329.002.00049	SC	03MAR95	-6, .	1	1	1	.	1	0	2	3	2	1	1	1	.	1	1	3	61
	8	05MAY95	58, .	1	1	1	1	1	0	3	2	1	1	2	1	1	1	0	3	60
329.002.00059	SC	03NOV94	-7, .	2	2	1	2	0	1	3	3	2	1	2	2	2	2	0	3	64
	8	05JAN95	57, .	1	0	0	3	3	1	3	3	3	2	0	3	1	2	1	0	65
329.002.00060	SC	24JAN95	-7, -63	1	1	1	1	1	0	1	1	1	1	1	1	2	1	1	1	43
	8	28MAR95	57, 1	0	0	1	1	1	1	1	0	1	3	0	1	2	1	1	0	36
329.002.00097	.	.	., .	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	56
	SC	20DEC94	-14, -72	1	1	0	1	0	2	0	0	2	0	1	1	1	1	3	2	44

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.002.00097	8	02MAR95	59, 1	2	0	3	0	1	2	0	0	2	1	1	1	1	2	2	1	46
	32	05SEP95	246, 188	1	1	3	2	1	2	1	2	2	2	1	2	2	1	3	2	72
329.002.00101	SC	20MAR95	-8, -66	3	1	0	3	0	3	2	1	3	3	1	3	3	1	3	1	81
	8	25MAY95	59, 1	3	3	3	3	0	3	2	0	2	3	3	3	3	2	3	2	94
329.002.00107	SC	18JAN96	-7, -63	0	1	1	1	3	2	2	3	1	0	2	1	0	3	0	1	54
	8	21MAR96	57, 1	1	1	2	1	1	1	2	2	1	0	1	2	1	2	1	2	56
	32	26SEP96	246, 190	0	1	1	1	2	0	3	3	0	0	1	2	1	2	0	1	54
329.002.00241	SC	25JAN96	-12, -68	1	1	1	0	0	3	0	2	1	1	0	1	3	0	3	0	61
	8	02APR96	57, 1	3	3	3	3	3	3	3	3	3	2	2	3	3	2	3	3	111
329.002.00246	SC	01APR96	-17, .	2	2	2	2	1	0	2	0	2	3	1	3	1	3	0	1	61
	8	18JUN96	62, .	2	2	0	2	1	0	2	0	1	3	2	3	1	1	0	1	62
329.002.00320	SC	09MAY96	-7, -68	0	1	1	1	1	1	1	3	1	0	1	3	0	2	3	1	66
	8	16JUL96	62, 1	0	0	2	1	3	1	1	3	1	0	0	3	0	3	3	0	64
329.002.00323	SC	04NOV96	-8, -66	1	1	2	1	1	1	1	1	1	0	1	3	1	2	3	0	58
	8	09JAN97	59, 1	2	2	2	1	2	2	2	2	1	0	2	0	2	2	3	1	84
	32	12JUN97	213, 155	0	2	3	2	2	2	2	2	1	0	2	3	2	2	3	2	88
329.003.00074	32	11OCT95	260, 204	2	2	1	2	2	2	3	3	2	2	2	3	2	2	2	3	95
329.003.00078	8	21JUN95	57, .	1	1	2	1	1	3	1	2	2	1	1	1	1	1	3	1	64

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.003.00080	SC	22NOV95	-5, .	1	2	0	2	2	0	2	1	1	1	1	3	1	3	0	1	50
329.003.00085	SC	26OCT94	-13, .	0	1	1	1	1	0	1	1	1	0	1	2	1	1	3	1	42
	8	03JAN95	57, .	0	3	3	3	0	3	2	2	0	0	3	2	1	3	0	3	77
329.003.00086	SC	09NOV94	-19, -76	1	0	1	1	0	2	1	1	2	0	0	3	0	0	3	0	51
	8	23JAN95	57, -1	2	0	2	2	0	3	2	2	3	1	0	0	2	2	3	2	76
	32	17AUG95	263, 206	2	1	3	2	0	2	2	2	3	2	1	2	3	2	3	1	88
329.003.00094	8	19DEC95	57, .	1	0	1	1	1	1	0	0	2	0	0	2	0	3	2	0	45
329.003.00251	SC	19MAR96	-9, .	1	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	18
329.003.00252	SC	19MAR96	-22, .	0	1	3	3	0	3	2	3	3	0	2	0	2	0	3	2	82
	8	04JUN96	56, .	0	2	2	3	0	3	2	3	3	0	2	2	2	1	3	2	77
329.003.00291	SC	01JUL96	-2, -67	1	1	1	0	1	0	1	2	1	1	1	1	0	1	1	1	33
329.003.00315	SC	29OCT96	-14, .	1	1	1	1	1	0	1	1	2	0	1	1	1	1	3	1	53
	8	07JAN97	57, .	1	2	1	2	2	2	2	3	3	1	2	2	2	2	3	3	81
329.003.00316	SC	05DEC96	-12, .	3	2	1	1	1	3	1	1	3	0	1	3	1	1	3	1	72
	8	11FEB97	57, .	0	2	2	1	1	2	0	1	3	0	1	3	1	1	3	0	69
329.004.00016	SC	01MAR95	-12, .	0	3	3	3	1	3	2	3	3	0	3	3	3	2	3	2	104
	5	19APR95	38, .	0	3	2	3	1	3	1	3	3	0	3	3	2	1	2	1	90

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.004.00018	SC	19APR95	-14, .	1	1	1	1	1	0	0	0	0	0	1	3	2	1	3	0	43
	8	29JUN95	58, .	2	2	2	2	0	0	3	0	2	2	2	3	3	0	3	3	76
329.004.00020	SC	02NOV95	-7, .	1	0	1	1	1	0	0	0	2	1	1	2	1	1	3	0	53
	2	24NOV95	16, .	2	1	1	1	1	1	0	1	1	1	1	1	1	1	3	0	58
329.004.00213	SC	18JUL96	-15, -69	0	0	.	.	2	2	1	2	0	0	1	2	0	1	2	1	47
	8	24SEP96	54, -1	0	0	.	0	2	1	1	2	1	0	0	2	0	2	2	1	49
	32	19MAR97	230, 176	0	2	1	1	2	2	2	2	2	0	1	2	0	2	3	1	65
329.005.00001	SC	11APR94	-9, .	0	1	0	.	2	1	1	1	1	1	.	3	0	1	1	1	41
	8	15JUN94	57, .	.	0	.	.	2	1	.	1	.	0	.	3	.	3	0	1	50
329.005.00005	SC	24OCT94	-8, .	1	1	1	1	1	2	2	1	1	2	1	2	1	1	0	1	47
329.005.00010	SC	07DEC94	-6, -63	3	0	1	0	3	2	1	1	1	2	1	1	1	3	3	1	59
	8	08FEB95	58, 1	3	2	2	1	3	3	3	2	2	3	2	2	1	3	3	3	102
	32	09AUG95	240, 183	3	2	2	1	3	3	3	2	3	3	2	3	1	3	3	3	109
329.005.00012	SC	12DEC94	-7, -66	1	2	2	3	1	0	3	3	0	0	3	3	2	2	3	1	74
	8	16FEB95	60, 1	1	3	2	2	1	0	2	3	0	1	2	3	2	2	2	1	77
329.005.00111	SC	05JAN95	-6, -62	2	2	.	1	2	0	2	2	2	1	.	3	2	2	3	.	83
	8	08MAR95	57, 1	.	2	2	2	2	2	2	2	2	1	2	3	2	3	3	2	98
	16	03MAY95	113, 57	.	2	2	2	3	1	2	2	2	1	.	.	2	3	.	.	100
329.005.00114	SC	23JAN95	-8, -65	2	2	1	2	2	0	0	2	2	2	2	2	0	0	3	0	75

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.005.00114	8	29MAR95	58, 1	2	2	2	1	1	1	1	2	2	2	2	2	0	1	1	1	62
	16	17MAY95	107, 50	1	2	2	1	2	1	1	2	2	2	2	2	0	2	1	1	66
329.005.00115	8	18APR95	72, 1	1	2	1	2	1	1	2	2	2	2	2	2	1	2	1	2	76
329.005.00120	SC	22AUG95	-8, .	1	2	1	2	2	1	1	2	1	1	1	3	0	2	1	1	57
	8	26OCT95	58, .	2	1	2	2	2	2	2	3	1	2	1	3	0	1	2	2	68
329.005.00253	SC	31JAN96	-8, .	0	0	2	0	1	1	0	2	2	0	0	1	0	2	1	0	38
	8	03APR96	56, .	1	0	1	0	1	0	0	1	1	0	0	1	0	1	0	0	29
329.005.00254	SC	08FEB96	-7, -62	1	0	1	1	1	1	0	1	0	1	0	1	0	2	2	0	35
	8	10APR96	56, 1	1	0	1	0	1	2	1	1	2	1	0	1	1	2	2	1	56
	32	16OCT96	245, 190	1	1	1	1	1	1	2	2	2	1	0	2	1	2	2	2	63
329.005.00293	SC	06MAR97	-6, .	0	1	2	1	1	0	1	1	2	0	1	3	2	1	0	1	47
	8	07MAY97	57, .	0	1	2	0	1	1	1	2	2	0	1	3	0	1	1	1	51
329.005.00298	SC	15MAY96	-7, -63	1	0	1	0	1	2	0	2	1	2	0	2	0	1	3	0	54
	8	17JUL96	57, 1	1	1	1	0	1	2	0	2	2	2	0	2	2	1	3	0	60
	32	13JAN97	237, 181	2	1	2	1	1	1	0	2	2	2	0	2	1	1	2	.	62
329.005.00331	SC	14NOV96	-7, .	0	1	1	2	1	3	1	3	1	0	0	1	0	1	3	0	52
	8	16JAN97	57, .	0	1	1	1	1	2	1	3	2	0	1	1	2	2	2	1	64
329.005.00334	SC	24JAN97	-7, .	2	1	2	3	1	3	3	2	2	3	1	0	0	2	3	2	89
	8	27MAR97	56, .	3	2	3	3	1	3	3	3	3	3	1	0	3	3	3	3	114

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.006.00037	SC	20JAN95	-8, .	0	2	3	2	2	3	3	3	2	0	2	3	2	1	3	3	92
329.006.00042	SC	01DEC95	-6, -63	0	0	1	1	1	0	1	3	0	0	0	1	0	1	2	0	35
	8	02FEB96	58, 1	1	1	1	0	1	0	1	3	0	0	1	1	0	1	1	1	44
	32	16JUL96	223, 166	0	0	1	0	1	1	1	3	1	0	1	1	0	1	1	0	43
329.006.00259	SC	22APR96	-32, .	2	3	2	3	3	2	3	3	2	1	3	3	1	2	3	3	102
	8	17JUL96	55, .	2	2	3	3	3	3	3	3	3	2	3	3	2	2	3	3	114
329.007.00141	SC	14SEP95	-7, .	2	0	1	1	3	1	1	3	1	1	1	2	.	3	1	2	69
329.007.00144	SC	30NOV95	-7, -63	1	0	2	2	0	2	1	1	1	0	1	1	1	1	3	1	57
	8	01FEB96	57, 1	0	1	2	2	0	2	2	1	2	1	1	2	1	1	2	2	65
329.007.00266	SC	29FEB96	-7, .	1	3	1	1	1	3	2	2	2	2	2	1	2	1	3	2	80
	8	02MAY96	57, .	1	2	1	1	1	2	2	2	2	2	2	1	0	1	3	2	80
329.007.00267	SC	29FEB96	-7, .	1	1	2	1	1	1	1	1	2	1	1	2	1	1	1	1	57
	8	02MAY96	57, .	1	1	2	1	1	1	2	2	1	1	1	1	1	1	1	1	58
329.007.00311	SC	26SEP96	-7, -67	3	3	1	2	3	1	3	2	3	3	3	3	3	2	0	3	104
	8	02DEC96	61, 1	3	3	0	3	3	3	3	3	3	3	3	3	2	3	3	3	113
329.008.00158	SC	06SEP95	-7, -69	0	3	3	3	2	3	3	1	3	0	1	3	2	3	0	3	86
	8	14NOV95	63, 1	0	2	3	3	1	0	3	1	1	1	2	3	3	3	3	3	89
329.008.00162	SC	26OCT95	-6, -71	1	0	1	0	2	0	1	1	2	0	0	3	0	2	2	0	37

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Listing of Self-Perception Profile Scores by Treatment Group, Part II
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Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.008.00162	8	05JAN96	66, 1	1	1	3	1	1	0	2	2	2	1	1	3	0	1	3	1	59
	32	02JUL96	245, 180	1	2	3	1	2	1	2	3	2	2	.	3	1	2	3	.	93
329.008.00191	SC	12JAN96	-20, -81	0	0	0	0	1	0	0	1	1	2	0	1	0	1	0	0	26
	8	02APR96	62, 1	1	0	1	0	1	1	1	2	2	0	0	0	0	0	2	1	41
329.009.00128	SC	05APR95	-6, .	0	0	2	0	3	1	3	3	0	0	0	1	0	3	2	3	55
329.009.00129	SC	22MAR95	-20, .	2	0	1	1	0	1	2	0	2	1	0	2	0	3	2	0	44
329.009.00135	SC	25SEP95	-7, .	1	2	1	1	2	2	2	1	1	1	1	1	1	2	2	1	62
329.009.00136	SC	26SEP95	-7, .	0	1	1	1	1	1	0	0	1	0	0	2	1	1	1	0	27
	8	28NOV95	57, .	2	1	1	2	1	1	0	2	2	1	1	1	1	2	1	1	66
329.009.00169	SC	25OCT95	-6, -71	2	2	1	3	0	3	0	0	0	1	2	3	3	0	3	0	77
	8	27DEC95	58, -8	2	3	1	3	2	3	3	2	2	2	3	3	3	1	3	2	102
329.009.00174	SC	14NOV95	-7, -64	2	2	2	2	2	1	2	2	2	1	2	3	2	3	2	2	82
	8	17JAN96	58, 1	2	2	1	2	1	3	2	1	2	2	1	2	2	2	3	2	83
329.009.00197	SC	20DEC95	-9, -63	1	2	1	2	3	1	3	3	2	3	3	3	2	2	1	3	85
	8	20FEB96	54, -1	2	3	1	.	3	1	3	2	3	2	3	1	1	3	0	3	88
	32	20AUG96	236, 182	2	3	2	.	3	1	3	3	3	2	3	3	2	3	1	3	97
329.009.00198	SC	19DEC95	-14, .	1	2	2	2	2	3	2	2	3	0	2	3	3	3	3	1	98
	8	27FEB96	57, .	2	2	2	2	3	3	2	2	2	2	1	3	2	3	3	2	92

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*		Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.009.00200	SC	17JAN96	-6,	.	1	1	1	2	2	0	3	2	2	0	1	1	2	2	0	2	57
329.009.00202	SC	14FEB96	-6,	.	0	1	1	1	0	1	2	1	1	0	1	1	1	1	2	1	48
329.009.00238	SC	28OCT96	-15,	.	1	2	1	1	1	2	2	1	2	1	2	1	2	2	2	1	72
	8	07JAN97	57,	.	2	2	2	2	1	1	1	2	2	1	2	1	2	2	2	1	71
329.009.00276	SC	17JAN97	-4,	.	1	0	0	1	0	0	0	2	2	0	1	1	3	2	3	0	49
	8	18MAR97	57,	.	1	1	1	2	1	2	2	2	0	0	1	2	1	2	2	1	67
329.009.00302	SC	20MAR96	-7,	.	3	2	3	3	1	2	1	3	3	3	2	3	1	1	2	1	95
329.009.00306	SC	03JUN96	-8,	.	1	1	1	1	1	1	1	0	1	0	0	0	2	1	0	0	56
	8	06AUG96	57,	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	113
329.009.00312	SC	30OCT96	-5,	.	1	1	2	2	3	0	3	3	2	0	1	3	3	3	1	1	79
	8	06JAN97	64,	.	1	2	3	3	2	0	2	3	0	0	1	3	2	3	1	1	84
329.009.00327	SC	09SEP96	-7,	.	1	1	3	1	1	0	1	1	2	1	1	1	2	1	3	1	64
	5	21OCT96	36,	.	1	0	1	0	1	0	0	0	1	1	0	3	1	1	1	0	26
329.009.00330	SC	15OCT96	-6,	.	3	2	3	3	1	2	3	2	3	3	3	0	2	1	3	0	100
329.010.00183	SC	21NOV95	-12,	.	3	1	.	3	0	3	3	3	3	0	2	3	1	0	3	0	102
329.010.00263	SC	24JUL96	-16,	.	0	0	2	0	3	0	2	2	0	0	2	2	3	3	0	3	61
	8	09OCT96	62,	.	1	2	1	1	3	0	2	2	3	2	3	3	1	3	1	2	74

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.010.00277	SC	23FEB96	-7, -63	1	2	2	1	1	1	2	2	1	2	2	2	1	2	1	2	65
	8	26APR96	57, 1	3	3	3	3	0	3	3	3	3	3	3	3	3	3	3	3	125
	24	07AUG96	160, 104	3	3	0	3	3	0	3	3	3	3	3	0	0	3	0	3	100
329.010.00282	SC	19JUL96	-7, .	2	1	1	2	1	2	2	2	2	2	1	1	1	2	3	1	72
	8	27SEP96	64, .	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3	2	93
329.011.00164	SC	15DEC95	-7, .	2	2	1	2	1	1	2	1	3	3	2	3	3	2	3	2	92
329.011.00210	SC	13SEP96	-15, -81	2	2	2	2	1	3	2	2	3	1	1	3	2	2	0	3	71
	8	02DEC96	66, -1	0	1	1	1	2	1	2	2	3	0	1	3	0	2	3	3	67
329.011.00285	SC	08MAY96	-10, .	1	0	3	0	2	0	1	1	1	1	1	2	0	1	1	0	37
	8	24JUL96	68, .	1	1	2	1	2	1	2	1	1	1	1	2	1	1	2	1	56
329.011.00287	SC	25JUN96	-8, .	0	0	2	0	0	0	0	1	2	0	0	1	1	0	2	0	32
	8	27AUG96	56, .	0	1	1	1	1	3	2	1	2	0	1	2	2	2	3	2	69
329.012.00027	SC	23NOV95	-13, .	1	0	1	1	1	1	0	0	1	0	0	3	1	2	2	1	53
329.012.00217	SC	14MAY96	-7, .	0	1	1	1	0	0	2	1	0	0	0	0	1	1	2	2	33
329.012.00218	SC	04JUN96	-12, -70	2	0	1	1	1	3	0	1	1	1	0	0	1	1	3	0	52
	8	13AUG96	59, 1	2	2	1	2	1	3	2	1	2	1	2	0	2	2	3	2	81
329.012.00224	SC	30AUG96	-17, -83	1	1	2	.	2	2	2	2	0	0	1	3	0	2	0	2	55
	8	20NOV96	66, -1	1	1	2	.	2	2	2	2	1	0	2	3	0	2	1	2	67

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Paroxetine - Protocol 329
Appendix C.6
Listing of Self-Perception Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Self-Perception Profile Scores 30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
329.012.00225	SC	19NOV96	-7, -71	1	1	1	1	2	1	2	2	1	2	1	2	1	2	2	1	70
	8	29JAN97	65, 1	1	1	1	1	3	1	1	2	1	1	1	2	0	3	3	1	71
	32	30JUL97	247, 183	1	1	1	2	2	2	2	2	1	2	1	2	1	2	2	2	78

* days relative to start of acute phase, days relative to start of continuation phase
For items 1, 3, 5, 6, 7, 8, 11, 12, 17, 19, 21, 23, 24, 25, 27, 29, 31, 33, 36, 37, 38, 40, 41, 43 and 45, the most positive self-esteem rating is indicated by checking the farthest left-hand box on the form and by the highest numerical score of 3.
For items 2, 4, 9, 10, 13, 14, 15, 16, 18, 20, 22, 26, 28, 30, 32, 34, 35, 39, 42 and 44, the most positive self-esteem rating is indicated by checking the farthest right-hand box on the form and by the highest numerical score of 3.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.001.00063	SC	02NOV94	-6, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	No	No	No	No	2
329.001.00065	SC	07NOV94	-10, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	No	No	No	No	2
329.001.00068	SC	01FEB95	-7, .	Yes	Yes	No	No	Yes	No	No	3	Yes	Yes	No	No	Yes	Yes	4
	8	05APR95	57, .	No	Yes	No	No	Yes	Yes	No	3	Yes	Yes	Yes	No	Yes	No	4
329.001.00072	SC	07MAR95	-13, .	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.001.00121	SC	22MAR95	-13, -69	No	Yes	Yes	Yes	No	No	No	3	No	No	No	No	No	No	0
	8	30MAY95	57, 1	No	Yes	No	Yes	Yes	No	No	3	Yes	Yes	No	Yes	No	No	3
329.001.00205	SC	29JAN96	-9, .	Yes	Yes	No	No	No	No	No	2	No	No	Yes	No	No	No	1
329.001.00206	SC	12FEB96	-9, .	No	No	Yes	No	No	No	No	1	Yes	No	No	No	No	No	1
	8	17APR96	57, .	No	No	No	Yes	Yes	No	No	2	No	No	Yes	No	No	No	1
329.002.00055	SC	09JUN94	-15, -70	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	No	No	No	No	2
	8	18AUG94	56, 1	Yes	No	Yes	Yes	Yes	No	Yes	5	Yes	Yes	No	No	No	No	2
	20	10NOV94	140, 85	Yes	Yes	Yes	No	Yes	No	Yes	5	Yes	Yes	No	Yes	Yes	Yes	5
329.002.00058	SC	08SEP94	-12, -70	No	Yes	No	No	No	No	No	1	No	No	No	No	Yes	No	1
	8	17NOV94	59, 1	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.002.00099	SC	23FEB95	-7, -62	Yes	Yes	Yes	No	Yes	Yes	No	5	Yes	No	No	No	Yes	No	2
	8	25APR95	55, -1	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	No	No	No	No	No	1
	32	26OCT95	239, 184	Yes	Yes	Yes	Yes	Yes	No	Yes	6	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.002.00102	SC	03APR95	-10, -64	No	Yes	No	No	Yes	Yes	Yes	4	No	Yes	No	Yes	Yes	Yes	4
	8	06JUN95	55, 1	No	Yes	Yes	No	No	No	Yes	3	No	No	No	No	No	No	0
	32	05DEC95	237, 183	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.002.00105	SC	20JUL95	-7, .	Yes	No	No	Yes	No	Yes	Yes	4	Yes	Yes	No	No	Yes	Yes	4
329.002.00106	SC	20JUL95	-7, .	Yes	Yes	No	Yes	No	Yes	No	4	Yes	No	No	No	No	Yes	2
329.002.00242	SC	26JAN96	-12, -70	No	Yes	No	No	No	Yes	No	2	Yes	Yes	No	Yes	Yes	No	4
	20	10JUL96	155, 97	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.002.00245	SC	21MAR96	-7, .	Yes	No	Yes	No	No	Yes	No	3	Yes	No	No	No	No	No	1
329.002.00319	SC	23APR96	-7, -63	No	Yes	No	No	Yes	Yes	No	3	Yes	Yes	Yes	Yes	Yes	No	5
	8	25JUN96	57, 1	No	No	No	No	Yes	Yes	No	2	No	No	No	No	No	No	0
	32	17DEC96	232, 176	No	Yes	No	No	Yes	No	No	2	Yes	No	No	No	No	Yes	2
329.003.00075	SC	18JAN95	-7, -63	No	Yes	Yes	Yes	No	No	Yes	4	Yes	Yes	Yes	No	No	Yes	4
	8	22MAR95	57, 1	No	No	Yes	No	Yes	No	No	2	Yes	Yes	Yes	No	No	No	3
	32	13SEP95	232, 176	No	No	No	No	No	Yes	No	1	No	Yes	No	No	Yes	No	2
329.003.00077	SC	01MAR95	-5, -64	Yes	Yes	Yes	Yes	No	Yes	Yes	6	Yes	Yes	No	Yes	No	No	3
329.003.00081	SC	04DEC95	-7, .	Yes	No	Yes	Yes	Yes	Yes	Yes	6	No	Yes	No	No	Yes	No	2
329.003.00087	SC	23JAN95	-8, .	Yes	Yes	Yes	Yes	No	No	Yes	5	No	No	No	Yes	No	No	1
329.003.00089	SC	24FEB95	-11, .	No	Yes	Yes	No	No	No	No	2	Yes	No	No	No	No	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.003.00089	8	02MAY95	57, .	No	Yes	No	No	No	Yes	No	2	No	No	No	No	No	No	0
329.003.00091	8	16MAY95	54, -1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	32	07NOV95	229, 175	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.003.00248	SC	14FEB96	-16, .	No	Yes	Yes	No	No	Yes	Yes	4	Yes	No	No	No	No	No	1
	8	23APR96	54, .	Yes	Yes	No	No	No	Yes	No	3	Yes	No	No	No	No	No	1
329.003.00250	SC	05MAR96	-9, -66	Yes	Yes	Yes	Yes	Yes	No	No	5	Yes	Yes	No	Yes	Yes	No	4
	8	09MAY96	57, -1	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	No	No	No	No	Yes	2
329.003.00292	SC	02AUG96	-5, -63	No	Yes	No	No	Yes	Yes	Yes	4	Yes	No	No	No	No	No	1
	8	04OCT96	59, 1	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.003.00313	SC	08MAY96	-9, .	Yes	No	Yes	Yes	No	Yes	Yes	5	Yes	Yes	Yes	Yes	Yes	Yes	6
329.004.00015	SC	30NOV94	-8, -65	No	Yes	No	Yes	No	Yes	No	3	Yes	Yes	Yes	Yes	Yes	Yes	6
	8	03FEB95	58, 1	No	Yes	No	No	No	No	No	1	No	Yes	Yes	Yes	Yes	Yes	5
	28	14JUN95	189, 132	No	Yes	No	No	No	No	No	1	No	Yes	Yes	Yes	Yes	No	4
329.004.00017	SC	15MAR95	-7, -63	No	Yes	No	No	Yes	Yes	No	3	No	Yes	No	No	No	No	1
	8	17MAY95	57, 1	No	Yes	No	No	No	Yes	No	2	No	No	No	No	No	No	0
	32	01NOV95	225, 169	No	No	No	No	Yes	Yes	No	2	No	No	No	No	No	No	0
329.004.00019	SC	24MAY95	-7, .	Yes	Yes	Yes	Yes	No	Yes	Yes	6	Yes	No	No	Yes	Yes	No	3
329.004.00212	SC	24MAY96	-10, .	No	Yes	No	Yes	Yes	Yes	Yes	5	Yes	Yes	Yes	.	No	No	4

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.004.00214	SC	27SEP96	-7, -67	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	No	Yes	Yes	5
	8	03DEC96	61, 1	Yes	No	Yes	Yes	Yes	No	No	4	Yes	Yes	Yes	No	No	Yes	4
329.005.00002	SC	20MAY94	-5, -61	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	Yes	No	No	2
329.005.00004	SC	22SEP94	-18, -77	No	Yes	No	No	Yes	Yes	No	3	No	No	Yes	No	No	No	1
	8	08DEC94	60, 1	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.005.00008	SC	10NOV94	-6, -61	No	No	No	No	No	Yes	No	1	No	No	No	No	No	No	0
	8	10JAN95	56, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	No	No	No	1
	24	10MAY95	176, 121	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.005.00011	SC	06DEC94	-7, -63	No	Yes	Yes	No	Yes	No	Yes	4	No	Yes	Yes	Yes	Yes	Yes	5
	8	07FEB95	57, 1	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	Yes	2
329.005.00109	SC	22DEC94	-8, -61	No	Yes	Yes	Yes	Yes	Yes	Yes	6	Yes	Yes	No	No	Yes	Yes	4
	8	21FEB95	54, 1	No	Yes	No	Yes	No	No	Yes	3	No	No	No	No	No	No	0
329.005.00112	SC	17JAN95	-9, -64	Yes	Yes	Yes	Yes	No	No	Yes	5	Yes	Yes	Yes	No	Yes	No	4
	8	22MAR95	56, 1	No	No	No	No	No	No	No	0	No	No	Yes	Yes	Yes	No	3
	20	21JUN95	147, 92	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.005.00116	SC	30JAN95	-8, -66	No	Yes	No	No	No	No	No	1	No	No	No	Yes	No	No	1
	8	06APR95	59, 1	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	24	26JUL95	170, 112	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.005.00119	SC	27JUN95	-14, -73	No	No	Yes	No	Yes	Yes	No	3	Yes	No	No	No	Yes	Yes	3
	8	08SEP95	60, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.005.00119	24	02JAN96	176, 117	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.005.00151	SC	29AUG95	-8, -65	No	Yes	No	No	No	No	No	1	No	No	No	No	Yes	No	1
	8	02NOV95	58, 1	No	Yes	No	No	No	No	No	1	No	Yes	No	No	No	No	1
	32	01MAY96	239, 182	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.005.00152	SC	12OCT95	-14, .	No	No	No	No	Yes	No	No	1	No	No	No	No	No	No	0
329.005.00257	SC	05MAR96	-6, -62	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	8	06MAY96	57, 1	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	32	21OCT96	225, 169	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.005.00258	SC	06FEB96	-35, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	8	07MAY96	57, .	No	Yes	No	No	No	No	No	1	Yes	Yes	No	No	No	No	2
329.005.00299	SC	28MAY96	-11, -71	Yes	Yes	Yes	No	Yes	Yes	No	5	No	Yes	Yes	Yes	Yes	No	4
	8	07AUG96	61, 1	No	Yes	No	No	No	No	No	1	No	Yes	Yes	No	Yes	No	3
	20	05NOV96	151, 91	No	Yes	No	No	No	No	No	1	No	Yes	No	Yes	Yes	No	3
329.005.00300	SC	12SEP96	-7, .	No	Yes	No	No	No	Yes	No	2	Yes	No	No	No	No	No	1
	8	14NOV96	57, .	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.005.00333	SC	15JAN97	-8, .	Yes	Yes	Yes	No	Yes	No	No	4	No	Yes	No	No	No	No	1
329.005.00336	SC	26FEB97	-6, .	Yes	No	Yes	Yes	Yes	No	Yes	5	No	Yes	No	Yes	Yes	Yes	4
	8	30APR97	58, .	Yes	Yes	Yes	Yes	No	No	Yes	5	Yes	Yes	No	No	Yes	Yes	4
329.006.00038	SC	01FEB95	-14, .	No	No	Yes	No	Yes	Yes	Yes	4	No	Yes	No	No	No	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.006.00039	SC	03FEB95	-5, -66	Yes	Yes	No	Yes	Yes	Yes	Yes	6	Yes	No	No	No	No	No	1
	8	05APR95	57, -5	Yes	Yes	No	Yes	Yes	No	No	4	Yes	No	No	No	No	No	1
329.006.00260	SC	12JUL96	-6, -64	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	8	18SEP96	63, 5	Yes	Yes	No	No	No	No	Yes	3	No	No	No	No	No	No	0
329.006.00261	SC	07NOV96	-19, -77	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	Yes	Yes	Yes	6
	8	23JAN97	59, 1	Yes	No	Yes	Yes	Yes	Yes	Yes	6	Yes	No	No	No	Yes	No	2
329.007.00140	SC	07SEP95	-8, -63	No	No	No	No	Yes	No	No	1	No	No	No	No	No	No	0
	8	09NOV95	56, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.007.00142	SC	12OCT95	-6, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	Yes	No	Yes	Yes	5
	8	21DEC95	65, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	Yes	No	Yes	No	4
329.007.00145	SC	04JAN96	-7, -63	Yes	Yes	No	No	No	No	No	2	Yes	No	No	No	No	No	1
	8	07MAR96	57, 1	Yes	Yes	No	No	No	No	No	2	Yes	No	No	No	No	Yes	2
	32	23AUG96	226, 170	No	No	No	No	No	No	No	0	Yes	No	No	Yes	No	No	2
329.007.00265	SC	25JAN96	-7, .	No	No	No	No	No	Yes	No	1	No	No	No	No	No	No	0
329.007.00268	SC	21MAR96	-11, -70	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	Yes	No	Yes	Yes	5
	8	30MAY96	60, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	32	05DEC96	249, 190	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.007.00294	SC	20FEB97	-8, .	Yes	Yes	Yes	No	Yes	Yes	Yes	6	No	Yes	No	No	Yes	No	2
329.007.00309	SC	02JUL96	-13, -65	Yes	Yes	Yes	No	No	Yes	Yes	5	No	Yes	Yes	Yes	Yes	No	4

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.007.00309	7	05SEP96	53, 1	No	Yes	No	No	No	No	Yes	2	No	Yes	No	No	No	No	1
	32	13MAR97	242, 190	No	No	Yes	No	Yes	Yes	Yes	4	Yes	Yes	No	No	No	Yes	3
329.007.00310	SC	19SEP96	-7, -67	No	Yes	No	No	No	No	No	1	No	Yes	No	Yes	Yes	No	3
	8	25NOV96	61, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	Yes	1
	32	12JUN97	260, 200	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.007.00318	SC	22NOV96	-10, .	No	Yes	No	No	No	No	No	1	No	Yes	No	No	No	No	1
329.008.00157	SC	16AUG95	-14, -69	Yes	Yes	No	No	No	Yes	Yes	4	Yes	No	No	Yes	Yes	No	3
	8	24OCT95	56, 1	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.008.00160	SC	25OCT95	-7, -73	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	No	No	Yes	Yes	4
	8	05JAN96	66, -1	No	No	No	No	Yes	No	No	1	Yes	No	No	No	No	No	1
	32	23JUL96	266, 200	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.008.00188	SC	14DEC95	-21, .	No	Yes	Yes	Yes	No	Yes	No	4	Yes	Yes	No	Yes	No	Yes	4
	8	27FEB96	55, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	No	Yes	No	Yes	4
329.008.00271	SC	25JAN96	-46,-110	Yes	Yes	Yes	Yes	No	Yes	Yes	6	Yes	No	No	No	No	No	1
	8	14MAY96	65, 1	Yes	Yes	Yes	Yes	No	No	No	4	Yes	No	No	No	Yes	No	2
	32	05NOV96	240, 176	Yes	Yes	Yes	Yes	No	Yes	Yes	6	Yes	No	No	No	No	Yes	2
329.008.00275	SC	30APR96	-8, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	No	Yes	No	4
	8	02JUL96	56, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	32	16DEC96	223, 168	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.009.00130	SC	12APR95	-6, -62	No	No	Yes	No	No	Yes	Yes	3	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
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Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.009.00130	8	13JUN95	57, 1	No	No	No	No	No	No	Yes	1	No	Yes	No	No	No	No	1
329.009.00131	SC	26APR95	-6, -62	No	Yes	No	No	No	Yes	No	2	No	No	No	No	No	No	0
	8	27JUN95	57, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.009.00133	SC	07JUN95	-6, .	Yes	Yes	Yes	Yes	No	Yes	No	5	Yes	Yes	Yes	Yes	Yes	Yes	6
329.009.00138	SC	02OCT95	-8, .	No	Yes	Yes	No	Yes	Yes	Yes	5	No	No	Yes	Yes	Yes	Yes	4
329.009.00170	SC	26OCT95	-12, -69	No	Yes	No	No	No	No	No	1	Yes	No	Yes	No	No	Yes	3
	8	03JAN96	58, 1	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
	32	24JUN96	231, 174	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.009.00173	SC	08NOV95	-12, -75	No	No	No	No	No	Yes	No	1	Yes	No	No	Yes	Yes	Yes	4
	8	22JAN96	64, 1	Yes	Yes	No	No	Yes	Yes	Yes	5	No	No	Yes	No	Yes	Yes	3
329.009.00193	SC	21NOV95	-7, .	Yes	.	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	No	No	No	Yes	3
	8	24JAN96	58, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	No	No	No	1
329.009.00196	SC	11DEC95	-7, .	Yes	Yes	No	Yes	No	Yes	No	4	Yes	Yes	No	No	No	No	2
	8	12FEB96	57, .	Yes	No	Yes	Yes	Yes	No	No	4	Yes	Yes	Yes	No	No	No	3
329.009.00201	SC	31JAN96	-6, .	Yes	No	Yes	No	Yes	Yes	Yes	5	No	No	Yes	No	Yes	No	2
	8	02APR96	57, .	No	No	Yes	No	No	Yes	No	2	No	No	No	No	.	.	0
329.009.00204	SC	13MAR96	-6, -62	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	8	14MAY96	57, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.009.00235	SC	10DEC96	-8, -62	No	No	No	No	No	No	No	0	No	No	No	No	Yes	No	1
	8	10FEB97	55, 1	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.009.00240	SC	03JAN97	-11, .	No	Yes	No	No	No	No	No	1	Yes	Yes	No	No	No	No	2
329.009.00303	SC	25MAR96	-8, -64	No	Yes	No	No	Yes	Yes	No	3	No	Yes	No	No	No	No	1
	8	28MAY96	57, 1	No	No	No	No	No	No	No	0	Yes	Yes	No	No	No	No	2
	32	10DEC96	253, 197	No	Yes	Yes	No	Yes	No	No	3	No	No	No	No	No	No	0
329.009.00304	SC	03APR96	-6, -62	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	Yes	Yes	Yes	Yes	6
	8	04JUN96	57, 1	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.009.00324	SC	21OCT96	-7, .	No	Yes	No	No	No	Yes	No	2	Yes	Yes	Yes	No	No	No	3
	8	27DEC96	61, .	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.009.00328	SC	30SEP96	-7, .	No	No	No	No	No	No	No	0	Yes	Yes	No	Yes	Yes	Yes	5
329.009.00329	SC	01OCT96	-8, .	No	Yes	No	Yes	No	No	No	2	No	No	Yes	No	Yes	No	2
	8	03DEC96	56, .	No	Yes	No	No	No	No	Yes	2	No	No	Yes	No	Yes	No	2
329.010.00182	SC	05DEC95	-14, .	No	Yes	No	No	Yes	Yes	Yes	4	Yes	Yes	No	Yes	Yes	Yes	5
329.010.00278	SC	02FEB96	-7, -63	Yes	Yes	No	No	Yes	Yes	Yes	5	No	Yes	No	No	Yes	No	2
	8	05APR96	57, 1	No	No	Yes	No	No	Yes	No	2	Yes	No	No	Yes	No	Yes	3
	32	19SEP96	224, 168	Yes	Yes	Yes	No	Yes	No	No	4	Yes	No	No	No	No	No	1
329.010.00280	SC	10MAY96	-7, -62	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
	8	11JUL96	56, 1	Yes	Yes	No	No	No	No	No	2	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.010.00280	12	21AUG96	97, 42	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.011.00283	SC	30JAN96	-9, -66	Yes	Yes	Yes	Yes	No	No	No	4	Yes	Yes	No	No	No	No	2
	8	04APR96	57, -1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.011.00288	SC	01JUL96	-24, .	No	Yes	Yes	Yes	Yes	Yes	Yes	6	Yes	No	No	Yes	Yes	Yes	4
329.012.00025	SC	17OCT95	-7, .	Yes	No	No	Yes	Yes	Yes	No	4	Yes	No	Yes	No	Yes	Yes	4
	8	19DEC95	57, .	Yes	No	No	Yes	Yes	Yes	Yes	5	Yes	Yes	Yes	No	Yes	No	4
329.012.00220	SC	04JUN96	-13, -73	Yes	Yes	No	Yes	No	Yes	Yes	5	No	Yes	No	No	No	No	1
	8	16AUG96	61, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.012.00222	SC	18JUN96	-10, -73	No	Yes	Yes	No	Yes	Yes	Yes	5	Yes	Yes	No	No	Yes	No	3
	8	30AUG96	64, 1	No	No	No	Yes	No	Yes	No	2	Yes	No	No	No	No	No	1
329.012.00226	SC	26NOV96	-7, .	Yes	Yes	No	Yes	No	Yes	Yes	5	Yes	Yes	No	Yes	No	Yes	4
329.012.00228	SC	04MAR97	-15, .	No	Yes	Yes	Yes	Yes	Yes	Yes	6	No	No	No	No	No	No	0
329.012.00231	SC	26FEB97	-9, -70	Yes	No	Yes	Yes	Yes	No	No	4	Yes	Yes	Yes	Yes	No	No	4
	8	07MAY97	62, 1	Yes	Yes	No	Yes	No	No	No	3	Yes	No	No	No	No	No	1
	24	19AUG97	166, 105	Yes	No	Yes	Yes	Yes	No	Yes	5	Yes	Yes	Yes	Yes	Yes	Yes	6

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.001.00061	SC	19JUL94	-10, .	Yes	Yes	No	No	No	Yes	.	4	Yes	No	No	No	No	No	1
329.001.00066	SC	14NOV94	-8, .	Yes	Yes	Yes	No	Yes	No	No	4	Yes	Yes	Yes	Yes	Yes	Yes	6
329.001.00067	SC	15NOV94	-7, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.001.00070	SC	14FEB95	-8, .	No	Yes	No	Yes	No	No	No	2	Yes	Yes	No	No	No	No	2
329.001.00122	SC	13JUN95	-7, -64	No	No	No	No	No	No	No	0	No	Yes	No	No	No	No	1
	8	16AUG95	58, 1	No	Yes	No	No	No	No	No	1	No	No	No	.	No	No	0
329.002.00050	SC	10MAR95	-13, .	Yes	Yes	No	Yes	Yes	Yes	Yes	6	No	No	No	No	No	No	0
	5	28APR95	37, .	Yes	Yes	No	No	Yes	No	No	3	Yes	No	No	No	No	No	1
329.002.00056	SC	24JUN94	-25, .	Yes	No	Yes	Yes	Yes	No	No	4	Yes	Yes	No	No	No	No	2
329.002.00057	SC	11AUG94	-28, -85	Yes	Yes	No	Yes	No	Yes	No	4	No	No	No	No	No	Yes	1
	8	03NOV94	57, -1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	16	11JAN95	126, 69	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.002.00098	SC	20DEC94	-14, .	No	Yes	Yes	Yes	Yes	Yes	Yes	6	Yes	No	No	No	No	No	1
	8	02MAR95	59, .	No	Yes	Yes	No	Yes	Yes	No	4	Yes	No	No	Yes	No	No	2
329.002.00100	SC	16FEB95	-19, -77	No	Yes	No	No	Yes	No	Yes	3	Yes	Yes	No	No	No	No	2
	8	04MAY95	59, 1	No	No	No	Yes	No	No	No	1	Yes	No	No	No	No	No	1
	16	06JUL95	122, 64	No	No	No	No	Yes	No	Yes	2	No	No	No	No	No	No	0
329.002.00103	SC	11APR95	-9, -65	No	Yes	No	No	Yes	Yes	No	3	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.002.00103	8	15JUN95	57, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	16	10AUG95	113, 57	No	No	No	Yes	Yes	Yes	No	3	Yes	No	No	No	No	No	1
329.002.00104	SC	28APR95	-6, -62	Yes	Yes	No	Yes	Yes	Yes	No	5	Yes	No	No	No	No	No	1
	8	29JUN95	57, 1	No	Yes	Yes	No	No	No	No	2	Yes	No	No	No	No	No	1
	32	02JAN96	244, 188	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	No	No	No	1
329.002.00243	SC	27FEB96	-16, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	Yes	Yes	No	5
329.002.00244	SC	14MAR96	-7, -64	No	Yes	Yes	Yes	No	Yes	No	4	Yes	Yes	No	No	No	No	2
	8	16MAY96	57, -1	Yes	No	No	Yes	No	No	No	2	Yes	No	No	No	No	No	1
329.002.00321	SC	15MAY96	-8, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	Yes	No	No	2
329.002.00322	SC	06JAN97	-3, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.003.00073	SC	11JAN95	-8, .	Yes	Yes	No	Yes	No	Yes	Yes	5	Yes	Yes	No	Yes	Yes	Yes	5
329.003.00076	SC	24JAN95	-7, -62	No	Yes	Yes	Yes	Yes	No	Yes	5	Yes	No	No	No	Yes	No	2
	32	11OCT95	254, 199	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.003.00082	SC	11DEC95	1, .	No	Yes	Yes	No	Yes	Yes	No	4	Yes	Yes	No	Yes	Yes	No	4
329.003.00088	SC	06FEB95	-22, .	Yes	Yes	No	Yes	No	No	Yes	4	Yes	Yes	Yes	No	Yes	Yes	5
329.003.00090	SC	08MAR95	-6, .	No	Yes	No	Yes	No	Yes	.	4	No	No	No	No	No	No	0
	8	16MAY95	64, .	No	Yes	No	Yes	No	Yes	Yes	4	No	No	No	No	Yes	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.003.00092	SC	13APR95	-20, -78	No	No	No	No	Yes	No	No	1	No	No	No	No	No	No	0
	8	30JUN95	59, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	32	02JAN96	245, 187	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.003.00093	SC	08JUN95	-13, -76	Yes	No	Yes	No	Yes	No	Yes	4	Yes	Yes	No	No	Yes	Yes	4
	8	22AUG95	63, -1	Yes	No	No	No	No	No	Yes	2	Yes	Yes	No	Yes	No	Yes	4
	16	03OCT95	105, 42	No	No	Yes	No	No	No	Yes	2	Yes	No	No	No	Yes	No	2
329.003.00247	SC	05JAN96	-27, -81	Yes	Yes	Yes	No	Yes	Yes	Yes	6	Yes	Yes	Yes	Yes	Yes	Yes	6
	8	26MAR96	55, 1	Yes	Yes	No	No	No	No	Yes	3	Yes	No	Yes	No	Yes	No	3
329.003.00249	SC	01MAR96	-6, .	Yes	Yes	No	Yes	No	No	No	3	Yes	No	No	No	No	No	1
	8	30APR96	55, .	No	Yes	No	Yes	No	No	Yes	3	No	No	No	Yes	No	No	1
329.003.00289	SC	12FEB96	-16, -72	No	No	No	No	Yes	Yes	No	2	No	No	No	No	No	No	0
	8	24APR96	57, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.003.00290	SC	06MAR96	-5, .	No	Yes	No	No	No	Yes	No	2	Yes	Yes	No	Yes	No	No	3
329.003.00314	SC	15OCT96	-7, .	Yes	Yes	Yes	Yes	No	No	Yes	5	Yes	Yes	Yes	Yes	Yes	Yes	6
329.003.00317	SC	12DEC96	-7, .	No	Yes	Yes	No	Yes	Yes	No	4	Yes	Yes	No	Yes	Yes	Yes	5
	8	11FEB97	55, .	No	Yes	No	No	No	No	No	1	Yes	No	No	Yes	Yes	Yes	4
329.004.00013	SC	05JUL94	-14, -73	No	Yes	No	Yes	Yes	Yes	Yes	5	Yes	Yes	No	No	No	No	2
	8	16SEP94	60, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.004.00014	SC	22NOV94	-7, .	Yes	Yes	No	Yes	Yes	Yes	No	5	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.004.00211	SC	24JAN96	-9, .	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.004.00215	SC	12MAR97	-8, .	Yes	Yes	Yes	Yes	Yes	No	No	5	Yes	No	No	No	No	No	1
329.005.00003	SC	12SEP94	-8, .	Yes	No	Yes	Yes	Yes	No	Yes	5	No	Yes	Yes	Yes	Yes	Yes	5
329.005.00006	SC	27OCT94	-8, -68	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
	8	03JAN95	61, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	24	28APR95	176, 116	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.005.00007	SC	02NOV94	-7, -70	Yes	Yes	Yes	Yes	Yes	No	No	5	No	Yes	Yes	Yes	Yes	Yes	5
	8	11JAN95	64, 1	Yes	Yes	Yes	No	No	No	.	4	No	No	Yes	No	Yes	Yes	3
	32	09AUG95	274, 211	No	No	No	No	No	No	No	0	No	Yes	No	No	Yes	Yes	3
329.005.00009	SC	07DEC94	-5, .	Yes	Yes	Yes	No	Yes	Yes	Yes	6	No	No	No	No	Yes	Yes	2
	8	07FEB95	58, .	Yes	No	No	No	Yes	Yes	No	3	No	No	No	No	No	No	0
329.005.00110	SC	04JAN95	-7, .	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.005.00113	SC	20JAN95	-10, .	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.005.00117	SC	06MAR95	-12, .	Yes	Yes	No	Yes	No	Yes	No	4	Yes	Yes	Yes	No	Yes	No	4
	8	15MAY95	59, .	No	Yes	No	No	No	No	No	1	No	Yes	No	No	No	No	1
329.005.00118	SC	09MAY95	-8, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	Yes	No	Yes	5
329.005.00153	SC	11JAN96	-14, -70	Yes	Yes	No	Yes	No	Yes	No	4	Yes	Yes	No	No	No	Yes	3
	8	21MAR96	57, 1	No	Yes	No	No	No	No	No	1	No	No	No	Yes	No	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.005.00153	32	04SEP96	224, 168	Yes	Yes	No	Yes	No	No	No	3	Yes	Yes	No	Yes	No	Yes	4
329.005.00255	SC	26FEB96	-7, .	No	Yes	No	No	No	Yes	No	2	No	Yes	No	No	No	No	1
	8	29APR96	57, .	No	No	No	No	No	Yes	No	1	No	No	No	No	No	No	0
329.005.00256	SC	20FEB96	-14, -70	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	Yes	No	Yes	5
	8	30APR96	57, 1	Yes	Yes	No	No	Yes	Yes	Yes	5	Yes	No	No	No	No	No	1
	16	02JUL96	120, 64	Yes	Yes	Yes	No	No	No	Yes	4	Yes	No	Yes	Yes	No	Yes	4
329.005.00295	SC	21MAR96	-7, .	No	Yes	No	Yes	No	No	No	2	No	No	No	Yes	No	No	1
	8	22MAY96	56, .	No	Yes	No	No	No	No	No	1	No	No	No	Yes	No	Yes	2
329.005.00297	SC	28MAR96	-22, .	No	No	Yes	No	No	Yes	No	2	Yes	Yes	No	No	No	No	2
329.005.00332	SC	05DEC96	-7, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	8	06FEB97	57, .	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.005.00335	SC	20FEB97	-8, .	Yes	Yes	No	No	Yes	Yes	No	4	No	No	No	No	No	No	0
	8	24APR97	56, .	No	No	No	No	Yes	Yes	No	2	No	No	No	No	No	No	0
329.006.00040	SC	10FEB95	-6, .	No	Yes	No	No	No	Yes	No	2	Yes	No	No	No	No	No	1
329.006.00041	SC	22MAR95	-14, -78	Yes	Yes	No	No	Yes	Yes	No	4	Yes	Yes	No	No	No	No	2
	8	31MAY95	57, -8	No	Yes	No	No	No	Yes	No	2	No	Yes	No	No	No	Yes	2
	32	21NOV95	231, 167	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.007.00139	SC	04MAY95	-4, .	Yes	Yes	Yes	No	No	No	No	3	Yes	Yes	Yes	No	Yes	Yes	5

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.007.00143	SC	26OCT95	-14, .	Yes	Yes	Yes	Yes	Yes	No	No	5	Yes	Yes	No	No	No	No	2
329.007.00146	SC	18JAN96	-7, -60	No	Yes	No	No	No	No	No	1	Yes	Yes	No	No	No	No	2
	8	18MAR96	54, 1	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	32	09SEP96	229, 176	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.007.00269	SC	04APR96	-7, .	No	Yes	No	No	No	Yes	No	2	No	No	Yes	No	Yes	No	2
	3	02MAY96	22, .	No	Yes	No	No	No	No	Yes	2	No	No	No	No	No	No	0
329.007.00270	SC	02MAY96	-7, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	7	27JUN96	50, .	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.007.00307	SC	09MAY96	-7, .	Yes	Yes	Yes	No	Yes	Yes	Yes	6	No	No	No	No	No	No	0
	8	25JUL96	71, .	No	No	Yes	No	No	Yes	Yes	3	No	Yes	No	No	No	Yes	2
329.007.00308	SC	27JUN96	-5, .	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.008.00159	SC	06SEP95	-7, -69	Yes	Yes	Yes	Yes	No	Yes	Yes	6	Yes	No	No	No	Yes	No	2
	8	14NOV95	63, 1	No	Yes	Yes	No	No	Yes	No	3	No	No	No	No	No	No	0
329.008.00161	SC	31OCT95	-16, -71	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	Yes	No	No	2
	8	10JAN96	56, 1	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.008.00187	SC	15NOV95	-14, .	No	Yes	No	Yes	No	Yes	No	3	Yes	Yes	No	Yes	Yes	Yes	5
	8	26JAN96	59, .	No	Yes	No	No	Yes	Yes	No	3	Yes	Yes	No	No	No	Yes	3
329.008.00192	SC	14FEB96	-20, .	No	No	No	No	No	No	No	0	No	Yes	No	No	No	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.008.00272	SC	19MAR96	-15, -71	No	Yes	No	No	No	No	No	1	No	Yes	Yes	No	No	No	2
	8	29MAY96	57, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.008.00273	SC	19APR96	-28, -91	Yes	Yes	Yes	No	Yes	Yes	No	5	Yes	Yes	No	No	No	No	2
	8	19JUL96	64, 1	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.009.00127	SC	03APR95	-7, .	No	No	No	No	No	Yes	No	1	No	No	No	Yes	Yes	Yes	3
329.009.00132	SC	17MAY95	-6, -63	No	Yes	No	No	Yes	Yes	No	3	No	No	No	No	No	No	0
	8	19JUL95	58, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.009.00134	SC	28JUN95	-8, .	No	Yes	No	No	No	Yes	No	2	No	Yes	No	No	Yes	No	2
	8	29AUG95	55, .	No	Yes	No	No	Yes	Yes	No	3	Yes	No	No	Yes	Yes	No	3
329.009.00137	SC	03OCT95	-7, .	No	No	No	Yes	No	Yes	Yes	3	Yes	Yes	Yes	Yes	No	No	4
	8	05DEC95	57, .	Yes	Yes	No	No	No	No	No	2	Yes	Yes	Yes	Yes	Yes	Yes	6
329.009.00171	SC	31OCT95	-7, .	No	Yes	Yes	Yes	Yes	No	Yes	5	Yes	Yes	No	No	No	No	2
329.009.00172	SC	06NOV95	-7, -64	No	Yes	No	No	No	Yes	No	2	Yes	Yes	No	No	Yes	Yes	4
	8	09JAN96	58, 1	No	Yes	No	No	Yes	No	No	2	Yes	No	No	No	No	No	1
	32	08JUL96	239, 182	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.009.00194	SC	28NOV95	-7, -63	No	No	No	No	No	Yes	No	1	Yes	Yes	No	Yes	Yes	Yes	5
	8	30JAN96	57, 1	Yes	No	Yes	Yes	No	Yes	Yes	5	Yes	No	Yes	No	No	Yes	3
	24	04JUN96	183, 127	No	Yes	No	No	No	No	No	1	No	Yes	No	Yes	No	Yes	3
329.009.00195	SC	06DEC95	-9, .	No	No	No	No	No	Yes	Yes	2	Yes	Yes	No	No	No	No	2

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.009.00199	SC	10JAN96	-6, .	No	Yes	No	No	No	No	No	1	.	.	.	.	.	.	.
	8	13MAR96	58, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.009.00203	SC	28FEB96	-5, .	No	Yes	No	Yes	Yes	Yes	No	4	Yes	Yes	No	No	No	No	2
329.009.00236	SC	17DEC96	-13, .	No	Yes	No	Yes	Yes	Yes	Yes	5	Yes	Yes	No	Yes	Yes	Yes	5
	4	27JAN97	29, .	Yes	Yes	Yes	No	Yes	Yes	No	5	No	Yes	No	No	No	No	1
329.009.00239	SC	11NOV96	-8, -65	No	Yes	No	No	No	Yes	No	2	Yes	Yes	No	Yes	No	No	3
	8	15JAN97	58, 1	No	Yes	No	No	No	No	No	1	No	Yes	No	Yes	Yes	No	3
329.009.00262	SC	07FEB97	-10, .	No	Yes	No	No	No	Yes	No	2	Yes	Yes	No	No	No	No	2
	8	14APR97	57, .	No	Yes	Yes	No	No	No	No	2	No	No	No	No	No	No	0
329.009.00264	SC	25OCT96	-7, .	Yes	Yes	Yes	No	Yes	Yes	No	5	Yes	No	No	No	Yes	Yes	3
	7	23DEC96	53, .	Yes	Yes	No	Yes	No	No	No	3	No	No	No	No	No	No	0
329.009.00301	SC	06MAR96	-13, -69	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
	8	14MAY96	57, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.009.00305	SC	01MAY96	-6, -63	Yes	Yes	Yes	No	No	No	Yes	4	Yes	No	No	No	No	No	1
	8	03JUL96	58, 1	Yes	Yes	Yes	No	No	No	No	3	Yes	No	No	No	No	Yes	2
	32	10JAN97	249, 192	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.009.00325	SC	21AUG96	-6, -61	No	Yes	No	No	Yes	Yes	No	3	No	No	No	No	No	No	0
	8	21OCT96	56, 1	No	No	Yes	No	Yes	Yes	No	3	No	No	No	No	No	No	0
	16	16DEC96	112, 57	No	Yes	Yes	Yes	Yes	Yes	Yes	6	No	Yes	No	Yes	No	Yes	3

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.009.00326	SC	26AUG96	-10, -63	No	Yes	No	No	No	Yes	No	2	Yes	No	No	No	No	No	1
	8	28OCT96	54, 1	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
	16	16DEC96	103, 50	Yes	Yes	No	No	Yes	Yes	No	4	No	No	No	No	No	No	0
329.010.00279	SC	08MAR96	-14, -70	No	Yes	No	No	No	No	No	1	No	Yes	Yes	No	No	No	2
	8	17MAY96	57, 1	No	Yes	No	No	No	No	No	1	Yes	Yes	Yes	No	Yes	No	4
	32	06NOV96	230, 174	No	Yes	No	No	Yes	No	No	2	Yes	Yes	No	No	Yes	No	3
329.010.00281	SC	19JUL96	-7, -68	No	No	Yes	No	No	No	No	1	Yes	No	No	No	No	No	1
	8	25SEP96	62, 1	No	No	Yes	No	No	No	Yes	2	No	No	No	No	No	No	0
	24	03JAN97	162, 101	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	No	No	No	No	2
329.011.00163	SC	18NOV95	-7, .	No	Yes	No	No	No	No	Yes	2	Yes	Yes	No	Yes	No	No	3
329.011.00208	SC	22AUG96	-15, -74	No	No	No	No	Yes	Yes	No	2	Yes	Yes	Yes	No	Yes	Yes	5
	8	03NOV96	59, -1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.011.00209	SC	23AUG96	-19, -81	No	No	No	No	No	No	No	0	No	No	No	No	Yes	No	1
	8	11NOV96	62, -1	Yes	Yes	Yes	No	No	No	No	3	No	Yes	No	No	No	Yes	2
329.011.00284	SC	13MAR96	-9, -65	Yes	Yes	No	No	Yes	Yes	Yes	5	Yes	Yes	No	Yes	Yes	Yes	5
	8	16MAY96	56, -1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.011.00286	SC	15MAY96	-22, -90	No	Yes	Yes	No	Yes	Yes	Yes	5	No	Yes	Yes	Yes	No	No	3
	8	09AUG96	65, -4	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.012.00026	SC	09NOV95	-19, .	No	Yes	Yes	No	No	Yes	No	3	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.012.00219	SC	24MAY96	-7, -67	No	Yes	No	No	No	Yes	No	2	Yes	Yes	No	No	Yes	No	3
	8	30JUL96	61, 1	No	No	No	No	No	No	No	0	No	Yes	No	No	No	No	1
	32	24JAN97	239, 179	No	No	No	No	No	No	No	0	No	Yes	No	No	No	No	1
329.012.00221	SC	18JUN96	-7, -70	No	Yes	No	No	Yes	No	Yes	3	Yes	Yes	No	No	No	No	2
	8	27AUG96	64, 1	No	No	No	No	No	Yes	No	1	No	Yes	No	No	No	Yes	2
329.012.00223	SC	23AUG96	-7, .	Yes	No	No	Yes	No	Yes	No	3	Yes	Yes	No	No	No	No	2
329.012.00227	SC	12DEC96	-6, -75	No	Yes	No	No	Yes	No	No	2	Yes	Yes	Yes	No	Yes	Yes	5
	8	25FEB97	70, 1	No	Yes	Yes	No	Yes	No	Yes	4	No	No	No	No	No	No	0
	32	19AUG97	245, 176	No	No	Yes	No	No	Yes	Yes	3	No	Yes	Yes	No	Yes	Yes	4
329.012.00230	SC	20FEB97	-8, -77	No	Yes	Yes	Yes	Yes	Yes	Yes	6	Yes	Yes	No	No	No	No	2
	8	08MAY97	70, 1	No	Yes	No	No	No	No	No	1	Yes	Yes	No	No	Yes	Yes	4

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.001.00062	SC	06OCT94	-14, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.001.00064	SC	04NOV94	-6, -60	No	Yes	No	No	No	No	No	1	Yes	No	No	No	Yes	No	2
	8	03JAN95	55, 1	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.001.00069	SC	07FEB95	-9, .	Yes	Yes	No	Yes	Yes	Yes	Yes	6	No	No	No	No	No	No	0
	8	13APR95	57, .	No	Yes	No	No	No	No	Yes	2	Yes	No	No	No	No	No	1
329.001.00071	SC	02FEB95	-21, .	No	Yes	No	No	No	Yes	No	2	No	No	No	No	No	No	0
	8	20APR95	57, .	Yes	Yes	No	Yes	No	Yes	No	4	No	No	No	No	No	No	0
329.001.00123	SC	14DEC95	-21, .	Yes	Yes	Yes	No	No	No	No	3	Yes	No	No	No	No	No	1
329.001.00207	SC	19FEB96	-9, .	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
	8	24APR96	57, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.002.00049	SC	03MAR95	-6, .	No	Yes	No	Yes	Yes	Yes	No	4	Yes	Yes	No	No	No	No	2
	8	05MAY95	58, .	Yes	Yes	No	Yes	Yes	Yes	No	5	No	Yes	Yes	Yes	Yes	No	4
329.002.00059	SC	03NOV94	-7, .	Yes	Yes	Yes	Yes	No	Yes	No	5	Yes	No	No	No	No	No	1
	8	05JAN95	57, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	No	No	No	No	No	No	0
329.002.00060	SC	24JAN95	-7, -63	No	Yes	No	Yes	Yes	Yes	Yes	5	No	No	No	Yes	No	No	1
	8	28MAR95	57, 1	No	Yes	Yes	No	Yes	Yes	No	4	Yes	Yes	No	No	No	Yes	3
329.002.00097	SC	20DEC94	-14, -72	No	Yes	No	No	Yes	No	Yes	3	Yes	No	Yes	Yes	Yes	No	4
	8	02MAR95	59, 1	No	Yes	No	Yes	No	No	Yes	3	Yes	Yes	No	No	No	No	2
	32	05SEP95	246, 188	No	No	No	Yes	No	No	Yes	2	No	No	No	No	No	Yes	1

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.002.00101	SC	20MAR95	-8, -66	No	Yes	Yes	Yes	No	Yes	Yes	5	Yes	Yes	No	No	No	No	2
	8	25MAY95	59, 1	No	Yes	No	Yes	Yes	No	Yes	4	Yes	Yes	No	No	Yes	Yes	4
329.002.00107	SC	18JAN96	-7, -63	Yes	No	Yes	Yes	Yes	No	Yes	5	Yes	Yes	No	Yes	No	No	3
	8	21MAR96	57, 1	No	Yes	No	Yes	No	No	No	2	No	No	No	No	No	No	0
	32	26SEP96	246, 190	Yes	Yes	No	No	Yes	No	No	3	Yes	No	No	No	No	No	1
329.002.00241	SC	25JAN96	-12, -68	No	No	No	Yes	Yes	No	No	2	Yes	No	No	Yes	Yes	Yes	4
	8	02APR96	57, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.002.00246	SC	01APR96	-17, .	No	Yes	Yes	Yes	Yes	No	No	4	Yes	No	Yes	No	Yes	Yes	4
	8	18JUN96	62, .	Yes	Yes	Yes	Yes	Yes	No	No	5	Yes	Yes	No	Yes	Yes	Yes	5
329.002.00320	SC	09MAY96	-7, -68	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	8	16JUL96	62, 1	No	No	No	No	No	Yes	No	1	No	No	No	Yes	No	No	1
329.002.00323	SC	04NOV96	-8, -66	No	Yes	Yes	No	Yes	No	No	3	No	No	Yes	No	No	No	1
	8	09JAN97	59, 1	No	No	Yes	No	No	No	No	1	No	No	No	No	No	No	0
	32	12JUN97	213, 155	No	No	Yes	No	No	No	Yes	2	No	No	No	No	No	No	0
329.003.00074	32	11OCT95	260, 204	No	No	No	Yes	No	No	No	1	Yes	No	No	No	No	No	1
329.003.00078	SC	11APR95	-15, .	Yes	Yes	Yes	Yes	No	No	Yes	5	Yes	Yes	Yes	No	Yes	Yes	5
	8	21JUN95	57, .	Yes	No	Yes	Yes	No	No	Yes	4	No	Yes	No	Yes	No	No	2
329.003.00080	SC	22NOV95	-5, .	No	Yes	Yes	Yes	Yes	No	Yes	5	No	Yes	No	No	No	No	1
329.003.00085	SC	26OCT94	-13, .	No	Yes	No	No	Yes	Yes	No	3	No	No	Yes	Yes	No	No	2

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.003.00085	8	03JAN95	57, .	No	Yes	No	No	No	Yes	No	2	Yes	No	No	No	No	No	1
329.003.00086	SC	09NOV94	-19, -76	Yes	Yes	No	Yes	No	No	No	3	Yes	Yes	Yes	Yes	Yes	Yes	6
	8	23JAN95	57, -1	No	Yes	No	No	No	No	Yes	2	Yes	Yes	Yes	No	Yes	Yes	5
	32	17AUG95	263, 206	No	Yes	No	No	Yes	Yes	No	3	Yes	Yes	Yes	No	Yes	Yes	5
329.003.00094	8	19DEC95	57, .	Yes	Yes	No	Yes	Yes	No	No	4	Yes	No	Yes	Yes	Yes	No	4
329.003.00251	SC	19MAR96	-9, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	No	No	No	1
329.003.00252	SC	19MAR96	-22, .	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
	8	04JUN96	56, .	No	Yes	No	No	No	No	No	1	Yes	Yes	Yes	No	No	No	3
329.003.00291	SC	01JUL96	-2, -67	Yes	Yes	No	Yes	Yes	Yes	No	5	Yes	Yes	No	Yes	No	Yes	4
329.003.00315	SC	29OCT96	-14, .	No	Yes	Yes	No	No	Yes	Yes	4	Yes	No	No	No	No	Yes	2
	8	07JAN97	57, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.003.00316	SC	05DEC96	-12, .	Yes	Yes	Yes	Yes	No	No	No	4	Yes	Yes	No	No	No	Yes	3
	8	11FEB97	57, .	No	Yes	No	No	No	Yes	No	2	Yes	Yes	No	Yes	Yes	Yes	5
329.004.00016	SC	01MAR95	-12, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	No	No	No	No	No	1
	5	19APR95	38, .	Yes	Yes	Yes	Yes	No	Yes	Yes	6	Yes	Yes	No	No	No	No	2
329.004.00018	SC	19APR95	-14, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	No	No	No	1
	8	29JUN95	58, .	No	Yes	No	Yes	No	No	No	2	No	No	No	No	No	No	0
329.004.00020	SC	02NOV95	-7, .	Yes	Yes	No	No	No	Yes	Yes	4	Yes	Yes	No	No	No	No	2

* days relative to start of acute phase, days relative to start of continuation phase
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Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.004.00020	2	24NOV95	16, .	Yes	Yes	No	Yes	Yes	Yes	Yes	6	Yes	Yes	Yes	Yes	No	No	4
329.004.00213	SC	18JUL96	-15, -69	Yes	Yes	No	Yes	Yes	No	No	4	No	No	No	No	No	No	0
	8	24SEP96	54, -1	Yes	Yes	No	No	No	No	No	2	Yes	No	Yes	No	No	No	2
	32	19MAR97	230, 176	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.005.00001	SC	11APR94	-9, .	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
	8	15JUN94	57, .	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.005.00005	SC	24OCT94	-8, .	No	Yes	Yes	No	Yes	No	Yes	4	No	No	Yes	No	No	No	1
329.005.00010	SC	07DEC94	-6, -63	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	No	No	No	No	No	1
	8	08FEB95	58, 1	No	No	No	No	No	No	Yes	1	No	No	No	No	No	No	0
	32	09AUG95	240, 183	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.005.00012	SC	12DEC94	-7, -66	Yes	Yes	Yes	Yes	Yes	No	No	5	Yes	Yes	No	No	No	No	2
	8	16FEB95	60, 1	No	Yes	Yes	No	Yes	No	No	3	No	No	No	No	No	No	0
329.005.00111	SC	05JAN95	-6, -62	Yes	Yes	Yes	Yes	.	Yes	No	6	Yes	No	No	No	No	No	1
	8	08MAR95	57, 1	No	No	No	Yes	No	No	Yes	2	No	Yes	No	No	No	No	1
	16	03MAY95	113, 57	No	No	No	No	No	No	No	0	.	.	.	.	.	.	.
329.005.00114	SC	23JAN95	-8, -65	Yes	Yes	No	No	No	No	No	2	Yes	No	No	No	No	No	1
	8	29MAR95	58, 1	Yes	Yes	Yes	No	No	No	Yes	4	Yes	Yes	No	No	No	No	2
	16	17MAY95	107, 50	No	Yes	No	No	No	No	Yes	2	Yes	No	No	No	No	No	1
329.005.00115	SC	27JAN95	-10, -81	Yes	Yes	No	No	Yes	Yes	Yes	5	Yes	No	No	No	No	No	1
	8	18APR95	72, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.005.00120	SC	22AUG95	-8, .	Yes	Yes	No	No	No	No	No	2	Yes	No	No	No	No	No	1
	8	26OCT95	58, .	Yes	Yes	No	Yes	Yes	No	Yes	5	Yes	No	No	No	Yes	No	2
329.005.00253	SC	31JAN96	-8, .	No	No	No	No	Yes	Yes	No	2	Yes	Yes	No	No	Yes	Yes	4
	8	03APR96	56, .	No	No	No	Yes	No	No	Yes	2	No	Yes	No	No	Yes	Yes	3
329.005.00254	SC	08FEB96	-7, -62	Yes	Yes	No	Yes	No	No	No	3	Yes	No	No	No	No	No	1
	8	10APR96	56, 1	No	Yes	No	No	Yes	No	No	2	Yes	No	No	No	No	No	1
	32	16OCT96	245, 190	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.005.00293	SC	06MAR97	-6, .	No	Yes	Yes	Yes	No	No	Yes	4	No	Yes	No	No	Yes	Yes	3
	8	07MAY97	57, .	No	No	No	No	No	No	No	0	Yes	Yes	No	No	No	Yes	3
329.005.00298	SC	15MAY96	-7, -63	No	Yes	Yes	Yes	Yes	Yes	.	6	Yes	Yes	No	Yes	Yes	No	4
	8	17JUL96	57, 1	No	Yes	No	No	Yes	No	No	2	No	No	No	No	No	No	0
	32	13JAN97	237, 181	No	Yes	No	No	Yes	No	No	2	Yes	No	No	No	No	No	1
329.005.00331	SC	14NOV96	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	No	No	No	No	No	Yes	1
	8	16JAN97	57, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	No	No	No	No	No	No	0
329.005.00334	SC	24JAN97	-7, .	No	Yes	No	Yes	Yes	No	Yes	4	No	Yes	Yes	Yes	Yes	Yes	5
	8	27MAR97	56, .	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.006.00037	SC	20JAN95	-8, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.006.00042	SC	01DEC95	-6, -63	No	Yes	Yes	No	Yes	Yes	Yes	5	Yes	Yes	Yes	Yes	Yes	Yes	6
	8	02FEB96	58, 1	No	Yes	Yes	No	No	Yes	No	3	Yes	Yes	No	Yes	Yes	Yes	5
	32	16JUL96	223, 166	No	Yes	No	No	No	No	Yes	2	No	Yes	No	Yes	No	Yes	3

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

				Sickness Impact Profile Scores														
				Section A								Section B						
Patient ID	Week	Date	Relative Days*	A1	A2	A3	A4	A5	A6	A7	Sec. A Total	B1	B2	B3	B4	B5	B6	Sec. B Total
329.006.00259	SC	22APR96	-32, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	No	No	No	No	No	1
	8	17JUL96	55, .	Yes	No	Yes	Yes	Yes	No	Yes	5	No	No	No	No	No	No	0
329.007.00141	SC	14SEP95	-7, .	No	No	No	Yes	Yes	No	No	2	No	Yes	Yes	No	Yes	No	3
329.007.00144	SC	30NOV95	-7, -63	No	No	Yes	Yes	No	No	Yes	3	No	No	Yes	No	Yes	No	2
	8	01FEB96	57, 1	No	No	Yes	Yes	Yes	No	Yes	4	No	No	No	No	No	No	0
329.007.00266	SC	29FEB96	-7, .	No	Yes	No	No	No	No	No	1	No	No	No	No	No	Yes	1
	8	02MAY96	57, .	No	No	No	No	No	No	No	0	No	No	No	Yes	No	No	1
329.007.00267	SC	29FEB96	-7, .	No	Yes	No	No	No	No	No	1	Yes	No	No	Yes	No	No	2
	8	02MAY96	57, .	No	Yes	No	No	No	No	No	1	Yes	No	No	No	No	No	1
329.007.00311	SC	26SEP96	-7, -67	No	Yes	No	No	No	No	No	1	Yes	Yes	Yes	No	No	No	3
	8	02DEC96	61, 1	No	Yes	No	No	No	No	No	1	Yes	Yes	Yes	No	Yes	No	4
329.008.00158	SC	06SEP95	-7, -69	Yes	Yes	No	Yes	.	Yes	Yes	6	Yes	No	No	No	No	No	1
	8	14NOV95	63, 1	No	No	No	No	No	No	No	0	No	Yes	No	No	No	No	1
329.008.00162	SC	26OCT95	-6, -71	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	Yes	Yes	No	3
	8	05JAN96	66, 1	Yes	Yes	No	No	Yes	No	No	3	Yes	Yes	No	Yes	Yes	No	4
	32	02JUL96	245, 180	Yes	Yes	No	No	No	Yes	No	3	No	No	No	Yes	No	No	1
329.008.00191	SC	12JAN96	-20, -81	No	Yes	No	No	Yes	Yes	No	3	Yes	Yes	No	No	No	Yes	3
	8	02APR96	62, 1	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
329.009.00128	SC	05APR95	-6, .	No	Yes	No	No	No	Yes	No	2	No	No	Yes	No	No	No	1

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.009.00129	SC	22MAR95	-20, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	Yes	Yes	Yes	Yes	6
329.009.00135	SC	25SEP95	-7, .	Yes	Yes	No	Yes	No	No	No	3	Yes	Yes	Yes	Yes	Yes	Yes	6
329.009.00136	SC	26SEP95	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	No	Yes	Yes	Yes	5
	8	28NOV95	57, .	No	Yes	No	No	No	No	No	1	Yes	No	No	Yes	No	No	2
329.009.00169	SC	25OCT95	-6, -71	No	No	No	Yes	No	Yes	Yes	3	Yes	Yes	Yes	No	Yes	No	4
	8	27DEC95	58, -8	No	No	No	No	No	No	No	0	Yes	No	No	No	No	No	1
329.009.00174	SC	14NOV95	-7, -64	No	No	No	No	No	Yes	No	1	Yes	Yes	No	No	Yes	No	3
	8	17JAN96	58, 1	No	Yes	No	No	No	No	No	1	No	Yes	No	No	No	Yes	2
329.009.00197	SC	20DEC95	-9, -63	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	8	20FEB96	54, -1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	32	20AUG96	236, 182	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.009.00198	SC	19DEC95	-14, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	Yes	Yes	Yes	Yes	5
	8	27FEB96	57, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	Yes	Yes	No	5
329.009.00200	SC	17JAN96	-6, .	No	Yes	No	No	No	Yes	No	2	Yes	Yes	Yes	Yes	Yes	Yes	6
329.009.00202	SC	14FEB96	-6, .	Yes	Yes	No	No	Yes	Yes	Yes	5	Yes	No	Yes	No	No	Yes	3
329.009.00238	SC	28OCT96	-15, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	Yes	Yes	No	No	Yes	Yes	4
	8	07JAN97	57, .	Yes	No	No	No	No	No	No	1	Yes	Yes	No	No	No	No	2
329.009.00276	SC	17JAN97	-4, .	Yes	No	Yes	Yes	Yes	Yes	Yes	6	Yes	Yes	No	No	No	Yes	3

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.009.00276	8	18MAR97	57, .	Yes	No	Yes	Yes	Yes	Yes	Yes	6	Yes	Yes	Yes	Yes	Yes	Yes	6
329.009.00302	SC	20MAR96	-7, .	Yes	Yes	Yes	No	No	No	No	3	Yes	Yes	Yes	No	Yes	No	4
329.009.00306	SC	03JUN96	-8, .	Yes	Yes	Yes	Yes	No	Yes	Yes	6	Yes	No	No	No	No	No	1
	8	06AUG96	57, .	No	No	Yes	Yes	Yes	No	No	3	Yes	Yes	No	No	Yes	No	3
329.009.00312	SC	30OCT96	-5, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	No	Yes	Yes	No	No	No	2
	8	06JAN97	64, .	Yes	Yes	Yes	Yes	Yes	No	Yes	6	No	No	No	No	No	No	0
329.009.00327	SC	09SEP96	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	No	Yes	No	4
	5	21OCT96	36, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	Yes	Yes	Yes	6
329.009.00330	SC	15OCT96	-6, .	No	No	No	No	No	Yes	No	1	No	No	No	No	No	Yes	1
329.010.00183	SC	21NOV95	-12, .	Yes	No	Yes	Yes	No	Yes	Yes	5	Yes	No	No	No	No	No	1
329.010.00263	SC	24JUL96	-16, .	Yes	Yes	No	No	No	No	No	2	Yes	No	No	No	Yes	Yes	3
	8	09OCT96	62, .	No	Yes	No	No	No	No	No	1	Yes	Yes	No	No	No	Yes	3
329.010.00277	SC	23FEB96	-7, -63	Yes	Yes	No	No	No	No	No	2	Yes	Yes	No	No	No	Yes	3
	8	26APR96	57, 1	No	Yes	No	No	No	No	No	1	No	No	No	No	No	No	0
	24	07AUG96	160, 104	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.010.00282	SC	19JUL96	-7, .	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
	8	27SEP96	64, .	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.011.00164	SC	15DEC95	-7, .	No	Yes	No	Yes	Yes	Yes	Yes	5	Yes	Yes	No	Yes	No	No	3

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part I
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section A A1	A2	A3	A4	A5	A6	A7	Sec. A Total	Section B B1	B2	B3	B4	B5	B6	Sec. B Total
329.011.00210	SC	13SEP96	-15, -81	Yes	No	No	Yes	No	Yes	No	3	Yes	Yes	Yes	No	Yes	No	4
	8	02DEC96	66, -1	Yes	No	No	No	No	No	Yes	2	No	Yes	Yes	Yes	Yes	Yes	5
329.011.00285	SC	08MAY96	-10, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	No	No	Yes	2
	8	24JUL96	68, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	No	No	Yes	No	3
329.011.00287	SC	25JUN96	-8, .	Yes	No	No	Yes	Yes	Yes	Yes	5	Yes	Yes	No	No	Yes	Yes	4
	8	27AUG96	56, .	No	Yes	No	No	Yes	Yes	No	3	No	No	No	No	No	No	0
329.012.00027	SC	23NOV95	-13, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	No	Yes	No	Yes	4
329.012.00217	SC	14MAY96	-7, .	No	Yes	Yes	Yes	Yes	No	Yes	5	Yes	Yes	Yes	Yes	Yes	Yes	6
329.012.00218	SC	04JUN96	-12, -70	No	Yes	No	Yes	Yes	No	Yes	4	Yes	No	No	No	No	No	1
	8	13AUG96	59, 1	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0
329.012.00224	SC	30AUG96	-17, -83	No	No	No	No	No	Yes	No	1	Yes	Yes	No	No	Yes	No	3
	8	20NOV96	66, -1	No	Yes	No	No	No	No	No	1	No	Yes	No	No	No	No	1
329.012.00225	SC	19NOV96	-7, -71	Yes	Yes	No	Yes	No	No	No	3	No	No	No	No	No	No	0
	8	29JAN97	65, 1	Yes	Yes	No	Yes	No	No	No	3	No	No	No	No	No	No	0
	32	30JUL97	247, 183	No	No	No	No	No	No	No	0	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section A = Sleep/Rest, Section B = Home Management
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.001.00063	SC	02NOV94	-6, .	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	.	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	15
329.001.00065	SC	07NOV94	-10, .	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	5
329.001.00068	SC	01FEB95	-7, .	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9
	8	05APR95	57, .	Yes	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	7
329.001.00072	SC	07MAR95	-13, .	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	2
329.001.00121	SC	22MAR95	-13, -69	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	10
	8	30MAY95	57, 1	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	3
329.001.00205	SC	29JAN96	-9, .	No	No	No	No	No	No	No	Yes	.	No	No	No	No	No	No	No	No	1
329.001.00206	SC	12FEB96	-9, .	No	No	No	Yes	Yes	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	8
	8	17APR96	57, .	No	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	10
329.002.00055	SC	09JUN94	-15, -70	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	15
	8	18AUG94	56, 1	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	No	11
	20	10NOV94	140, 85	Yes	No	No	Yes	No	No	Yes	No	No	No	Yes	No	Yes	Yes	No	Yes	No	7
329.002.00058	SC	08SEP94	-12, -70	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	12
	8	17NOV94	59, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	1
329.002.00099	SC	23FEB95	-7, -62	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	Yes	4
	8	25APR95	55, -1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	26OCT95	239, 184	Yes	No	No	Yes	No	No	No	No	Yes	No	No	Yes	No	Yes	No	No	No	5

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.002.00102	SC	03APR95	-10, -64	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No	No	8
	8	06JUN95	55, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	05DEC95	237, 183	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.002.00105	SC	20JUL95	-7, .	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	Yes	4
329.002.00106	SC	20JUL95	-7, .	Yes	No	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	12
329.002.00242	SC	26JAN96	-12, -70	No	No	No	Yes	No	No	No	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	7
	20	10JUL96	155, 97	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	1
329.002.00245	SC	21MAR96	-7, .	No	No	No	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	Yes	Yes	5
329.002.00319	SC	23APR96	-7, -63	No	No	No	Yes	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No	3
	8	25JUN96	57, 1	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	2
	32	17DEC96	232, 176	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	1
329.003.00075	SC	18JAN95	-7, -63	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	7
	8	22MAR95	57, 1	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	11
	32	13SEP95	232, 176	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	5
329.003.00077	SC	01MAR95	-5, -64	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	14
329.003.00081	SC	04DEC95	-7, .	No	No	Yes	No	.	No	Yes	.	.	No	No	Yes	Yes	Yes	Yes	No	Yes	9
329.003.00087	SC	23JAN95	-8, .	Yes	No	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	9
329.003.00089	SC	24FEB95	-11, .	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	No	Yes	9

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.003.00089	8	02MAY95	57, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.003.00091	8	16MAY95	54, -1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	07NOV95	229, 175	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.003.00248	SC	14FEB96	-16, .	No	No	No	Yes	Yes	No	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	No	7
	8	23APR96	54, .	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	6
329.003.00250	SC	05MAR96	-9, -66	No	No	No	Yes	No	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	No	No	8
	8	09MAY96	57, -1	No	No	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	No	8
329.003.00292	SC	02AUG96	-5, -63	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	6
	8	04OCT96	59, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	1
329.003.00313	SC	08MAY96	-9, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	17
329.004.00015	SC	30NOV94	-8, -65	Yes	No	No	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	No	No	No	Yes	7
	8	03FEB95	58, 1	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	No	2
	28	14JUN95	189, 132	No	No	No	Yes	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	3
329.004.00017	SC	15MAR95	-7, -63	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	11
	8	17MAY95	57, 1	No	No	No	Yes	No	No	No	No	No	No	Yes	.	Yes	Yes	No	No	No	4
	32	01NOV95	225, 169	No	No	No	Yes	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	No	4
329.004.00019	SC	24MAY95	-7, .	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	9
329.004.00212	SC	24MAY96	-10, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	16

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.004.00214	SC	27SEP96	-7, -67	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	15
	8	03DEC96	61, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes	Yes	Yes	No	No	15
329.005.00002	SC	20MAY94	-5, -61	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	14
329.005.00004	SC	22SEP94	-18, -77	No	No	No	No	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No	Yes	4
	8	08DEC94	60, 1	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	1
329.005.00008	SC	10NOV94	-6, -61	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	8	10JAN95	56, 1	Yes	No	Yes	Yes	No	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	6
	24	10MAY95	176, 121	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	1
329.005.00011	SC	06DEC94	-7, -63	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	13
	8	07FEB95	57, 1	No	No	No	No	No	No	No	No	No	Yes	No	No	Yes	Yes	No	No	No	3
329.005.00109	SC	22DEC94	-8, -61	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	13
	8	21FEB95	54, 1	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	14
329.005.00112	SC	17JAN95	-9, -64	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	.	Yes	No	Yes	No	Yes	9
	8	22MAR95	56, 1	No	Yes	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	9
	20	21JUN95	147, 92	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.005.00116	SC	30JAN95	-8, -66	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	12
	8	06APR95	59, 1	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes	3
	24	26JUL95	170, 112	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.005.00119	SC	27JUN95	-14, -73	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
	8	08SEP95	60, 1	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	3

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.005.00119	24	02JAN96	176, 117	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	Yes	No	3
329.005.00151	SC	29AUG95	-8, -65	Yes	No	No	No	Yes	No	No	No	.	No	No	Yes	Yes	No	No	No	Yes	5
	8	02NOV95	58, 1	Yes	No	No	No	No	Yes	No	No	.	No	No	Yes	Yes	No	No	No	No	4
	32	01MAY96	239, 182	No	No	No	No	No	No	No	No	.	No	No	No	Yes	No	No	No	No	1
329.005.00152	SC	12OCT95	-14, .	No	No	No	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	9
329.005.00257	SC	05MAR96	-6, -62	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	9
	8	06MAY96	57, 1	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	6
	32	21OCT96	225, 169	No	No	No	No	No	No	No	No	.	No	No	No	No	No	No	No	No	0
329.005.00258	SC	06FEB96	-35, .	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	1
	8	07MAY96	57, .	No	No	No	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	8
329.005.00299	SC	28MAY96	-11, -71	Yes	Yes	No	No	No	No	No	No	.	No	No	Yes	No	No	No	No	No	3
	8	07AUG96	61, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	1
	20	05NOV96	151, 91	No	Yes	No	No	No	No	No	No	.	No	No	Yes	No	No	No	No	No	2
329.005.00300	SC	12SEP96	-7, .	No	No	No	No	No	No	No	No	.	No	No	No	No	Yes	No	No	No	1
	8	14NOV96	57, .	No	No	No	Yes	No	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	8
329.005.00333	SC	15JAN97	-8, .	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	6
329.005.00336	SC	26FEB97	-6, .	Yes	No	No	Yes	No	Yes	Yes	Yes	.	Yes	No	Yes	Yes	Yes	Yes	Yes	No	12
	8	30APR97	58, .	Yes	No	Yes	Yes	No	No	Yes	No	.	No	Yes	Yes	No	No	Yes	No	No	7
329.006.00038	SC	01FEB95	-14, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	16

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores — Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.006.00039	SC	03FEB95	-5, -66	No	Yes	No	Yes	No	No	No	Yes	No	No	No	Yes	Yes	No	No	No	No	5
	8	05APR95	57, -5	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	No	No	No	9
329.006.00260	SC	12JUL96	-6, -64	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	2
	8	18SEP96	63, 5	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	1
329.006.00261	SC	07NOV96	-19, -77	No	No	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	12
	8	23JAN97	59, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	4
329.007.00140	SC	07SEP95	-8, -63	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	3
	8	09NOV95	56, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.007.00142	SC	12OCT95	-6, .	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	No	9
	8	21DEC95	65, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	14
329.007.00145	SC	04JAN96	-7, -63	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	No	No	Yes	No	No	Yes	No	No	8
	8	07MAR96	57, 1	Yes	Yes	No	No	No	Yes	Yes	No	No	No	No	Yes	No	No	Yes	No	No	6
	32	23AUG96	226, 170	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.007.00265	SC	25JAN96	-7, .	No	No	No	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes	No	Yes	No	5
329.007.00268	SC	21MAR96	-11, -70	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	5
	8	30MAY96	60, 1	No	No	Yes	No	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	3
	32	05DEC96	249, 190	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	1
329.007.00294	SC	20FEB97	-8, .	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	11
329.007.00309	SC	02JUL96	-13, -65	No	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	No	7

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.007.00309	7	05SEP96	53, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	1
	32	13MAR97	242, 190	No	No	No	Yes	No	Yes	Yes	No	No	Yes	Yes	No	No	Yes	No	No	No	6
329.007.00310	SC	19SEP96	-7, -67	No	No	No	No	No	Yes	No	No	Yes	No	Yes	No	Yes	Yes	Yes	No	No	6
	8	25NOV96	61, 1	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	3
	32	12JUN97	260, 200	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.007.00318	SC	22NOV96	-10, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.008.00157	SC	16AUG95	-14, -69	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	10
	8	24OCT95	56, 1	Yes	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	Yes	No	No	No	5
329.008.00160	SC	25OCT95	-7, -73	Yes	No	No	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	15
	8	05JAN96	66, -1	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	2
	32	23JUL96	266, 200	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.008.00188	SC	14DEC95	-21, .	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	14
	8	27FEB96	55, .	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	14
329.008.00271	SC	25JAN96	-46,-110	Yes	No	Yes	Yes	Yes	No	Yes	No	No	Yes	No	Yes	Yes	Yes	No	No	No	9
	8	14MAY96	65, 1	No	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	Yes	No	No	No	4
	32	05NOV96	240, 176	Yes	Yes	No	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No	10
329.008.00275	SC	30APR96	-8, -63	No	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	No	No	No	No	5
	8	02JUL96	56, 1	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	1
	32	16DEC96	223, 168	No	No	No	No	No	No	No	No	.	No	No	No	No	No	No	No	No	0
329.009.00130	SC	12APR95	-6, -62	No	No	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	No	No	Yes	4

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.009.00130	8	13JUN95	57, 1	No	No	No	Yes	No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	Yes	5
329.009.00131	SC	26APR95	-6, -62	No	No	No	No	Yes	No	Yes	No	Yes	Yes	No	Yes	No	No	No	No	Yes	6
	8	27JUN95	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.009.00133	SC	07JUN95	-6, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	14
329.009.00138	SC	02OCT95	-8, .	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	13
329.009.00170	SC	26OCT95	-12, -69	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	No	Yes	Yes	No	No	No	No	7
	8	03JAN96	58, 1	No	No	No	No	No	No	Yes	No	No	Yes	No	Yes	No	No	No	No	No	3
	32	24JUN96	231, 174	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	1
329.009.00173	SC	08NOV95	-12, -75	Yes	No	Yes	No	Yes	Yes	No	Yes	No	Yes	No	Yes	.	Yes	.	Yes	No	10
	8	22JAN96	64, 1	Yes	Yes	No	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	5
329.009.00193	SC	21NOV95	-7, .	Yes	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	12
	8	24JAN96	58, .	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No	No	Yes	8
329.009.00196	SC	11DEC95	-7, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	12
	8	12FEB96	57, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	12
329.009.00201	SC	31JAN96	-6, .	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	4
	8	02APR96	57, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	1
329.009.00204	SC	13MAR96	-6, -62	No	No	No	No	No	No	No	No	.	No	No	No	No	No	No	No	No	0
	8	14MAY96	57, 1	No	No	No	No	No	No	No	No	.	No	No	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.009.00235	SC	10DEC96	-8, -62	No	No	No	Yes	No	No	No	No	.	No	No	No	No	Yes	No	No	No	2
	8	10FEB97	55, 1	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	1
329.009.00240	SC	03JAN97	-11, .	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No	Yes	Yes	No	No	No	Yes	7
329.009.00303	SC	25MAR96	-8, -64	Yes	No	No	No	Yes	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	Yes	7
	8	28MAY96	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	10DEC96	253, 197	No	No	No	No	No	No	.	.	.	.	.	.	.	.	.	.	.	0
329.009.00304	SC	03APR96	-6, -62	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No	No	7
	8	04JUN96	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.009.00324	SC	21OCT96	-7, .	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	Yes	No	Yes	No	No	5
	8	27DEC96	61, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.009.00328	SC	30SEP96	-7, .	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	No	No	No	8
329.009.00329	SC	01OCT96	-8, .	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	Yes	Yes	Yes	No	No	Yes	8
	8	03DEC96	56, .	No	Yes	No	No	Yes	Yes	No	No	No	No	No	Yes	Yes	No	Yes	No	No	6
329.010.00182	SC	05DEC95	-14, .	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	11
329.010.00278	SC	02FEB96	-7, -63	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	14
	8	05APR96	57, 1	No	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	Yes	Yes	Yes	No	7
	32	19SEP96	224, 168	No	No	No	Yes	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	3
329.010.00280	SC	10MAY96	-7, -62	Yes	No	No	Yes	No	No	No	No	No	Yes	No	No	Yes	No	Yes	No	No	5
	8	11JUL96	56, 1	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	2

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.010.00280	12	21AUG96	97, 42	No	No	No	Yes	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No	3
329.011.00283	SC	30JAN96	-9, -66	No	No	No	Yes	No	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	7
	8	04APR96	57, -1	No	No	No	No	No	No	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	No	5
329.011.00288	SC	01JUL96	-24, .	No	Yes	No	No	No	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	10
329.012.00025	SC	17OCT95	-7, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	13
	8	19DEC95	57, .	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	12
329.012.00220	SC	04JUN96	-13, -73	No	No	No	Yes	No	No	No	Yes	No	No	Yes	No	Yes	No	No	No	No	4
	8	16AUG96	61, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.012.00222	SC	18JUN96	-10, -73	No	No	No	Yes	No	Yes	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	9
	8	30AUG96	64, 1	No	No	No	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	9
329.012.00226	SC	26NOV96	-7, .	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	No	No	Yes	No	Yes	10
329.012.00228	SC	04MAR97	-15, .	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	Yes	Yes	Yes	No	Yes	9
329.012.00231	SC	26FEB97	-9, -70	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	5
	8	07MAY97	62, 1	No	No	No	No	No	No	No	No	Yes	No	No	No	Yes	Yes	Yes	No	No	4
	24	19AUG97	166, 105	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	8

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.001.00061	SC	19JUL94	-10, .	No	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	5
329.001.00066	SC	14NOV94	-8, .	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	No	8
329.001.00067	SC	15NOV94	-7, .	Yes	No	No	No	No	Yes	No	No	No	No	No	Yes	Yes	No	Yes	Yes	No	6
329.001.00070	SC	14FEB95	-8, .	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	4
329.001.00122	SC	13JUN95	-7, -64	Yes	Yes	No	Yes	No	Yes	Yes	Yes	.	No	Yes	No	Yes	Yes	Yes	No	No	11
	8	16AUG95	58, 1	Yes	No	No	No	No	Yes	Yes	Yes	.	No	No	Yes	No	No	No	No	No	5
329.002.00050	SC	10MAR95	-13, .	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	1
	5	28APR95	37, .	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	2
329.002.00056	SC	24JUN94	-25, .	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	No	Yes	10
329.002.00057	SC	11AUG94	-28, -85	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	14
	8	03NOV94	57, -1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	16	11JAN95	126, 69	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.002.00098	SC	20DEC94	-14, .	Yes	No	No	No	No	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	9
	8	02MAR95	59, .	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	No	Yes	10
329.002.00100	SC	16FEB95	-19, -77	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	12
	8	04MAY95	59, 1	Yes	No	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	6
	16	06JUL95	122, 64	No	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes	No	No	7
329.002.00103	SC	11APR95	-9, -65	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	No	10

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Section C = Social Interaction
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores — Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.002.00103	8	15JUN95	57, 1	No	No	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	3
	16	10AUG95	113, 57	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	3
329.002.00104	SC	28APR95	-6, -62	No	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	7
	8	29JUN95	57, 1	No	No	No	Yes	No	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	6
	32	02JAN96	244, 188	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	Yes	No	No	3
329.002.00243	SC	27FEB96	-16, .	Yes	No	No	Yes	No	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	No	Yes	10
329.002.00244	SC	14MAR96	-7, -64	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	10
	8	16MAY96	57, -1	Yes	No	No	Yes	No	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes	7
329.002.00321	SC	15MAY96	-8, .	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	No	11
329.002.00322	SC	06JAN97	-3, .	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No	Yes	No	Yes	No	No	5
329.003.00073	SC	11JAN95	-8, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	14
329.003.00076	SC	24JAN95	-7, -62	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	No	No	No	No	9
	32	11OCT95	254, 199	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	1
329.003.00082	SC	11DEC95	1, .	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	11
329.003.00088	SC	06FEB95	-22, .	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	8
329.003.00090	SC	08MAR95	-6, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	12
	8	16MAY95	64, .	Yes	No	No	Yes	No	Yes	Yes	Yes	.	Yes	No	Yes	Yes	No	Yes	Yes	Yes	12

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.003.00092	SC	13APR95	-20, -78	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	1
	8	30JUN95	59, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	02JAN96	245, 187	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.003.00093	SC	08JUN95	-13, -76	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	No	7
	8	22AUG95	63, -1	Yes	No	No	No	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	3
	16	03OCT95	105, 42	Yes	No	No	Yes	No	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No	5
329.003.00247	SC	05JAN96	-27, -81	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	10
	8	26MAR96	55, 1	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes	9
329.003.00249	SC	01MAR96	-6, .	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	13
	8	30APR96	55, .	Yes	No	Yes	No	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	6
329.003.00289	SC	12FEB96	-16, -72	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	.	Yes	Yes	Yes	Yes	Yes	No	Yes	13
	8	24APR96	57, 1	No	No	No	No	No	No	No	No	.	Yes	No	Yes	No	No	No	No	No	2
329.003.00290	SC	06MAR96	-5, .	Yes	Yes	No	No	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	7
329.003.00314	SC	15OCT96	-7, .	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	15
329.003.00317	SC	12DEC96	-7, .	Yes	No	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	No	No	Yes	No	Yes	8
	8	11FEB97	55, .	Yes	Yes	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	No	No	No	No	Yes	8
329.004.00013	SC	05JUL94	-14, -73	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	No	Yes	Yes	No	No	Yes	9
	8	16SEP94	60, 1	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	1
329.004.00014	SC	22NOV94	-7, .	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No	5

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores — Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.004.00211	SC	24JAN96	-9, .	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	8
329.004.00215	SC	12MAR97	-8, .	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	3
329.005.00003	SC	12SEP94	-8, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	.	Yes	No	Yes	Yes	Yes	Yes	Yes	No	13
329.005.00006	SC	27OCT94	-8, -68	No	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes	No	No	No	Yes	9
	8	03JAN95	61, 1	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	2
	24	28APR95	176, 116	No	No	No	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes	No	No	No	No	5
329.005.00007	SC	02NOV94	-7, -70	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	16
	8	11JAN95	64, 1	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	14
	32	09AUG95	274, 211	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes	5
329.005.00009	SC	07DEC94	-5, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	No	No	10
	8	07FEB95	58, .	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	Yes	No	No	2
329.005.00110	SC	04JAN95	-7, .	No	No	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	No	No	2
329.005.00113	SC	20JAN95	-10, .	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	.	Yes	Yes	No	Yes	Yes	Yes	14
329.005.00117	SC	06MAR95	-12, .	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	Yes	10
	8	15MAY95	59, .	Yes	No	No	No	No	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No	5
329.005.00118	SC	09MAY95	-8, .	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	14
329.005.00153	SC	11JAN96	-14, -70	Yes	No	No	No	No	Yes	Yes	No	Yes	.	No	Yes	No	Yes	Yes	No	No	7
	8	21MAR96	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.005.00153	32	04SEP96	224, 168	No	No	No	No	No	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	No	No	5
329.005.00255	SC	26FEB96	-7, .	No	No	No	Yes	Yes	No	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8
	8	29APR96	57, .	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	1
329.005.00256	SC	20FEB96	-14, -70	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	3
	8	30APR96	57, 1	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	Yes	No	No	3
	16	02JUL96	120, 64	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	1
329.005.00295	SC	21MAR96	-7, .	No	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	9
	8	22MAY96	56, .	No	No	No	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No	No	4
329.005.00297	SC	28MAR96	-22, .	No	No	No	Yes	No	Yes	Yes	No	No	No	Yes	No	Yes	No	Yes	Yes	No	7
329.005.00332	SC	05DEC96	-7, .	No	No	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes	No	Yes	No	Yes	6
	8	06FEB97	57, .	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	No	No	Yes	3
329.005.00335	SC	20FEB97	-8, .	Yes	No	No	No	No	No	No	No	.	No	No	No	No	No	No	No	No	1
	8	24APR97	56, .	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	1
329.006.00040	SC	10FEB95	-6, .	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	Yes	No	9
329.006.00041	SC	22MAR95	-14, -78	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	11
	8	31MAY95	57, -8	Yes	No	No	No	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	6
	32	21NOV95	231, 167	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.007.00139	SC	04MAY95	-4, .	No	No	No	No	Yes	Yes	No	No	.	Yes	No	Yes	Yes	No	No	No	Yes	6

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Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.007.00143	SC	26OCT95	-14, .	Yes	No	No	Yes	No	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	No	6
329.007.00146	SC	18JAN96	-7, -60	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	Yes	No	No	Yes	6
	8	18MAR96	54, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	09SEP96	229, 176	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.007.00269	SC	04APR96	-7, .	No	No	No	No	Yes	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	7
	3	02MAY96	22, .	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	Yes	Yes	No	4
329.007.00270	SC	02MAY96	-7, .	Yes	No	No	Yes	No	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	5
	7	27JUN96	50, .	Yes	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	3
329.007.00307	SC	09MAY96	-7, .	Yes	No	No	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	Yes	No	No	Yes	8
	8	25JUL96	71, .	No	No	No	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	No	Yes	No	Yes	7
329.007.00308	SC	27JUN96	-5, .	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	9
329.008.00159	SC	06SEP95	-7, -69	No	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	No	Yes	7
	8	14NOV95	63, 1	No	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	Yes	3
329.008.00161	SC	31OCT95	-16, -71	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	14
	8	10JAN96	56, 1	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	Yes	Yes	Yes	No	No	6
329.008.00187	SC	15NOV95	-14, .	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	11
	8	26JAN96	59, .	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	Yes	Yes	Yes	No	9
329.008.00192	SC	14FEB96	-20, .	No	No	No	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	7

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores — Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.008.00272	SC	19MAR96	-15, -71	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	2
	8	29MAY96	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.008.00273	SC	19APR96	-28, -91	No	No	No	Yes	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	No	4
	8	19JUL96	64, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.009.00127	SC	03APR95	-7, .	No	No	Yes	Yes	No	No	No	Yes	No	No	No	Yes	Yes	Yes	No	No	Yes	7
329.009.00132	SC	17MAY95	-6, -63	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	No	No	No	8
	8	19JUL95	58, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.009.00134	SC	28JUN95	-8, .	Yes	No	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	11
	8	29AUG95	55, .	No	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes	4
329.009.00137	SC	03OCT95	-7, .	Yes	No	Yes	Yes	No	No	No	No	No	No	No	Yes	No	Yes	No	No	Yes	6
	8	05DEC95	57, .	Yes	No	Yes	Yes	Yes	No	No	No	.	Yes	No	Yes	Yes	Yes	Yes	No	No	10
329.009.00171	SC	31OCT95	-7, .	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	12
329.009.00172	SC	06NOV95	-7, -64	No	No	No	No	No	Yes	Yes	Yes	.	No	No	Yes	No	No	No	No	No	4
	8	09JAN96	58, 1	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	3
	32	08JUL96	239, 182	No	No	No	Yes	No	No	No	No	.	No	Yes	Yes	No	No	No	No	No	3
329.009.00194	SC	28NOV95	-7, -63	Yes	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	4
	8	30JAN96	57, 1	Yes	Yes	No	Yes	No	No	Yes	No	No	No	Yes	No	No	Yes	No	Yes	No	7
	24	04JUN96	183, 127	Yes	No	No	Yes	No	No	No	No	Yes	Yes	No	No	Yes	No	No	No	No	5
329.009.00195	SC	06DEC95	-9, .	Yes	Yes	No	Yes	Yes	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	11

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.009.00199	SC	10JAN96	-6, .	.	.	.	.	.	.	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	14
	8	13MAR96	58, .	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	1
329.009.00203	SC	28FEB96	-5, .	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	Yes	No	Yes	No	Yes	6
329.009.00236	SC	17DEC96	-13, .	Yes	No	No	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	Yes	No	No	8
	4	27JAN97	29, .	No	No	No	Yes	.	No	No	No	No	No	.	No	.	No	.	No	No	1
329.009.00239	SC	11NOV96	-8, -65	Yes	No	No	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	10
	8	15JAN97	58, 1	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	1
329.009.00262	SC	07FEB97	-10, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	.	Yes	No	Yes	Yes	No	Yes	No	No	12
	8	14APR97	57, .	Yes	No	Yes	No	No	No	No	No	.	No	No	No	No	No	No	No	No	2
329.009.00264	SC	25OCT96	-7, .	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	Yes	No	No	3
	7	23DEC96	53, .	Yes	No	No	No	No	No	No	No	No	No	No	Yes	.	.	No	No	No	2
329.009.00301	SC	06MAR96	-13, -69	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	1
	8	14MAY96	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.009.00305	SC	01MAY96	-6, -63	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	8	03JUL96	58, 1	Yes	No	No	No	No	No	Yes	No	No	No	Yes	Yes	No	Yes	No	No	No	5
	32	10JAN97	249, 192	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	1
329.009.00325	SC	21AUG96	-6, -61	Yes	No	No	Yes	No	Yes	No	No	No	Yes	No	Yes	No	No	Yes	No	No	6
	8	21OCT96	56, 1	Yes	No	No	No	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	5
	16	16DEC96	112, 57	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	No	Yes	11

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.009.00326	SC	26AUG96	-10, -63	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	.	No	No	Yes	Yes	No	Yes	No	No	11
	8	28OCT96	54, 1	No	No	No	No	No	No	No	No	.	No	No	Yes	No	No	Yes	No	No	2
	16	16DEC96	103, 50	No	No	Yes	Yes	Yes	No	No	No	.	No	Yes	Yes	Yes	No	Yes	No	No	7
329.010.00279	SC	08MAR96	-14, -70	Yes	No	Yes	No	No	No	No	No	No	No	No	No	Yes	.	Yes	Yes	No	5
	8	17MAY96	57, 1	Yes	No	No	No	No	No	No	No	.	No	No	Yes	Yes	No	Yes	No	Yes	5
	32	06NOV96	230, 174	No	Yes	No	Yes	Yes	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	8
329.010.00281	SC	19JUL96	-7, -68	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	3
	8	25SEP96	62, 1	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	1
	24	03JAN97	162, 101	Yes	No	No	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	No	Yes	No	No	7
329.011.00163	SC	18NOV95	-7, .	No	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	No	Yes	Yes	No	10
329.011.00208	SC	22AUG96	-15, -74	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	14
	8	03NOV96	59, -1	No	No	No	No	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	3
329.011.00209	SC	23AUG96	-19, -81	Yes	No	No	No	Yes	No	No	Yes	No	No	Yes	No	No	No	No	No	Yes	5
	8	11NOV96	62, -1	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	1
329.011.00284	SC	13MAR96	-9, -65	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	14
	8	16MAY96	56, -1	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	1
329.011.00286	SC	15MAY96	-22, -90	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	Yes	No	3
	8	09AUG96	65, -4	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.012.00026	SC	09NOV95	-19, .	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	11

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.012.00219	SC	24MAY96	-7, -67	Yes	No	No	No	No	Yes	No	No	No	No	No	Yes	Yes	No	Yes	Yes	Yes	7
	8	30JUL96	61, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	24JAN97	239, 179	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.012.00221	SC	18JUN96	-7, -70	No	No	No	Yes	Yes	Yes	No	No	No	No	Yes	No	Yes	Yes	Yes	No	Yes	8
	8	27AUG96	64, 1	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	2
329.012.00223	SC	23AUG96	-7, .	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	No	Yes	No	Yes	10
329.012.00227	SC	12DEC96	-6, -75	No	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No	No	Yes	No	No	4
	8	25FEB97	70, 1	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No	No	Yes	No	No	3
	32	19AUG97	245, 176	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No	No	Yes	No	No	3
329.012.00230	SC	20FEB97	-8, -77	Yes	No	Yes	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	Yes	No	No	7
	8	08MAY97	70, 1	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No	Yes	No	No	10

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.001.00062	SC	06OCT94	-14, .	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	Yes	No	No	3
329.001.00064	SC	04NOV94	-6, -60	No	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	Yes	Yes	No	No	5
	8	03JAN95	55, 1	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	3
329.001.00069	SC	07FEB95	-9, .	Yes	No	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	12
	8	13APR95	57, .	No	No	No	Yes	No	No	No	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	7
329.001.00071	SC	02FEB95	-21, .	No	No	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	3
	8	20APR95	57, .	Yes	No	No	No	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	6
329.001.00123	SC	14DEC95	-21, .	No	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	13
329.001.00207	SC	19FEB96	-9, .	Yes	Yes	No	No	No	No	Yes	No	Yes	No	No	Yes	Yes	No	No	No	Yes	7
	8	24APR96	57, .	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	Yes	4
329.002.00049	SC	03MAR95	-6, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	.	15
	8	05MAY95	58, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	15
329.002.00059	SC	03NOV94	-7, .	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	Yes	Yes	No	Yes	No	Yes	10
	8	05JAN95	57, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	14
329.002.00060	SC	24JAN95	-7, -63	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	Yes	No	No	7
	8	28MAR95	57, 1	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	9
329.002.00097	SC	20DEC94	-14, -72	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	Yes	No	No	9
	8	02MAR95	59, 1	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	No	Yes	4
	32	05SEP95	246, 188	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	Yes	No	2

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.002.00101	SC	20MAR95	-8, -66	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	No	No	10
	8	25MAY95	59, 1	Yes	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	3
329.002.00107	SC	18JAN96	-7, -63	Yes	No	No	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	8
	8	21MAR96	57, 1	Yes	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	3
	32	26SEP96	246, 190	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	Yes	No	No	3
329.002.00241	SC	25JAN96	-12, -68	No	No	No	No	Yes	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	6
	8	02APR96	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	4
329.002.00246	SC	01APR96	-17, .	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	No	No	Yes	No	Yes	No	Yes	8
	8	18JUN96	62, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	13
329.002.00320	SC	09MAY96	-7, -68	No	No	No	No	No	Yes	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	6
	8	16JUL96	62, 1	No	No	No	Yes	No	No	No	No	.	Yes	No	Yes	Yes	No	Yes	Yes	Yes	7
329.002.00323	SC	04NOV96	-8, -66	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No	6
	8	09JAN97	59, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	12JUN97	213, 155	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.003.00074	32	11OCT95	260, 204	No	No	Yes	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	No	3
329.003.00078	SC	11APR95	-15, .	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	10
	8	21JUN95	57, .	Yes	No	No	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	9
329.003.00080	SC	22NOV95	-5, .	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	8
329.003.00085	SC	26OCT94	-13, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	12

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.003.00085	8	03JAN95	57, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	12
329.003.00086	SC	09NOV94	-19, -76	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	12
	8	23JAN95	57, -1	No	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	Yes	Yes	No	No	5
	32	17AUG95	263, 206	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	3
329.003.00094	8	19DEC95	57, .	Yes	No	No	Yes	Yes	Yes	No	No	.	Yes	No	Yes	Yes	No	Yes	Yes	No	10
329.003.00251	SC	19MAR96	-9, .	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	8
329.003.00252	SC	19MAR96	-22, .	No	No	No	Yes	No	Yes	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	6
	8	04JUN96	56, .	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	4
329.003.00291	SC	01JUL96	-2, -67	Yes	No	No	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	15
329.003.00315	SC	29OCT96	-14, .	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	No	No	No	No	No	7
	8	07JAN97	57, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.003.00316	SC	05DEC96	-12, .	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	5
	8	11FEB97	57, .	Yes	No	No	Yes	No	Yes	No	No	No	No	No	No	Yes	Yes	Yes	No	Yes	7
329.004.00016	SC	01MAR95	-12, .	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes	No	No	No	Yes	7
	5	19APR95	38, .	No	No	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9
329.004.00018	SC	19APR95	-14, .	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	10
	8	29JUN95	58, .	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	1
329.004.00020	SC	02NOV95	-7, .	No	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	No	Yes	No	Yes	5

* days relative to start of acute phase, days relative to start of continuation phase
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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.004.00020	2	24NOV95	16, .	No	No	No	Yes	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes	No	No	No	6
329.004.00213	SC	18JUL96	-15, -69	Yes	No	No	No	Yes	No	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	8
	8	24SEP96	54, -1	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	Yes	4
	32	19MAR97	230, 176	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	4
329.005.00001	SC	11APR94	-9, .	No	Yes	Yes	No	No	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No	No	6
	8	15JUN94	57, .	Yes	No	No	No	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	No	7
329.005.00005	SC	24OCT94	-8, .	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	12
329.005.00010	SC	07DEC94	-6, -63	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	10
	8	08FEB95	58, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	09AUG95	240, 183	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	3
329.005.00012	SC	12DEC94	-7, -66	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	11
	8	16FEB95	60, 1	No	No	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	No	No	No	No	7
329.005.00111	SC	05JAN95	-6, -62	Yes	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	No	Yes	8
	8	08MAR95	57, 1	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	1
	16	03MAY95	113, 57	No	No	No	No	No	No	No	No	.	No	No	No	No	No	No	No	.	0
329.005.00114	SC	23JAN95	-8, -65	Yes	No	No	No	No	Yes	Yes	No	Yes	No	No	Yes	Yes	No	No	No	Yes	7
	8	29MAR95	58, 1	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	13
	16	17MAY95	107, 50	No	No	No	No	No	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	7
329.005.00115	SC	27JAN95	-10, -81	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	4
	8	18APR95	72, 1	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	1

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.005.00120	SC	22AUG95	-8, .	No	No	No	No	No	No	No	Yes	.	No	Yes	No	No	No	No	No	No	2
	8	26OCT95	58, .	No	No	No	No	No	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	4
329.005.00253	SC	31JAN96	-8, .	Yes	No	No	Yes	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	No	8
	8	03APR96	56, .	No	No	Yes	Yes	No	Yes	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	9
329.005.00254	SC	08FEB96	-7, -62	No	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	11
	8	10APR96	56, 1	No	No	No	Yes	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No	3
	32	16OCT96	245, 190	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	2
329.005.00293	SC	06MAR97	-6, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	No	10
	8	07MAY97	57, .	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	3
329.005.00298	SC	15MAY96	-7, -63	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	12
	8	17JUL96	57, 1	Yes	No	No	No	No	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	No	No	6
	32	13JAN97	237, 181	Yes	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	4
329.005.00331	SC	14NOV96	-7, .	Yes	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	11
	8	16JAN97	57, .	Yes	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	No	3
329.005.00334	SC	24JAN97	-7, .	No	Yes	No	Yes	Yes	No	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	11
	8	27MAR97	56, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	2
329.006.00037	SC	20JAN95	-8, .	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No	5
329.006.00042	SC	01DEC95	-6, -63	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	Yes	No	Yes	No	Yes	9
	8	02FEB96	58, 1	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	3
	32	16JUL96	223, 166	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	Yes	No	No	2

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.006.00259	SC	22APR96	-32, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	1
	8	17JUL96	55, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.007.00141	SC	14SEP95	-7, .	Yes	No	No	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	7
329.007.00144	SC	30NOV95	-7, -63	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	1
	8	01FEB96	57, 1	Yes	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	Yes	No	No	4
329.007.00266	SC	29FEB96	-7, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	8	02MAY96	57, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.007.00267	SC	29FEB96	-7, .	Yes	No	No	No	Yes	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No	5
	8	02MAY96	57, .	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.007.00311	SC	26SEP96	-7, -67	Yes	No	No	Yes	No	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	No	No	No	8
	8	02DEC96	61, 1	No	No	No	No	No	No	No	No	No	Yes	Yes	No	Yes	Yes	No	No	No	4
329.008.00158	SC	06SEP95	-7, -69	Yes	No	No	Yes	No	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	No	6
	8	14NOV95	63, 1	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	No	4
329.008.00162	SC	26OCT95	-6, -71	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	13
	8	05JAN96	66, 1	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	10
	32	02JUL96	245, 180	Yes	No	No	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	No	4
329.008.00191	SC	12JAN96	-20, -81	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	13
	8	02APR96	62, 1	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	Yes	No	No	2
329.009.00128	SC	05APR95	-6, .	No	No	No	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	3

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.009.00129	SC	22MAR95	-20, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	17
329.009.00135	SC	25SEP95	-7, .	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	No	No	Yes	9
329.009.00136	SC	26SEP95	-7, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	14
	8	28NOV95	57, .	Yes	Yes	No	No	No	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	Yes	9
329.009.00169	SC	25OCT95	-6, -71	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	13
	8	27DEC95	58, -8	Yes	No	No	No	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No	No	4
329.009.00174	SC	14NOV95	-7, -64	No	Yes	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	No	3
	8	17JAN96	58, 1	No	No	No	No	No	No	No	No	.	No	No	No	Yes	No	No	No	No	1
329.009.00197	SC	20DEC95	-9, -63	Yes	No	No	No	No	Yes	No	No	.	No	No	Yes	No	No	No	No	No	3
	8	20FEB96	54, -1	No	No	No	No	No	No	No	No	.	No	No	No	No	No	No	No	No	0
	32	20AUG96	236, 182	No	No	No	No	No	No	No	No	.	No	No	No	No	No	No	No	No	0
329.009.00198	SC	19DEC95	-14, .	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	14
	8	27FEB96	57, .	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	13
329.009.00200	SC	17JAN96	-6, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	16
329.009.00202	SC	14FEB96	-6, .	No	No	No	Yes	No	Yes	No	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	8
329.009.00238	SC	28OCT96	-15, .	No	No	No	No	No	No	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	7
	8	07JAN97	57, .	No	No	No	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes	No	Yes	Yes	6
329.009.00276	SC	17JAN97	-4, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	14

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.009.00276	8	18MAR97	57, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	16
329.009.00302	SC	20MAR96	-7, .	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No	No	11
329.009.00306	SC	03JUN96	-8, .	No	No	No	No	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	9
	8	06AUG96	57, .	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	11
329.009.00312	SC	30OCT96	-5, .	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	11
	8	06JAN97	64, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	14
329.009.00327	SC	09SEP96	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	16
	5	21OCT96	36, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	14
329.009.00330	SC	15OCT96	-6, .	No	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	Yes	No	Yes	Yes	6
329.010.00183	SC	21NOV95	-12, .	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	10
329.010.00263	SC	24JUL96	-16, .	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	11
	8	09OCT96	62, .	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	2
329.010.00277	SC	23FEB96	-7, -63	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	7
	8	26APR96	57, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	1
	24	07AUG96	160, 104	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.010.00282	SC	19JUL96	-7, .	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	3
	8	27SEP96	64, .	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	1
329.011.00164	SC	15DEC95	-7, .	Yes	No	No	No	No	Yes	Yes	No	No	Yes	No	No	Yes	Yes	No	No	Yes	7

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part II
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores – Section C C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	Sec. C Total
329.011.00210	SC	13SEP96	-15, -81	No	No	No	No	No	No	No	No	Yes	No	No	No	Yes	No	Yes	No	No	3
	8	02DEC96	66, -1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
329.011.00285	SC	08MAY96	-10, .	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	11
	8	24JUL96	68, .	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	15
329.011.00287	SC	25JUN96	-8, .	No	No	No	Yes	No	No	No	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	7
	8	27AUG96	56, .	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	4
329.012.00027	SC	23NOV95	-13, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	No	12
329.012.00217	SC	14MAY96	-7, .	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	13
329.012.00218	SC	04JUN96	-12, -70	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	12
	8	13AUG96	59, 1	No	No	No	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	No	2
329.012.00224	SC	30AUG96	-17, -83	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	1
	8	20NOV96	66, -1	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	1
329.012.00225	SC	19NOV96	-7, -71	No	No	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes	7
	8	29JAN97	65, 1	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0
	32	30JUL97	247, 183	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section C = Social Interaction
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.001.00063	SC	02NOV94	-6, .	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	Yes	No	Yes	2
329.001.00065	SC	07NOV94	-10, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	No	Yes	Yes	Yes	3
329.001.00068	SC	01FEB95	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	No	Yes	Yes	Yes	3
	8	05APR95	57, .	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	No	No	Yes	1
329.001.00072	SC	07MAR95	-13, .	No	No	No	No	No	No	Yes	No	No	No	1	No	No	No	No	No	0
329.001.00121	SC	22MAR95	-13, -69	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	7	No	Yes	Yes	Yes	Yes	4
	8	30MAY95	57, 1	No	No	No	No	No	Yes	Yes	Yes	No	No	3	No	No	No	Yes	Yes	2
329.001.00205	SC	29JAN96	-9, .	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.001.00206	SC	12FEB96	-9, .	No	No	No	No	Yes	No	No	No	No	Yes	2	Yes	No	No	No	No	1
	8	17APR96	57, .	No	No	No	No	No	No	No	No	No	No	0	No	Yes	Yes	No	No	2
329.002.00055	SC	09JUN94	-15, -70	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	8	Yes	Yes	No	Yes	Yes	4
	8	18AUG94	56, 1	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	8	No	No	No	No	Yes	1
	20	10NOV94	140, 85	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	7	Yes	No	No	Yes	Yes	3
329.002.00058	SC	08SEP94	-12, -70	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Yes	6	No	Yes	Yes	Yes	Yes	4
	8	17NOV94	59, 1	No	Yes	No	No	Yes	No	Yes	No	No	No	3	No	No	No	Yes	Yes	2
329.002.00099	SC	23FEB95	-7, -62	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	7	Yes	No	No	Yes	No	2
	8	25APR95	55, -1	No	Yes	Yes	No	No	No	Yes	No	Yes	Yes	5	No	No	No	No	No	0
	32	26OCT95	239, 184	No	No	Yes	No	No	No	Yes	No	Yes	Yes	4	No	No	No	Yes	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.002.00102	SC	03APR95	-10, -64	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	Yes	Yes	Yes	5
	8	06JUN95	55, 1	Yes	Yes	No	Yes	No	No	Yes	Yes	No	No	5	No	Yes	Yes	Yes	Yes	4
	32	05DEC95	237, 183	Yes	Yes	No	Yes	Yes	No	No	No	No	No	4	No	No	No	Yes	Yes	2
329.002.00105	SC	20JUL95	-7, .	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	7	No	No	No	No	No	0
329.002.00106	SC	20JUL95	-7, .	No	Yes	No	Yes	No	Yes	Yes	No	Yes	No	5	Yes	Yes	Yes	Yes	Yes	5
329.002.00242	SC	26JAN96	-12, -70	No	Yes	Yes	No	No	No	Yes	Yes	No	Yes	5	No	No	No	Yes	Yes	2
	20	10JUL96	155, 97	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.002.00245	SC	21MAR96	-7, .	Yes	No	No	No	No	No	No	No	No	Yes	2	No	No	No	No	No	0
329.002.00319	SC	23APR96	-7, -63	Yes	No	No	No	No	Yes	Yes	Yes	No	No	4	No	No	Yes	No	No	1
	8	25JUN96	57, 1	No	No	No	No	No	No	Yes	No	No	No	1	No	No	Yes	Yes	No	2
	32	17DEC96	232, 176	No	No	No	No	Yes	No	Yes	No	No	No	2	No	No	Yes	No	No	1
329.003.00075	SC	18JAN95	-7, -63	No	Yes	No	No	No	No	No	Yes	No	Yes	3	Yes	No	Yes	No	Yes	3
	8	22MAR95	57, 1	No	Yes	No	No	Yes	No	No	Yes	Yes	Yes	5	Yes	Yes	Yes	No	No	3
	32	13SEP95	232, 176	No	No	No	No	Yes	No	No	Yes	No	Yes	3	Yes	No	No	No	No	1
329.003.00077	SC	01MAR95	-5, -64	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	8	No	Yes	Yes	Yes	Yes	4
329.003.00081	SC	04DEC95	-7, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	Yes	Yes	5
329.003.00087	SC	23JAN95	-8, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	Yes	Yes	Yes	5
329.003.00089	SC	24FEB95	-11, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	7	No	No	Yes	No	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

				Sickness Impact Profile Scores																	
			Relative	Section D											Section E						
Patient ID	Week	Date	Days*	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	E1	E2	E3	E4	E5	Sec. E Total
329.003.00089	8	02MAY95	57, .	Yes	No	No	No	No	No	No	Yes	No	No	2	No	No	No	No	No	0
329.003.00091	8	16MAY95	54, -1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	32	07NOV95	229, 175	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	Yes	1
329.003.00248	SC	14FEB96	-16, .	No	No	Yes	Yes	No	No	No	No	No	Yes	3	No	Yes	Yes	Yes	Yes	4
	8	23APR96	54, .	No	No	Yes	No	Yes	No	No	No	No	Yes	3	No	No	No	No	Yes	1
329.003.00250	SC	05MAR96	-9, -66	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	Yes	No	Yes	Yes	3
	8	09MAY96	57, -1	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	Yes	No	Yes	Yes	3
329.003.00292	SC	02AUG96	-5, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	9	Yes	No	No	Yes	Yes	3
	8	04OCT96	59, 1	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes	6	No	No	No	No	Yes	1
329.003.00313	SC	08MAY96	-9, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	Yes	Yes	No	4
329.004.00015	SC	30NOV94	-8, -65	No	Yes	Yes	No	No	No	Yes	No	No	Yes	4	No	No	Yes	No	No	1
	8	03FEB95	58, 1	No	Yes	No	No	No	No	No	No	No	No	1	No	No	No	No	No	0
	28	14JUN95	189, 132	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.004.00017	SC	15MAR95	-7, -63	No	No	No	Yes	Yes	No	No	No	Yes	No	3	No	Yes	Yes	No	No	2
	8	17MAY95	57, 1	No	No	No	No	Yes	Yes	Yes	No	No	No	3	No	No	Yes	Yes	No	2
	32	01NOV95	225, 169	No	Yes	No	No	No	Yes	No	No	No	No	2	No	No	Yes	Yes	No	2
329.004.00019	SC	24MAY95	-7, .	No	No	No	Yes	Yes	No	No	Yes	No	No	3	No	Yes	Yes	No	No	2
329.004.00212	SC	24MAY96	-10, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	Yes	Yes	Yes	5

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.004.00214	SC	27SEP96	-7, -67	No	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	7	No	No	Yes	No	Yes	2
	8	03DEC96	61, 1	No	No	Yes	No	Yes	No	Yes	Yes	No	Yes	5	No	No	Yes	No	Yes	2
329.005.00002	SC	20MAY94	-5, -61	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	Yes	Yes	Yes	3
329.005.00004	SC	22SEP94	-18, -77	Yes	No	Yes	No	No	No	No	No	No	Yes	3	No	Yes	No	No	No	1
	8	08DEC94	60, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.005.00008	SC	10NOV94	-6, -61	No	No	No	No	Yes	No	Yes	Yes	No	No	3	No	No	No	No	No	0
	8	10JAN95	56, 1	No	No	Yes	No	No	No	Yes	Yes	No	No	3	No	No	No	No	No	0
	24	10MAY95	176, 121	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.005.00011	SC	06DEC94	-7, -63	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	Yes	No	Yes	No	Yes	3
	8	07FEB95	57, 1	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	7	No	No	No	No	No	0
329.005.00109	SC	22DEC94	-8, -61	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	No	No	No	Yes	1
	8	21FEB95	54, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	No	No	No	Yes	1
329.005.00112	SC	17JAN95	-9, -64	No	Yes	Yes	Yes	No	No	No	No	Yes	Yes	5	No	No	Yes	No	Yes	2
	8	22MAR95	56, 1	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	20	21JUN95	147, 92	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.005.00116	SC	30JAN95	-8, -66	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	7	No	No	No	No	Yes	1
	8	06APR95	59, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	Yes	1
	24	26JUL95	170, 112	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.005.00119	SC	27JUN95	-14, -73	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	6	No	Yes	No	No	Yes	2
	8	08SEP95	60, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

				Sickness Impact Profile Scores																	
				Section D											Section E						
Patient ID	Week	Date	Relative Days*	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	E1	E2	E3	E4	E5	Sec. E Total
329.005.00119	24	02JAN96	176, 117	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.005.00151	SC	29AUG95	-8, -65	No	No	Yes	No	No	No	No	No	No	No	1	No	No	No	.	Yes	1
	8	02NOV95	58, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	32	01MAY96	239, 182	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	Yes	1
329.005.00152	SC	12OCT95	-14, .	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	Yes	7	No	No	No	No	Yes	1
329.005.00257	SC	05MAR96	-6, -62	No	No	No	No	No	No	Yes	No	No	No	1	No	No	Yes	No	Yes	2
	8	06MAY96	57, 1	No	No	No	No	No	No	Yes	No	Yes	No	2	No	No	No	No	No	0
	32	21OCT96	225, 169	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.005.00258	SC	06FEB96	-35, .	No	Yes	No	No	Yes	No	No	Yes	No	No	3	No	Yes	Yes	No	No	2
	8	07MAY96	57, .	No	Yes	Yes	Yes	No	No	No	No	Yes	Yes	5	Yes	Yes	Yes	Yes	Yes	5
329.005.00299	SC	28MAY96	-11, -71	Yes	No	No	No	No	No	No	Yes	Yes	Yes	4	Yes	No	No	No	No	1
	8	07AUG96	61, 1	Yes	No	No	Yes	No	No	No	No	No	No	2	No	No	No	No	No	0
	20	05NOV96	151, 91	Yes	No	No	No	No	No	No	No	No	No	1	No	No	No	No	No	0
329.005.00300	SC	12SEP96	-7, .	No	No	No	No	No	No	No	No	No	No	0	No	Yes	No	No	No	1
	8	14NOV96	57, .	No	No	No	No	No	No	No	Yes	Yes	Yes	3	No	No	Yes	No	Yes	2
329.005.00333	SC	15JAN97	-8, .	No	No	No	Yes	Yes	No	No	Yes	No	.	3	No	Yes	Yes	.	Yes	4
329.005.00336	SC	26FEB97	-6, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	No	Yes	Yes	Yes	4
	8	30APR97	58, .	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	9	No	No	Yes	No	No	1
329.006.00038	SC	01FEB95	-14, .	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	7	No	Yes	Yes	No	Yes	3

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.006.00039	SC	03FEB95	-5, -66	No	No	Yes	No	Yes	No	No	No	No	No	2	No	Yes	Yes	No	No	2
	8	05APR95	57, -5	No	No	No	No	No	No	No	No	No	No	0	No	Yes	Yes	No	Yes	3
329.006.00260	SC	12JUL96	-6, -64	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	Yes	1
	8	18SEP96	63, 5	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.006.00261	SC	07NOV96	-19, -77	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	Yes	Yes	5
	8	23JAN97	59, 1	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	8	No	No	No	Yes	Yes	2
329.007.00140	SC	07SEP95	-8, -63	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	8	09NOV95	56, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.007.00142	SC	12OCT95	-6, .	No	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	6	No	Yes	Yes	Yes	No	3
	8	21DEC95	65, .	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	6	Yes	No	Yes	Yes	No	3
329.007.00145	SC	04JAN96	-7, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	9	No	Yes	No	Yes	No	2
	8	07MAR96	57, 1	Yes	Yes	Yes	Yes	No	No	No	No	No	No	4	No	Yes	No	Yes	No	2
	32	23AUG96	226, 170	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.007.00265	SC	25JAN96	-7, .	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	7	No	No	No	No	Yes	1
329.007.00268	SC	21MAR96	-11, -70	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	8	No	No	Yes	Yes	Yes	3
	8	30MAY96	60, 1	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	5	No	No	No	No	No	0
	32	05DEC96	249, 190	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.007.00294	SC	20FEB97	-8, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	No	Yes	Yes	Yes	4
329.007.00309	SC	02JUL96	-13, -65	Yes	Yes	No	Yes	No	Yes	No	Yes	No	Yes	6	No	No	No	Yes	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.007.00309	7	05SEP96	53, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	32	13MAR97	242, 190	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	7	No	No	No	Yes	No	1
329.007.00310	SC	19SEP96	-7, -67	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	7	No	No	Yes	No	No	1
	8	25NOV96	61, 1	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	5	No	No	No	No	No	0
	32	12JUN97	260, 200	No	No	No	Yes	Yes	No	Yes	No	No	No	3	No	No	No	No	No	0
329.007.00318	SC	22NOV96	-10, .	No	No	No	No	No	Yes	Yes	No	No	No	2	No	No	No	No	No	0
329.008.00157	SC	16AUG95	-14, -69	No	Yes	Yes	No	No	No	Yes	Yes	No	Yes	5	No	No	Yes	No	No	1
	8	24OCT95	56, 1	Yes	No	No	Yes	No	No	Yes	No	No	No	3	No	No	Yes	No	No	1
329.008.00160	SC	25OCT95	-7, -73	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	9	No	Yes	Yes	Yes	Yes	4
	8	05JAN96	66, -1	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes	6	No	No	No	No	No	0
	32	23JUL96	266, 200	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.008.00188	SC	14DEC95	-21, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	9	No	Yes	Yes	No	Yes	3
	8	27FEB96	55, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	Yes	Yes	No	Yes	3
329.008.00271	SC	25JAN96	-46,-110	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	Yes	No	Yes	Yes	Yes	4
	8	14MAY96	65, 1	No	No	No	Yes	Yes	No	No	Yes	No	Yes	4	No	No	Yes	Yes	No	2
	32	05NOV96	240, 176	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	7	Yes	Yes	No	Yes	No	3
329.008.00275	SC	30APR96	-8, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	No	Yes	Yes	4
	8	02JUL96	56, 1	No	Yes	No	Yes	No	No	No	No	No	No	2	Yes	No	No	No	No	1
	32	16DEC96	223, 168	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.009.00130	SC	12APR95	-6, -62	No	No	Yes	No	No	No	Yes	No	No	No	2	No	No	No	No	No	0

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Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.009.00130	8	13JUN95	57, 1	No	No	No	No	No	No	Yes	No	No	No	1	No	No	No	Yes	Yes	2
329.009.00131	SC	26APR95	-6, -62	Yes	Yes	No	No	No	No	No	No	Yes	No	3	No	No	Yes	Yes	Yes	3
	8	27JUN95	57, 1	No	No	No	No	No	No	Yes	No	No	No	1	No	No	No	No	Yes	1
329.009.00133	SC	07JUN95	-6, .	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	5	No	Yes	Yes	No	Yes	3
329.009.00138	SC	02OCT95	-8, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	No	No	No	Yes	1
329.009.00170	SC	26OCT95	-12, -69	No	No	No	Yes	No	No	No	Yes	No	Yes	3	No	No	Yes	Yes	Yes	3
	8	03JAN96	58, 1	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	5	No	No	Yes	Yes	No	2
	32	24JUN96	231, 174	No	No	No	No	No	No	No	No	No	No	0	No	No	Yes	No	No	1
329.009.00173	SC	08NOV95	-12, -75	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	8	No	No	No	No	Yes	1
	8	22JAN96	64, 1	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	6	No	No	No	No	No	0
329.009.00193	SC	21NOV95	-7, .	Yes	No	Yes	.	No	No	Yes	No	No	Yes	4	No	No	No	No	No	0
	8	24JAN96	58, .	No	Yes	No	No	No	No	No	Yes	No	Yes	3	No	No	No	No	No	0
329.009.00196	SC	11DEC95	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	9	Yes	Yes	No	Yes	No	3
	8	12FEB96	57, .	No	No	No	Yes	No	No	No	No	No	No	1	No	No	No	No	Yes	1
329.009.00201	SC	31JAN96	-6, .	No	No	No	No	No	No	No	Yes	No	No	1	No	No	No	No	No	0
	8	02APR96	57, .	No	No	No	No	No	No	Yes	No	No	No	1	No	No	No	No	No	0
329.009.00204	SC	13MAR96	-6, -62	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	8	14MAY96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.009.00235	SC	10DEC96	-8, -62	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	8	10FEB97	55, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	Yes	Yes	2
329.009.00240	SC	03JAN97	-11, .	No	No	No	Yes	No	No	No	Yes	No	Yes	3	No	Yes	No	Yes	No	2
329.009.00303	SC	25MAR96	-8, -64	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	No	Yes	Yes	Yes	Yes	4
	8	28MAY96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	Yes	Yes	2
	32	10DEC96	253, 197	.	.	.	.	.	.	.	.	.	.	.	No	No	No	No	No	0
329.009.00304	SC	03APR96	-6, -62	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	No	No	No	No	No	0
	8	04JUN96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.009.00324	SC	21OCT96	-7, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	No	No	Yes	Yes	2
	8	27DEC96	61, .	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.009.00328	SC	30SEP96	-7, .	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	7	Yes	No	Yes	Yes	Yes	4
329.009.00329	SC	01OCT96	-8, .	No	Yes	No	Yes	No	Yes	Yes	No	Yes	No	5	No	No	Yes	No	No	1
	8	03DEC96	56, .	No	Yes	Yes	No	No	No	Yes	No	No	No	3	No	No	No	No	No	0
329.010.00182	SC	05DEC95	-14, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	Yes	Yes	No	Yes	3
329.010.00278	SC	02FEB96	-7, -63	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	8	No	No	Yes	No	Yes	2
	8	05APR96	57, 1	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	5	No	No	No	No	No	0
	32	19SEP96	224, 168	Yes	Yes	No	No	No	No	Yes	Yes	Yes	No	5	No	No	No	No	No	0
329.010.00280	SC	10MAY96	-7, -62	No	No	Yes	No	No	No	No	No	No	No	1	No	No	No	No	No	0
	8	11JUL96	56, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.010.00280	12	21AUG96	97, 42	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.011.00283	SC	30JAN96	-9, -66	Yes	No	No	Yes	No	No	Yes	Yes	No	Yes	5	No	Yes	No	No	No	1
	8	04APR96	57, -1	No	Yes	No	No	No	No	Yes	No	No	No	2	No	No	No	No	Yes	1
329.011.00288	SC	01JUL96	-24, .	Yes	Yes	No	Yes	No	No	No	Yes	No	Yes	5	No	No	No	No	No	0
329.012.00025	SC	17OCT95	-7, .	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	8	No	Yes	Yes	No	No	2
	8	19DEC95	57, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	Yes	No	No	Yes	2
329.012.00220	SC	04JUN96	-13, -73	No	No	Yes	Yes	Yes	No	No	Yes	No	Yes	5	No	No	No	Yes	Yes	2
	8	16AUG96	61, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.012.00222	SC	18JUN96	-10, -73	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	8	No	No	Yes	No	No	1
	8	30AUG96	64, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	9	No	No	No	No	No	0
329.012.00226	SC	26NOV96	-7, .	No	No	No	Yes	No	Yes	Yes	Yes	No	Yes	5	Yes	Yes	Yes	Yes	Yes	5
329.012.00228	SC	04MAR97	-15, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	7	No	No	No	Yes	No	1
329.012.00231	SC	26FEB97	-9, -70	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	8	No	No	No	Yes	Yes	2
	8	07MAY97	62, 1	Yes	No	Yes	No	No	No	No	No	No	No	2	No	No	No	No	No	0
	24	19AUG97	166, 105	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	9	Yes	No	No	Yes	Yes	3

* days relative to start of acute phase, days relative to start of continuation phase
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Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.001.00061	SC	19JUL94	-10, .	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	6	No	No	Yes	Yes	Yes	3
329.001.00066	SC	14NOV94	-8, .	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	6	Yes	Yes	Yes	Yes	Yes	5
329.001.00067	SC	15NOV94	-7, .	No	No	No	Yes	No	No	No	Yes	No	Yes	3	No	No	Yes	No	No	1
329.001.00070	SC	14FEB95	-8, .	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	No	No	No	0
329.001.00122	SC	13JUN95	-7, -64	No	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	6	No	No	Yes	No	No	1
	8	16AUG95	58, 1	No	Yes	No	No	Yes	No	Yes	No	No	Yes	4	No	No	Yes	Yes	Yes	3
329.002.00050	SC	10MAR95	-13, .	No	Yes	No	Yes	No	No	No	No	No	Yes	3	No	No	No	Yes	No	1
	5	28APR95	37, .	No	No	No	Yes	No	No	No	No	No	No	1	No	No	No	Yes	No	1
329.002.00056	SC	24JUN94	-25, .	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	5	No	No	Yes	No	No	1
329.002.00057	SC	11AUG94	-28, -85	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	7	Yes	No	No	No	No	1
	8	03NOV94	57, -1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	16	11JAN95	126, 69	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.002.00098	SC	20DEC94	-14, .	Yes	No	No	Yes	Yes	No	Yes	Yes	No	Yes	6	Yes	Yes	Yes	No	Yes	4
	8	02MAR95	59, .	No	Yes	No	No	Yes	No	No	Yes	No	Yes	4	No	Yes	Yes	No	No	2
329.002.00100	SC	16FEB95	-19, -77	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	9	No	Yes	No	Yes	Yes	3
	8	04MAY95	59, 1	Yes	No	Yes	No	No	No	No	No	No	No	2	Yes	Yes	No	Yes	Yes	4
	16	06JUL95	122, 64	Yes	Yes	Yes	No	No	No	No	Yes	No	No	4	No	Yes	No	Yes	Yes	3
329.002.00103	SC	11APR95	-9, -65	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	7	No	No	No	No	Yes	1

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.002.00103	8	15JUN95	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	16	10AUG95	113, 57	Yes	No	No	No	No	No	No	No	No	No	1	No	No	No	No	No	0
329.002.00104	SC	28APR95	-6, -62	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	8	No	No	No	No	No	0
	8	29JUN95	57, 1	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	7	No	No	No	Yes	No	1
	32	02JAN96	244, 188	No	Yes	Yes	Yes	No	No	Yes	No	No	No	4	No	No	No	No	Yes	1
329.002.00243	SC	27FEB96	-16, .	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	8	No	No	Yes	No	Yes	2
329.002.00244	SC	14MAR96	-7, -64	Yes	No	Yes	No	No	No	No	Yes	No	Yes	4	No	Yes	Yes	Yes	Yes	4
	8	16MAY96	57, -1	No	No	No	No	No	No	No	Yes	No	No	1	No	Yes	No	No	No	1
329.002.00321	SC	15MAY96	-8, .	Yes	No	Yes	Yes	No	No	No	Yes	No	Yes	5	Yes	Yes	No	No	No	2
329.002.00322	SC	06JAN97	-3, .	Yes	Yes	No	No	No	No	No	No	No	No	2	No	No	No	No	Yes	1
329.003.00073	SC	11JAN95	-8, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	Yes	No	Yes	Yes	4
329.003.00076	SC	24JAN95	-7, -62	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	8	No	Yes	No	No	Yes	2
	32	11OCT95	254, 199	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.003.00082	SC	11DEC95	1, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	Yes	No	4
329.003.00088	SC	06FEB95	-22, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	7	Yes	No	Yes	No	No	2
329.003.00090	SC	08MAR95	-6, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	Yes	Yes	Yes	Yes	4
	8	16MAY95	64, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	No	No	3

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.003.00092	SC	13APR95	-20, -78	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	5	No	No	No	No	Yes	1
	8	30JUN95	59, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	32	02JAN96	245, 187	No	No	Yes	Yes	No	No	No	No	No	No	2	No	No	No	Yes	Yes	2
329.003.00093	SC	08JUN95	-13, -76	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	No	No	Yes	Yes	2
	8	22AUG95	63, -1	No	Yes	No	No	Yes	No	No	No	Yes	No	3	No	No	No	No	No	0
	16	03OCT95	105, 42	Yes	No	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	No	Yes	4
329.003.00247	SC	05JAN96	-27, -81	Yes	Yes	No	No	Yes	Yes	No	No	Yes	Yes	6	No	Yes	No	Yes	No	2
	8	26MAR96	55, 1	No	No	Yes	Yes	Yes	No	No	No	No	No	3	No	No	No	No	No	0
329.003.00249	SC	01MAR96	-6, .	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	8	Yes	Yes	No	Yes	Yes	4
	8	30APR96	55, .	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	No	No	Yes	Yes	No	2
329.003.00289	SC	12FEB96	-16, -72	No	No	No	Yes	Yes	No	Yes	No	No	Yes	4	No	Yes	Yes	No	No	2
	8	24APR96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	Yes	Yes	No	No	2
329.003.00290	SC	06MAR96	-5, .	No	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	6	Yes	Yes	Yes	Yes	Yes	5
329.003.00314	SC	15OCT96	-7, .	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	No	No	3
329.003.00317	SC	12DEC96	-7, .	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	7	No	Yes	Yes	Yes	Yes	4
	8	11FEB97	55, .	Yes	No	Yes	No	Yes	No	No	No	Yes	Yes	5	No	Yes	Yes	Yes	Yes	4
329.004.00013	SC	05JUL94	-14, -73	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	Yes	Yes	Yes	5
	8	16SEP94	60, 1	Yes	No	No	No	No	No	Yes	No	No	No	2	Yes	No	No	Yes	Yes	3
329.004.00014	SC	22NOV94	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	9	Yes	Yes	Yes	Yes	Yes	5

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.004.00211	SC	24JAN96	-9, .	No	No	No	Yes	Yes	No	No	No	No	No	2	No	No	No	No	No	0
329.004.00215	SC	12MAR97	-8, .	No	Yes	Yes	No	Yes	No	No	Yes	No	Yes	5	No	No	No	Yes	Yes	2
329.005.00003	SC	12SEP94	-8, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	Yes	Yes	No	Yes	3
329.005.00006	SC	27OCT94	-8, -68	Yes	No	Yes	No	Yes	No	No	Yes	Yes	Yes	6	No	Yes	Yes	Yes	No	3
	8	03JAN95	61, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	Yes	No	1
	24	28APR95	176, 116	No	No	No	No	Yes	No	No	No	No	Yes	2	No	No	No	No	No	0
329.005.00007	SC	02NOV94	-7, -70	No	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	6	No	No	Yes	Yes	No	2
	8	11JAN95	64, 1	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	Yes	Yes	5
	32	09AUG95	274, 211	No	Yes	No	No	Yes	No	No	Yes	No	Yes	4	No	No	No	Yes	Yes	2
329.005.00009	SC	07DEC94	-5, .	Yes	No	No	Yes	Yes	No	No	Yes	Yes	Yes	6	No	Yes	Yes	No	No	2
	8	07FEB95	58, .	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	7	No	No	Yes	Yes	Yes	3
329.005.00110	SC	04JAN95	-7, .	Yes	No	No	Yes	No	No	No	Yes	No	No	3	No	No	No	No	No	0
329.005.00113	SC	20JAN95	-10, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	No	No	Yes	3
329.005.00117	SC	06MAR95	-12, .	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	Yes	No	No	1
	8	15MAY95	59, .	Yes	Yes	Yes	No	Yes	No	No	No	Yes	Yes	6	No	No	Yes	No	No	1
329.005.00118	SC	09MAY95	-8, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	Yes	Yes	Yes	5
329.005.00153	SC	11JAN96	-14, -70	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	7	No	No	No	No	Yes	1
	8	21MAR96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.005.00153	32	04SEP96	224, 168	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.005.00255	SC	26FEB96	-7, .	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	7	No	No	No	No	No	0
	8	29APR96	57, .	No	No	No	No	No	No	No	No	No	No	0	No	No	Yes	No	No	1
329.005.00256	SC	20FEB96	-14, -70	No	No	Yes	Yes	No	No	No	Yes	No	No	3	No	No	Yes	No	Yes	2
	8	30APR96	57, 1	No	No	No	No	No	No	No	No	No	Yes	1	No	No	No	No	No	0
	16	02JUL96	120, 64	No	No	No	Yes	No	No	No	No	No	No	1	No	No	Yes	No	Yes	2
329.005.00295	SC	21MAR96	-7, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	Yes	No	No	No	1
	8	22MAY96	56, .	Yes	Yes	No	No	No	No	Yes	Yes	No	No	4	No	No	No	No	Yes	1
329.005.00297	SC	28MAR96	-22, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	7	No	No	Yes	Yes	Yes	3
329.005.00332	SC	05DEC96	-7, .	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	8	No	No	No	Yes	Yes	2
	8	06FEB97	57, .	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	8	No	No	No	Yes	Yes	2
329.005.00335	SC	20FEB97	-8, .	No	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	6	No	No	No	Yes	Yes	2
	8	24APR97	56, .	No	No	No	No	No	No	No	Yes	No	Yes	2	No	No	No	No	Yes	1
329.006.00040	SC	10FEB95	-6, .	No	Yes	No	No	No	No	No	No	No	No	1	No	Yes	Yes	No	Yes	3
329.006.00041	SC	22MAR95	-14, -78	.	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	Yes	Yes	5
	8	31MAY95	57, -8	No	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	6	Yes	Yes	Yes	Yes	Yes	5
	32	21NOV95	231, 167	No	No	No	No	Yes	No	Yes	No	No	No	2	Yes	No	No	No	No	1
329.007.00139	SC	04MAY95	-4, .	No	No	No	No	No	No	No	Yes	No	No	1	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.007.00143	SC	26OCT95	-14, .	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	7	No	No	Yes	No	Yes	2
329.007.00146	SC	18JAN96	-7, -60	No	No	No	Yes	No	No	No	Yes	No	No	2	No	No	Yes	No	No	1
	8	18MAR96	54, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	32	09SEP96	229, 176	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.007.00269	SC	04APR96	-7, .	No	No	No	Yes	Yes	No	No	Yes	No	No	3	Yes	No	No	No	No	1
	3	02MAY96	22, .	No	No	No	No	Yes	No	Yes	No	No	No	2	No	No	No	No	No	0
329.007.00270	SC	02MAY96	-7, .	Yes	Yes	No	No	No	No	No	No	No	No	2	No	Yes	No	No	Yes	2
	7	27JUN96	50, .	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.007.00307	SC	09MAY96	-7, .	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	No	No	Yes	1
	8	25JUL96	71, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	No	Yes	Yes	Yes	4
329.007.00308	SC	27JUN96	-5, .	No	Yes	No	No	Yes	Yes	No	No	No	No	3	No	No	No	No	No	0
329.008.00159	SC	06SEP95	-7, -69	Yes	No	No	No	Yes	No	No	No	No	Yes	3	Yes	No	No	Yes	Yes	3
	8	14NOV95	63, 1	Yes	No	No	No	Yes	No	Yes	Yes	No	No	4	Yes	No	No	No	Yes	2
329.008.00161	SC	31OCT95	-16, -71	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	Yes	Yes	Yes	Yes	4
	8	10JAN96	56, 1	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	6	No	No	Yes	Yes	Yes	3
329.008.00187	SC	15NOV95	-14, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	Yes	Yes	5
	8	26JAN96	59, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	Yes	Yes	5
329.008.00192	SC	14FEB96	-20, .	Yes	No	No	Yes	No	Yes	Yes	No	Yes	Yes	6	Yes	No	No	No	Yes	2

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

				Sickness Impact Profile Scores																	
				Section D											Section E						
Patient ID	Week	Date	Relative Days*	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	E1	E2	E3	E4	E5	Sec. E Total
329.008.00272	SC	19MAR96	-15, -71	No	No	No	No	No	No	No	No	No	Yes	1	No	No	No	No	No	0
	8	29MAY96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.008.00273	SC	19APR96	-28, -91	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	No	No	No	No	0
	8	19JUL96	64, 1	No	Yes	No	Yes	No	No	Yes	No	No	Yes	4	No	No	No	No	Yes	1
329.009.00127	SC	03APR95	-7, .	No	No	No	Yes	No	No	No	Yes	No	No	2	No	Yes	No	No	No	1
329.009.00132	SC	17MAY95	-6, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	Yes	Yes	Yes	Yes	4
	8	19JUL95	58, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.009.00134	SC	28JUN95	-8, .	No	Yes	No	No	Yes	No	Yes	No	Yes	Yes	5	Yes	Yes	No	No	No	2
	8	29AUG95	55, .	No	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	6	No	No	No	Yes	Yes	2
329.009.00137	SC	03OCT95	-7, .	No	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	6	Yes	No	No	No	No	1
	8	05DEC95	57, .	No	No	No	No	Yes	No	No	Yes	No	Yes	3	Yes	No	No	No	No	1
329.009.00171	SC	31OCT95	-7, .	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	7	No	Yes	Yes	No	Yes	3
329.009.00172	SC	06NOV95	-7, -64	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	7	No	Yes	Yes	Yes	Yes	4
	8	09JAN96	58, 1	Yes	Yes	No	No	Yes	No	Yes	No	Yes	Yes	6	No	Yes	Yes	No	No	2
	32	08JUL96	239, 182	No	Yes	Yes	No	No	No	No	No	No	No	2	No	No	No	No	Yes	1
329.009.00194	SC	28NOV95	-7, -63	Yes	No	Yes	Yes	No	No	Yes	.	No	Yes	6	Yes	No	No	No	No	1
	8	30JAN96	57, 1	Yes	No	No	No	No	Yes	No	No	Yes	No	3	Yes	Yes	Yes	No	Yes	4
	24	04JUN96	183, 127	No	No	No	No	No	No	No	Yes	No	No	1	No	Yes	No	No	No	1
329.009.00195	SC	06DEC95	-9, .	No	No	No	No	Yes	No	No	No	No	Yes	2	Yes	No	No	No	No	1

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.009.00199	SC	10JAN96	-6, .	No	No	No	No	.	.	.	.	.	.	0	.	.	.	.	.	.
	8	13MAR96	58, .	No	No	No	No	Yes	No	Yes	No	No	No	2	No	No	No	No	No	0
329.009.00203	SC	28FEB96	-5, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	No	No	Yes	1
329.009.00236	SC	17DEC96	-13, .	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	7	Yes	Yes	No	Yes	Yes	4
	4	27JAN97	29, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	8	.	.	.	.	.	.
329.009.00239	SC	11NOV96	-8, -65	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	6	No	Yes	Yes	No	No	2
	8	15JAN97	58, 1	Yes	Yes	Yes	No	No	No	No	No	No	No	3	No	No	No	No	No	0
329.009.00262	SC	07FEB97	-10, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	Yes	Yes	Yes	Yes	4
	8	14APR97	57, .	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.009.00264	SC	25OCT96	-7, .	No	No	No	No	No	No	No	No	No	Yes	1	Yes	No	No	No	Yes	2
	7	23DEC96	53, .	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.009.00301	SC	06MAR96	-13, -69	No	No	No	Yes	No	No	No	No	No	No	1	No	No	No	No	No	0
	8	14MAY96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.009.00305	SC	01MAY96	-6, -63	No	No	No	Yes	No	No	No	No	No	No	1	Yes	No	No	No	Yes	2
	8	03JUL96	58, 1	No	No	No	No	No	No	Yes	No	No	No	1	No	No	No	No	No	0
	32	10JAN97	249, 192	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.009.00325	SC	21AUG96	-6, -61	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	No	Yes	No	No	Yes	2
	8	21OCT96	56, 1	No	Yes	Yes	No	Yes	Yes	Yes	No	No	No	5	No	No	No	No	Yes	1
	16	16DEC96	112, 57	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	No	Yes	No	No	Yes	2

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.009.00326	SC	26AUG96	-10, -63	No	No	No	Yes	No	No	Yes	No	No	Yes	3	Yes	No	Yes	Yes	Yes	4
	8	28OCT96	54, 1	No	No	No	Yes	No	No	No	No	No	No	1	No	No	Yes	Yes	Yes	3
	16	16DEC96	103, 50	No	Yes	Yes	Yes	.	No	Yes	Yes	Yes	No	7	No	No	No	Yes	Yes	2
329.010.00279	SC	08MAR96	-14, -70	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	7	No	No	No	No	No	0
	8	17MAY96	57, 1	No	No	Yes	No	No	No	Yes	No	No	No	2	No	No	No	No	No	0
	32	06NOV96	230, 174	No	No	Yes	No	No	No	No	No	No	No	1	No	No	No	No	No	0
329.010.00281	SC	19JUL96	-7, -68	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	8	25SEP96	62, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	24	03JAN97	162, 101	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	7	No	No	No	No	No	0
329.011.00163	SC	18NOV95	-7, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	Yes	No	No	No	2
329.011.00208	SC	22AUG96	-15, -74	No	No	No	No	No	No	No	No	Yes	No	1	No	No	No	No	Yes	1
	8	03NOV96	59, -1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.011.00209	SC	23AUG96	-19, -81	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	5	No	No	No	No	No	0
	8	11NOV96	62, -1	No	No	Yes	Yes	No	No	No	Yes	No	No	3	No	Yes	No	No	Yes	2
329.011.00284	SC	13MAR96	-9, -65	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	5	No	Yes	Yes	Yes	Yes	4
	8	16MAY96	56, -1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.011.00286	SC	15MAY96	-22, -90	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	5	No	No	No	No	No	0
	8	09AUG96	65, -4	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.012.00026	SC	09NOV95	-19, .	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	5	Yes	No	No	No	Yes	2

* days relative to start of acute phase, days relative to start of continuation phase
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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = IMIPRAMINE

				Sickness Impact Profile Scores																	
			Relative	Section D											Section E						
Patient ID	Week	Date	Days*	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	E1	E2	E3	E4	E5	Sec. E Total
329.012.00219	SC	24MAY96	-7, -67	No	No	No	No	Yes	No	No	Yes	No	Yes	3	Yes	No	No	No	Yes	2
	8	30JUL96	61, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	32	24JAN97	239, 179	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.012.00221	SC	18JUN96	-7, -70	No	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	6	No	No	Yes	Yes	Yes	3
	8	27AUG96	64, 1	No	No	No	No	No	Yes	Yes	No	No	No	2	No	No	No	No	Yes	1
329.012.00223	SC	23AUG96	-7, .	No	Yes	No	No	Yes	No	Yes	Yes	No	Yes	5	No	Yes	Yes	No	Yes	3
329.012.00227	SC	12DEC96	-6, -75	No	No	No	Yes	Yes	No	No	Yes	No	Yes	4	No	No	No	No	Yes	1
	8	25FEB97	70, 1	Yes	No	No	Yes	Yes	No	Yes	Yes	No	Yes	6	Yes	No	No	Yes	Yes	3
	32	19AUG97	245, 176	Yes	No	No	No	No	No	No	No	Yes	No	2	No	Yes	No	No	Yes	2
329.012.00230	SC	20FEB97	-8, -77	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	No	No	Yes	Yes	3
	8	08MAY97	70, 1	No	Yes	No	Yes	No	No	Yes	No	Yes	Yes	5	No	Yes	No	Yes	Yes	3

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.001.00062	SC	06OCT94	-14, .	Yes	No	No	Yes	No	No	Yes	No	No	Yes	4	No	No	No	No	No	0
329.001.00064	SC	04NOV94	-6, -60	No	No	No	Yes	No	No	Yes	No	No	Yes	3	No	No	No	No	No	0
	8	03JAN95	55, 1	No	No	No	No	No	No	No	Yes	No	No	1	No	No	No	No	No	0
329.001.00069	SC	07FEB95	-9, .	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	8	No	No	No	Yes	Yes	2
	8	13APR95	57, .	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	7	No	No	No	No	Yes	1
329.001.00071	SC	02FEB95	-21, .	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes	6	No	No	No	Yes	No	1
	8	20APR95	57, .	No	Yes	Yes	No	No	No	Yes	No	No	Yes	4	No	No	No	Yes	Yes	2
329.001.00123	SC	14DEC95	-21, .	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	No	No	No	No	No	0
329.001.00207	SC	19FEB96	-9, .	Yes	No	No	Yes	Yes	No	Yes	No	Yes	Yes	6	No	No	Yes	No	No	1
	8	24APR96	57, .	No	No	No	No	Yes	No	Yes	No	Yes	Yes	4	No	No	Yes	No	No	1
329.002.00049	SC	03MAR95	-6, .	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	7	No	Yes	Yes	Yes	Yes	4
	8	05MAY95	58, .	No	No	Yes	Yes	No	No	Yes	Yes	No	No	4	No	Yes	Yes	Yes	Yes	4
329.002.00059	SC	03NOV94	-7, .	No	No	No	No	No	No	No	Yes	No	Yes	2	No	No	No	No	Yes	1
	8	05JAN95	57, .	No	No	Yes	No	No	No	No	Yes	No	Yes	3	No	No	Yes	No	No	1
329.002.00060	SC	24JAN95	-7, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	Yes	Yes	Yes	Yes	4
	8	28MAR95	57, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	No	Yes	Yes	4
329.002.00097	SC	20DEC94	-14, -72	Yes	No	Yes	No	Yes	No	Yes	Yes	No	Yes	6	Yes	No	Yes	No	Yes	3
	8	02MAR95	59, 1	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	No	No	No	No	Yes	1
	32	05SEP95	246, 188	No	No	No	No	No	Yes	Yes	Yes	No	No	3	Yes	No	No	No	Yes	2

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

				Sickness Impact Profile Scores																	
			Relative	Section D											Section E						
Patient ID	Week	Date	Days*	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	E1	E2	E3	E4	E5	Sec. E Total
329.002.00101	SC	20MAR95	-8, -66	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	7	Yes	No	Yes	Yes	Yes	4
	8	25MAY95	59, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	9	No	No	No	No	No	0
329.002.00107	SC	18JAN96	-7, -63	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	8	Yes	Yes	Yes	Yes	No	4
	8	21MAR96	57, 1	Yes	Yes	No	No	No	No	No	Yes	No	No	3	No	No	Yes	No	Yes	2
	32	26SEP96	246, 190	Yes	Yes	No	No	No	No	Yes	No	No	No	3	No	No	Yes	No	No	1
329.002.00241	SC	25JAN96	-12, -68	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	9	No	Yes	No	Yes	Yes	3
	8	02APR96	57, 1	No	No	No	No	No	No	Yes	Yes	No	No	2	No	No	No	Yes	Yes	2
329.002.00246	SC	01APR96	-17, .	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes	7	Yes	Yes	Yes	No	Yes	4
	8	18JUN96	62, .	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	7	Yes	Yes	No	Yes	No	3
329.002.00320	SC	09MAY96	-7, -68	Yes	Yes	No	No	No	No	Yes	No	Yes	No	4	No	No	Yes	Yes	Yes	3
	8	16JUL96	62, 1	No	Yes	No	No	No	No	Yes	No	No	No	2	No	No	Yes	Yes	Yes	3
329.002.00323	SC	04NOV96	-8, -66	Yes	Yes	Yes	No	Yes	No	No	Yes	No	Yes	6	No	No	Yes	No	Yes	2
	8	09JAN97	59, 1	No	No	No	No	Yes	No	No	Yes	No	Yes	3	No	No	No	No	Yes	1
	32	12JUN97	213, 155	No	No	No	No	Yes	No	No	Yes	No	No	2	No	No	No	No	Yes	1
329.003.00074	32	11OCT95	260, 204	Yes	No	No	No	Yes	No	Yes	No	No	Yes	4	Yes	No	No	No	No	1
329.003.00078	SC	11APR95	-15, .	No	No	Yes	Yes	Yes	No	No	Yes	No	Yes	5	No	No	Yes	No	Yes	2
	8	21JUN95	57, .	Yes	No	Yes	Yes	Yes	No	No	No	No	Yes	5	No	No	Yes	No	No	1
329.003.00080	SC	22NOV95	-5, .	Yes	Yes	Yes	No	No	No	Yes	Yes	No	Yes	6	No	No	No	No	No	0
329.003.00085	SC	26OCT94	-13, .	No	No	No	Yes	Yes	No	No	Yes	No	Yes	4	No	No	Yes	No	No	1

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

				Sickness Impact Profile Scores																	
			Relative	Section D											Section E						
Patient ID	Week	Date	Days*	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	E1	E2	E3	E4	E5	Sec. E Total
329.003.00085	8	03JAN95	57, .	No	No	No	No	Yes	No	No	Yes	No	No	2	No	No	Yes	No	No	1
329.003.00086	SC	09NOV94	-19, -76	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	6	No	No	No	No	No	0
	8	23JAN95	57, -1	No	No	No	Yes	No	No	Yes	Yes	No	Yes	4	No	No	No	No	No	0
	32	17AUG95	263, 206	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	7	No	No	No	Yes	No	1
329.003.00094	8	19DEC95	57, .	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	.	8	No	Yes	Yes	Yes	No	3
329.003.00251	SC	19MAR96	-9, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	No	No	Yes	Yes	2
329.003.00252	SC	19MAR96	-22, .	Yes	No	Yes	Yes	No	No	No	Yes	No	No	4	No	No	No	Yes	Yes	2
	8	04JUN96	56, .	No	No	Yes	Yes	No	No	No	No	No	Yes	3	No	No	No	Yes	Yes	2
329.003.00291	SC	01JUL96	-2, -67	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	8	No	Yes	Yes	Yes	Yes	4
329.003.00315	SC	29OCT96	-14, .	No	No	No	Yes	No	No	Yes	Yes	No	No	3	No	Yes	Yes	No	No	2
	8	07JAN97	57, .	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.003.00316	SC	05DEC96	-12, .	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	Yes	No	No	No	No	1
	8	11FEB97	57, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	7	Yes	No	No	No	No	1
329.004.00016	SC	01MAR95	-12, .	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	7	No	No	No	No	No	0
	5	19APR95	38, .	No	No	Yes	No	Yes	No	No	No	Yes	Yes	4	No	No	No	Yes	No	1
329.004.00018	SC	19APR95	-14, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	No	Yes	Yes	Yes	4
	8	29JUN95	58, .	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	7	No	No	No	Yes	Yes	2
329.004.00020	SC	02NOV95	-7, .	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	7	No	No	No	No	.	0

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.004.00020	2	24NOV95	16, .	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	8	No	No	No	No	No	0
329.004.00213	SC	18JUL96	-15, -69	No	No	No	Yes	No	No	Yes	Yes	No	Yes	4	Yes	Yes	No	Yes	Yes	4
	8	24SEP96	54, -1	Yes	No	No	Yes	No	No	Yes	No	No	No	3	Yes	No	Yes	Yes	Yes	4
	32	19MAR97	230, 176	No	Yes	No	Yes	No	No	Yes	Yes	No	No	4	No	No	No	Yes	Yes	2
329.005.00001	SC	11APR94	-9, .	No	No	Yes	No	Yes	No	Yes	No	Yes	No	4	No	Yes	Yes	No	Yes	3
	8	15JUN94	57, .	No	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	6	Yes	Yes	Yes	Yes	Yes	5
329.005.00005	SC	24OCT94	-8, .	No	No	No	No	Yes	Yes	Yes	No	Yes	Yes	5	No	Yes	No	No	Yes	2
329.005.00010	SC	07DEC94	-6, -63	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	5	No	No	Yes	No	Yes	2
	8	08FEB95	58, 1	No	No	No	No	Yes	No	No	Yes	No	No	2	No	No	Yes	No	No	1
	32	09AUG95	240, 183	No	No	No	No	No	No	No	No	No	No	0	No	No	Yes	No	No	1
329.005.00012	SC	12DEC94	-7, -66	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9	No	Yes	Yes	Yes	No	3
	8	16FEB95	60, 1	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	No	6	No	Yes	No	No	Yes	2
329.005.00111	SC	05JAN95	-6, -62	No	No	No	No	Yes	No	No	No	No	No	1	No	No	Yes	No	No	1
	8	08MAR95	57, 1	No	No	No	No	No	No	No	No	No	.	0	No	No	.	No	No	0
	16	03MAY95	113, 57	No	No	No	No	No	No	No	Yes	No	No	1	No	No	No	No	No	0
329.005.00114	SC	23JAN95	-8, -65	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	8	29MAR95	58, 1	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	8	Yes	Yes	Yes	Yes	Yes	5
	16	17MAY95	107, 50	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.005.00115	SC	27JAN95	-10, -81	No	No	No	No	No	No	Yes	Yes	No	Yes	3	No	No	No	No	No	0
	8	18APR95	72, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.005.00120	SC	22AUG95	-8, .	No	Yes	No	No	Yes	Yes	No	No	Yes	Yes	5	No	Yes	Yes	Yes	No	3
	8	26OCT95	58, .	No	No	No	No	No	No	Yes	No	No	No	1	No	No	Yes	Yes	Yes	3
329.005.00253	SC	31JAN96	-8, .	No	No	No	Yes	Yes	No	No	No	No	No	2	No	No	No	No	No	0
	8	03APR96	56, .	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	8	No	No	No	No	No	0
329.005.00254	SC	08FEB96	-7, -62	No	No	No	No	No	No	No	Yes	Yes	Yes	3	No	Yes	Yes	No	Yes	3
	8	10APR96	56, 1	No	No	No	No	No	No	No	No	No	Yes	1	No	Yes	Yes	Yes	Yes	4
	32	16OCT96	245, 190	No	No	No	No	No	No	No	No	No	Yes	1	No	No	Yes	No	No	1
329.005.00293	SC	06MAR97	-6, .	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	7	No	No	Yes	Yes	Yes	3
	8	07MAY97	57, .	No	Yes	No	No	No	No	Yes	No	No	No	2	No	No	Yes	Yes	Yes	3
329.005.00298	SC	15MAY96	-7, -63	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	No	No	.	0
	8	17JUL96	57, 1	No	Yes	No	Yes	Yes	No	Yes	No	Yes	No	5	No	No	No	No	No	0
	32	13JAN97	237, 181	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	5	No	No	No	No	No	0
329.005.00331	SC	14NOV96	-7, .	Yes	No	No	Yes	Yes	No	No	Yes	No	Yes	5	Yes	Yes	Yes	No	No	3
	8	16JAN97	57, .	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	7	No	No	No	No	No	0
329.005.00334	SC	24JAN97	-7, .	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	7	Yes	No	Yes	No	Yes	3
	8	27MAR97	56, .	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.006.00037	SC	20JAN95	-8, .	No	No	No	No	No	Yes	No	No	No	No	1	No	Yes	Yes	No	Yes	3
329.006.00042	SC	01DEC95	-6, -63	No	No	No	Yes	No	No	Yes	Yes	Yes	No	4	No	Yes	Yes	No	Yes	3
	8	02FEB96	58, 1	No	No	Yes	Yes	No	No	No	No	No	No	2	No	No	Yes	No	Yes	2
	32	16JUL96	223, 166	No	Yes	No	Yes	No	No	No	Yes	No	No	3	No	No	Yes	Yes	Yes	3

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.006.00259	SC	22APR96	-32, .	No	No	Yes	No	No	No	No	No	No	Yes	2	No	No	No	No	No	0
	8	17JUL96	55, .	No	No	Yes	No	No	No	No	No	No	No	1	No	No	No	No	No	0
329.007.00141	SC	14SEP95	-7, .	No	Yes	Yes	No	No	Yes	Yes	No	No	No	4	No	Yes	Yes	Yes	Yes	4
329.007.00144	SC	30NOV95	-7, -63	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	5	No	Yes	No	No	Yes	2
	8	01FEB96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	Yes	No	No	1
329.007.00266	SC	29FEB96	-7, .	No	Yes	No	Yes	No	No	No	No	No	No	2	No	No	No	No	Yes	1
	8	02MAY96	57, .	No	No	Yes	Yes	No	No	No	No	No	No	2	No	No	No	No	No	0
329.007.00267	SC	29FEB96	-7, .	No	Yes	No	Yes	Yes	No	Yes	No	No	Yes	5	No	No	No	No	No	0
	8	02MAY96	57, .	No	No	Yes	Yes	No	No	Yes	No	No	No	3	No	No	No	No	No	0
329.007.00311	SC	26SEP96	-7, -67	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	5	Yes	No	No	Yes	Yes	3
	8	02DEC96	61, 1	No	Yes	Yes	Yes	No	No	No	No	Yes	No	4	Yes	No	Yes	No	Yes	3
329.008.00158	SC	06SEP95	-7, -69	No	No	Yes	No	No	No	Yes	No	No	Yes	3	No	No	Yes	Yes	Yes	3
	8	14NOV95	63, 1	No	No	No	No	No	No	Yes	No	No	No	1	No	No	Yes	No	No	1
329.008.00162	SC	26OCT95	-6, -71	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	Yes	Yes	Yes	No	Yes	4
	8	05JAN96	66, 1	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	No	Yes	No	No	1
	32	02JUL96	245, 180	No	No	No	No	No	No	Yes	Yes	No	No	2	No	No	No	No	Yes	1
329.008.00191	SC	12JAN96	-20, -81	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8	No	Yes	Yes	No	Yes	3
	8	02APR96	62, 1	No	No	No	No	Yes	No	No	No	No	No	1	No	No	No	Yes	Yes	2
329.009.00128	SC	05APR95	-6, .	No	No	No	No	No	No	No	No	No	No	0	No	No	Yes	Yes	No	2

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.009.00129	SC	22MAR95	-20, .	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	8	Yes	Yes	Yes	Yes	Yes	5
329.009.00135	SC	25SEP95	-7, .	No	No	Yes	No	Yes	No	No	No	No	Yes	3	No	Yes	Yes	No	No	2
329.009.00136	SC	26SEP95	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	No	Yes	Yes	4
	8	28NOV95	57, .	Yes	No	No	No	No	No	No	No	No	Yes	2	Yes	No	No	No	No	1
329.009.00169	SC	25OCT95	-6, -71	No	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	6	Yes	No	Yes	Yes	Yes	4
	8	27DEC95	58, -8	No	No	No	No	No	No	No	No	No	No	0	Yes	No	No	Yes	Yes	3
329.009.00174	SC	14NOV95	-7, -64	No	No	No	No	No	No	No	No	No	Yes	1	No	No	No	No	No	0
	8	17JAN96	58, 1	No	No	No	No	No	No	No	Yes	No	No	1	No	No	No	No	No	0
329.009.00197	SC	20DEC95	-9, -63	No	No	No	No	No	No	No	Yes	No	No	1	Yes	No	No	No	No	1
	8	20FEB96	54, -1	No	No	No	Yes	No	No	No	No	No	No	1	No	No	No	No	No	0
	32	20AUG96	236, 182	No	No	Yes	No	No	No	No	No	No	No	1	No	No	Yes	Yes	No	2
329.009.00198	SC	19DEC95	-14, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	Yes	Yes	Yes	No	3
	8	27FEB96	57, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	Yes	Yes	Yes	No	3
329.009.00200	SC	17JAN96	-6, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	No	No	No	No	0
329.009.00202	SC	14FEB96	-6, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	No	Yes	Yes	Yes	3
329.009.00238	SC	28OCT96	-15, .	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	9	No	Yes	No	Yes	Yes	3
	8	07JAN97	57, .	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	7	No	Yes	Yes	Yes	No	3
329.009.00276	SC	17JAN97	-4, .	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	7	No	Yes	Yes	Yes	Yes	4

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.009.00276	8	18MAR97	57, .	Yes	No	Yes	No	No	No	Yes	No	No	No	3	No	Yes	Yes	Yes	Yes	4
329.009.00302	SC	20MAR96	-7, .	No	No	Yes	Yes	No	No	Yes	Yes	No	Yes	5	No	No	No	Yes	No	1
329.009.00306	SC	03JUN96	-8, .	No	No	No	No	No	Yes	No	Yes	No	No	2	No	Yes	No	No	No	1
	8	06AUG96	57, .	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No	6	Yes	Yes	No	No	Yes	3
329.009.00312	SC	30OCT96	-5, .	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes	6	No	No	Yes	No	Yes	2
	8	06JAN97	64, .	Yes	No	No	No	No	No	Yes	Yes	No	Yes	4	No	No	Yes	No	No	1
329.009.00327	SC	09SEP96	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	No	Yes	No	3
	5	21OCT96	36, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	Yes	Yes	Yes	Yes	Yes	5
329.009.00330	SC	15OCT96	-6, .	Yes	No	No	Yes	Yes	No	No	Yes	Yes	No	5	No	Yes	Yes	No	Yes	3
329.010.00183	SC	21NOV95	-12, .	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	Yes	No	No	Yes	2
329.010.00263	SC	24JUL96	-16, .	Yes	No	Yes	No	Yes	No	Yes	No	No	Yes	5	Yes	Yes	No	Yes	No	3
	8	09OCT96	62, .	No	No	No	Yes	No	No	No	Yes	No	No	2	No	No	Yes	No	No	1
329.010.00277	SC	23FEB96	-7, -63	Yes	No	Yes	Yes	No	No	No	Yes	No	Yes	5	No	No	Yes	No	Yes	2
	8	26APR96	57, 1	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
	24	07AUG96	160, 104	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.010.00282	SC	19JUL96	-7, .	No	No	No	No	No	No	Yes	No	No	No	1	No	No	No	No	No	0
	8	27SEP96	64, .	No	No	No	No	No	No	No	No	No	No	0	No	No	No	No	No	0
329.011.00164	SC	15DEC95	-7, .	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	7	No	No	No	Yes	Yes	2

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part III
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section D D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	Sec. D Total	Section E E1	E2	E3	E4	E5	Sec. E Total
329.011.00210	SC	13SEP96	-15, -81	Yes	No	Yes	Yes	Yes	No	Yes	No	No	No	5	No	No	No	No	.	0
	8	02DEC96	66, -1	Yes	Yes	Yes	Yes	No	No	No	No	No	No	4	No	No	No	No	Yes	1
329.011.00285	SC	08MAY96	-10, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	Yes	Yes	Yes	Yes	4
	8	24JUL96	68, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	No	Yes	Yes	Yes	3
329.011.00287	SC	25JUN96	-8, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	9	No	No	No	No	Yes	1
	8	27AUG96	56, .	Yes	Yes	No	Yes	No	No	No	No	No	No	3	No	No	No	No	Yes	1
329.012.00027	SC	23NOV95	-13, .	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9	No	No	Yes	Yes	Yes	3
329.012.00217	SC	14MAY96	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10	No	Yes	Yes	Yes	Yes	4
329.012.00218	SC	04JUN96	-12, -70	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	5	No	No	Yes	No	Yes	2
	8	13AUG96	59, 1	No	No	No	No	No	No	No	No	No	Yes	1	No	No	No	No	Yes	1
329.012.00224	SC	30AUG96	-17, -83	No	Yes	Yes	Yes	Yes	No	Yes	No	No	No	5	No	No	Yes	Yes	No	2
	8	20NOV96	66, -1	No	Yes	No	Yes	Yes	No	Yes	No	No	No	4	No	No	Yes	Yes	No	2
329.012.00225	SC	19NOV96	-7, -71	No	No	Yes	No	No	No	Yes	No	Yes	No	3	No	No	No	Yes	No	1
	8	29JAN97	65, 1	No	No	Yes	No	No	Yes	Yes	No	No	No	3	No	Yes	No	No	No	1
	32	30JUL97	247, 183	No	No	No	No	No	No	Yes	No	No	No	1	No	No	No	No	No	0

* days relative to start of acute phase, days relative to start of continuation phase
Section D = Alertness Behavior, Section E = Communication
Section totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.001.00063	SC	02NOV94	-6, .	No	Yes	No	No	Yes	Yes	Yes	Yes	5	3	4	46
329.001.00065	SC	07NOV94	-10, .	Yes	Yes	Yes	No	No	No	No	No	3	2	4	35
329.001.00068	SC	01FEB95	-7, .	No	Yes	No	No	Yes	No	No	No	2	3	4	38
	8	05APR95	57, .	No	No	No	No	Yes	No	Yes	Yes	3	2	3	32
329.001.00072	SC	07MAR95	-13, .	No	No	No	No	No	No	No	No	0	1	2	7
329.001.00121	SC	22MAR95	-13, -69	Yes	Yes	No	No	Yes	Yes	Yes	No	5	2	3	34
	8	30MAY95	57, 1	No	No	Yes	No	No	No	No	No	1	2	3	20
329.001.00205	SC	29JAN96	-9, .	No	No	No	No	No	No	No	No	0	2	2	8
329.001.00206	SC	12FEB96	-9, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	1	3	23
	8	17APR96	57, .	No	Yes	Yes	Yes	No	Yes	No	Yes	5	1	4	25
329.002.00055	SC	09JUN94	-15, -70	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	5	5	52
	8	18AUG94	56, 1	Yes	Yes	No	No	Yes	Yes	Yes	No	5	2	3	37
	20	10NOV94	140, 85	Yes	Yes	Yes	No	No	Yes	Yes	No	5	3	3	38
329.002.00058	SC	08SEP94	-12, -70	Yes	Yes	No	No	No	Yes	Yes	Yes	5	3	3	35
	8	17NOV94	59, 1	No	No	Yes	No	No	No	No	No	1	2	2	12
329.002.00099	SC	23FEB95	-7, -62	Yes	Yes	No	No	Yes	No	No	Yes	4	2	3	29
	8	25APR95	55, -1	No	No	No	No	Yes	No	Yes	No	2	1	2	17
	32	26OCT95	239, 184	Yes	Yes	No	No	Yes	No	Yes	No	4	3	3	26

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Paroxetine - Protocol 329
Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.002.00102	SC	03APR95	-10, -64	Yes	Yes	Yes	No	No	Yes	Yes	No	5	2	3	41
	8	06JUN95	55, 1	No	No	No	No	No	No	No	No	0	2	2	16
	32	05DEC95	237, 183	No	No	No	No	No	No	No	No	0	3	2	12
329.002.00105	SC	20JUL95	-7, .	No	Yes	No	No	No	No	Yes	Yes	3	3	4	29
329.002.00106	SC	20JUL95	-7, .	Yes	Yes	Yes	No	No	Yes	Yes	No	5	3	5	41
329.002.00242	SC	26JAN96	-12, -70	No	No	No	No	No	No	No	No	0	2	3	25
	20	10JUL96	155, 97	No	No	No	No	No	No	No	No	0	2	3	6
329.002.00245	SC	21MAR96	-7, .	No	No	No	No	No	No	No	No	0	3	3	17
329.002.00319	SC	23APR96	-7, -63	Yes	No	Yes	Yes	Yes	No	Yes	No	5	2	5	28
	8	25JUN96	57, 1	No	No	No	No	No	No	No	No	0	1	2	10
	32	17DEC96	232, 176	No	No	No	No	No	No	No	No	0	1	2	11
329.003.00075	SC	18JAN95	-7, -63	Yes	No	Yes	Yes	No	Yes	No	No	4	3	4	32
	8	22MAR95	57, 1	Yes	Yes	Yes	No	No	Yes	No	No	4	3	3	34
	32	13SEP95	232, 176	Yes	No	Yes	No	No	No	Yes	No	3	3	4	22
329.003.00077	SC	01MAR95	-5, -64	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	1	4	46
329.003.00081	SC	04DEC95	-7, .	Yes	No	No	No	Yes	No	No	No	2	3	4	40
329.003.00087	SC	23JAN95	-8, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	43

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F: F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.003.00089	SC	24FEB95	-11, .	No	Yes	No	No	No	Yes	No	No	2	1	4	27
	8	02MAY95	57, .	No	No	No	No	No	No	No	No	0	2	1	7
329.003.00091	8	16MAY95	54, -1	No	No	No	No	No	No	No	No	0	2	2	4
	32	07NOV95	229, 175	No	No	No	No	No	No	No	No	0	2	2	5
329.003.00248	SC	14FEB96	-16, .	Yes	No	No	No	No	No	No	No	1	3	5	28
	8	23APR96	54, .	No	No	No	No	No	No	No	No	0	2	2	18
329.003.00250	SC	05MAR96	-9, -66	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	3	3	43
	8	09MAY96	57, -1	Yes	No	No	No	Yes	No	No	No	2	3	2	35
329.003.00292	SC	02AUG96	-5, -63	No	Yes	No	No	Yes	Yes	Yes	Yes	5	4	5	37
	8	04OCT96	59, 1	Yes	Yes	Yes	No	No	No	No	No	3	2	2	17
329.003.00313	SC	08MAY96	-9, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	5	5	58
329.004.00015	SC	30NOV94	-8, -65	Yes	Yes	Yes	Yes	Yes	Yes	No	No	6	2	4	33
	8	03FEB95	58, 1	Yes	No	Yes	No	Yes	No	No	No	3	3	3	18
	28	14JUN95	189, 132	No	No	No	No	No	No	No	No	0	2	2	12
329.004.00017	SC	15MAR95	-7, -63	No	Yes	No	No	Yes	No	No	Yes	3	2	5	30
	8	17MAY95	57, 1	No	No	No	No	No	No	No	No	0	2	2	15
	32	01NOV95	225, 169	No	No	No	No	No	No	No	No	0	2	3	15
329.004.00019	SC	24MAY95	-7, .	No	Yes	Yes	Yes	Yes	Yes	No	No	5	2	2	32

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.004.00212	SC	24MAY96	-10, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	4	3	55
329.004.00214	SC	27SEP96	-7, -67	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	3	48
	8	03DEC96	61, 1	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	3	42
329.005.00002	SC	20MAY94	-5, -61	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	3	3	49
329.005.00004	SC	22SEP94	-18, -77	No	Yes	No	No	Yes	Yes	No	No	3	1	3	19
	8	08DEC94	60, 1	No	No	Yes	No	No	No	No	No	1	2	2	7
329.005.00008	SC	10NOV94	-6, -61	No	No	No	No	No	Yes	Yes	No	2	1	2	9
	8	10JAN95	56, 1	Yes	Yes	No	No	No	Yes	Yes	Yes	5	1	2	25
	24	10MAY95	176, 121	No	No	No	No	No	No	No	No	0	1	2	4
329.005.00011	SC	06DEC94	-7, -63	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	3	45
	8	07FEB95	57, 1	Yes	Yes	No	No	Yes	No	No	No	3	1	2	19
329.005.00109	SC	22DEC94	-8, -61	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	2	3	45
	8	21FEB95	54, 1	Yes	Yes	No	Yes	No	No	No	No	3	2	2	35
329.005.00112	SC	17JAN95	-9, -64	Yes	Yes	Yes	No	.	Yes	Yes	Yes	7	3	4	38
	8	22MAR95	56, 1	.	.	.	.	.	.	.	.	.	.	.	15
	20	21JUN95	147, 92	No	No	No	No	No	No	No	No	0	2	2	4
329.005.00116	SC	30JAN95	-8, -66	No	Yes	No	No	No	Yes	No	No	2	2	3	29
	8	06APR95	59, 1	No	No	No	No	No	No	No	No	0	2	3	10
	24	26JUL95	170, 112	No	No	No	No	No	No	No	No	0	1	2	3

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.005.00119	SC	27JUN95	-14, -73	No	No	Yes	No	No	No	No	No	1	2	3	30
	8	08SEP95	60, 1	No	No	No	No	No	No	No	No	0	2	3	8
	24	02JAN96	176, 117	No	No	No	No	No	No	No	No	0	2	3	9
329.005.00151	SC	29AUG95	-8, -65	No	Yes	No	No	Yes	No	No	Yes	3	2	3	18
	8	02NOV95	58, 1	Yes	Yes	No	No	Yes	Yes	No	No	4	1	5	16
	32	01MAY96	239, 182	No	No	No	No	No	No	No	No	0	1	4	8
329.005.00152	SC	12OCT95	-14, .	Yes	Yes	No	No	No	Yes	Yes	No	4	2	3	27
329.005.00257	SC	05MAR96	-6, -62	No	Yes	Yes	No	No	Yes	No	No	3	3	2	21
	8	06MAY96	57, 1	Yes	No	Yes	No	No	No	No	No	2	2	2	15
	32	21OCT96	225, 169	No	No	No	No	No	No	No	No	0	2	1	3
329.005.00258	SC	06FEB96	-35, .	No	No	No	No	No	No	No	No	0	1	2	10
	8	07MAY96	57, .	No	No	Yes	Yes	Yes	No	Yes	No	4	2	2	29
329.005.00299	SC	28MAY96	-11, -71	Yes	No	No	No	No	No	No	No	1	2	2	22
	8	07AUG96	61, 1	No	No	No	No	Yes	No	No	No	1	2	2	12
	20	05NOV96	151, 91	No	No	No	No	Yes	No	No	No	1	2	2	12
329.005.00300	SC	12SEP96	-7, .	No	No	No	No	No	No	No	No	0	2	2	9
	8	14NOV96	57, .	No	Yes	No	No	Yes	No	Yes	No	3	2	3	22
329.005.00333	SC	15JAN97	-8, .	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	3	4	31
329.005.00336	SC	26FEB97	-6, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	3	4	49

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.005.00336	8	30APR97	58, .	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	7	4	5	43
329.006.00038	SC	01FEB95	-14, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	3	4	45
329.006.00039	SC	03FEB95	-5, -66	Yes	Yes	No	No	Yes	No	Yes	No	4	3	5	28
	8	05APR95	57, -5	Yes	Yes	Yes	No	No	Yes	No	No	4	3	4	28
329.006.00260	SC	12JUL96	-6, -64	No	No	Yes	No	Yes	Yes	No	No	3	2	3	12
	8	18SEP96	63, 5	No	No	No	No	No	No	No	No	0	4	3	11
329.006.00261	SC	07NOV96	-19, -77	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	3	4	54
	8	23JAN97	59, 1	No	No	No	No	Yes	No	No	Yes	2	3	4	31
329.007.00140	SC	07SEP95	-8, -63	Yes	Yes	No	No	No	No	No	No	2	1	2	9
	8	09NOV95	56, 1	Yes	No	No	No	No	No	No	No	1	1	2	4
329.007.00142	SC	12OCT95	-6, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	4	4	43
	8	21DEC95	65, .	Yes	Yes	No	No	Yes	Yes	No	Yes	5	3	4	45
329.007.00145	SC	04JAN96	-7, -63	No	No	No	No	No	Yes	Yes	Yes	3	3	3	31
	8	07MAR96	57, 1	Yes	Yes	No	No	No	Yes	Yes	Yes	5	1	5	27
	32	23AUG96	226, 170	No	No	Yes	Yes	Yes	No	No	No	3	1	1	7
329.007.00265	SC	25JAN96	-7, .	Yes	No	Yes	No	Yes	No	Yes	No	4	2	4	24
329.007.00268	SC	21MAR96	-11, -70	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	1	3	38
	8	30MAY96	60, 1	No	No	Yes	No	No	No	No	No	1	2	3	14

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.007.00268	32	05DEC96	249, 190	No	No	No	No	No	No	No	No	0	3	2	6
329.007.00294	SC	20FEB97	-8, .	Yes	No	Yes	No	Yes	Yes	Yes	No	5	3	4	45
329.007.00309	SC	02JUL96	-13, -65	Yes	No	No	No	Yes	No	Yes	No	3	3	3	32
	7	05SEP96	53, 1	No	No	No	No	No	No	No	No	0	2	2	8
	32	13MAR97	242, 190	Yes	Yes	No	No	Yes	Yes	No	Yes	5	3	3	32
329.007.00310	SC	19SEP96	-7, -67	No	No	Yes	No	No	No	No	No	1	2	3	24
	8	25NOV96	61, 1	No	No	No	No	No	No	No	No	0	2	2	13
	32	12JUN97	260, 200	No	No	No	No	No	No	No	No	0	1	1	5
329.007.00318	SC	22NOV96	-10, .	Yes	Yes	No	No	No	No	No	No	2	1	1	8
329.008.00157	SC	16AUG95	-14, -69	Yes	Yes	No	No	Yes	No	No	No	3	2	3	31
	8	24OCT95	56, 1	Yes	Yes	Yes	No	No	Yes	Yes	No	5	2	4	22
329.008.00160	SC	25OCT95	-7, -73	Yes	Yes	No	No	No	Yes	Yes	No	4	3	4	50
	8	05JAN96	66, -1	Yes	No	Yes	No	No	No	No	No	2	2	3	17
	32	23JUL96	266, 200	No	No	Yes	No	No	No	No	No	1	1	1	3
329.008.00188	SC	14DEC95	-21, .	Yes	Yes	No	No	No	Yes	Yes	No	4	3	4	45
	8	27FEB96	55, .	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	3	4	51
329.008.00271	SC	25JAN96	-46,-110	Yes	Yes	Yes	No	No	No	No	No	3	3	3	36
	8	14MAY96	65, 1	No	No	No	No	Yes	No	Yes	No	2	3	4	25
	32	05NOV96	240, 176	Yes	Yes	Yes	No	No	Yes	Yes	Yes	6	2	4	40

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.008.00275	SC	30APR96	-8, -63	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	4	4	44
	8	02JUL96	56, 1	No	No	Yes	No	No	No	No	No	1	3	3	11
	32	16DEC96	223, 168	No	No	No	No	No	No	No	No	0	3	3	7
329.009.00130	SC	12APR95	-6, -62	No	No	Yes	Yes	No	No	No	No	2	2	3	16
	8	13JUN95	57, 1	Yes	No	Yes	Yes	No	No	No	No	3	2	3	18
329.009.00131	SC	26APR95	-6, -62	Yes	Yes	Yes	No	No	Yes	No	No	4	2	3	23
	8	27JUN95	57, 1	Yes	No	No	No	No	No	No	No	1	1	1	5
329.009.00133	SC	07JUN95	-6, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	3	4	45
329.009.00138	SC	02OCT95	-8, .	Yes	Yes	Yes	Yes	Yes	No	Yes	No	6	3	4	45
329.009.00170	SC	26OCT95	-12, -69	No	No	No	No	Yes	No	No	No	1	1	3	22
	8	03JAN96	58, 1	No	No	No	No	No	No	No	No	0	1	3	16
	32	24JUN96	231, 174	No	Yes	No	No	No	Yes	No	No	2	1	3	9
329.009.00173	SC	08NOV95	-12, -75	Yes	.	Yes	Yes	No	.	Yes	Yes	7	4	5	40
	8	22JAN96	64, 1	Yes	No	Yes	No	No	No	No	No	2	3	3	27
329.009.00193	SC	21NOV95	-7, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	39
	8	24JAN96	58, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	7	2	4	32
329.009.00196	SC	11DEC95	-7, .	Yes	Yes	Yes	Yes	No	Yes	Yes	No	6	3	4	43
	8	12FEB96	57, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	3	3	35

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.009.00201	SC	31JAN96	-6, .	No	Yes	No	No	No	Yes	Yes	Yes	4	2	2	20
	8	02APR96	57, .	No	No	Yes	No	No	No	Yes	No	2	1	2	9
329.009.00204	SC	13MAR96	-6, -62	No	No	No	No	No	No	No	No	0	2	2	4
	8	14MAY96	57, 1	No	No	No	No	No	No	No	No	0	1	2	3
329.009.00235	SC	10DEC96	-8, -62	No	No	No	No	No	No	No	No	0	2	2	7
	8	10FEB97	55, 1	No	No	No	No	Yes	No	No	No	1	2	2	9
329.009.00240	SC	03JAN97	-11, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	28
329.009.00303	SC	25MAR96	-8, -64	Yes	Yes	No	No	No	Yes	Yes	No	4	3	4	35
	8	28MAY96	57, 1	No	No	No	No	No	No	No	No	0	.	.	4
	32	10DEC96	253, 197	No	No	No	No	No	No	No	No	0	2	2	11
329.009.00304	SC	03APR96	-6, -62	Yes	Yes	No	No	No	Yes	Yes	No	4	4	5	38
	8	04JUN96	57, 1	No	No	No	No	No	No	No	No	0	2	3	6
329.009.00324	SC	21OCT96	-7, .	Yes	No	Yes	Yes	No	Yes	Yes	Yes	6	1	3	31
	8	27DEC96	61, .	No	No	No	No	No	No	No	No	0	2	1	3
329.009.00328	SC	30SEP96	-7, .	No	No	Yes	Yes	Yes	No	No	No	3	3	3	33
329.009.00329	SC	01OCT96	-8, .	No	No	Yes	No	Yes	No	Yes	No	3	3	3	27
	8	03DEC96	56, .	No	Yes	No	Yes	No	No	No	No	2	2	3	20
329.010.00182	SC	05DEC95	-14, .	Yes	Yes	Yes	No	No	Yes	Yes	No	5	3	4	44

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

				Sickness Impact Profile Scores											
			Relative	Section F									Present		
Patient ID	Week	Date	Days*	F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Health	QOL	Total
329.010.00278	SC	02FEB96	-7, -63	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	7	2	4	44
	8	05APR96	57, 1	Yes	Yes	No	No	Yes	Yes	No	No	4	2	3	26
	32	19SEP96	224, 168	No	Yes	No	No	No	No	Yes	No	2	4	2	21
329.010.00280	SC	10MAY96	-7, -62	No	Yes	Yes	No	Yes	No	No	No	3	1	3	14
	8	11JUL96	56, 1	No	No	No	No	No	No	No	No	0	1	2	7
	12	21AUG96	97, 42	No	No	No	No	No	No	No	No	0	2	3	9
329.011.00283	SC	30JAN96	-9, -66	Yes	No	No	No	Yes	No	No	No	2	2	4	27
	8	04APR96	57, -1	No	No	Yes	No	No	No	No	No	1	2	4	15
329.011.00288	SC	01JUL96	-24, .	Yes	No	No	No	No	Yes	Yes	No	3	2	3	33
329.012.00025	SC	17OCT95	-7, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	3	42
	8	19DEC95	57, .	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	2	4	45
329.012.00220	SC	04JUN96	-13, -73	No	No	No	No	No	No	No	No	0	3	3	23
	8	16AUG96	61, 1	No	No	No	No	No	No	No	No	0	1	1	2
329.012.00222	SC	18JUN96	-10, -73	Yes	Yes	Yes	No	No	Yes	Yes	No	5	2	3	36
	8	30AUG96	64, 1	No	No	Yes	No	No	No	No	No	1	3	2	27
329.012.00226	SC	26NOV96	-7, .	Yes	Yes	Yes	No	No	No	Yes	No	4	2	3	38
329.012.00228	SC	04MAR97	-15, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	3	35
329.012.00231	SC	26FEB97	-9, -70	No	No	Yes	Yes	Yes	No	Yes	Yes	5	3	4	35

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Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PAROXETINE

				Sickness Impact Profile Scores											
			Relative	Section F									Present		
Patient ID	Week	Date	Days*	F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Health	QOL	Total
329.012.00231	8	07MAY97	62, 1	No	No	Yes	No	No	No	No	No	1	2	2	15
	24	19AUG97	166, 105	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	7	4	3	45

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.001.00061	SC	19JUL94	-10, .	Yes	No	No	No	No	Yes	Yes	Yes	4	2	2	26
329.001.00066	SC	14NOV94	-8, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	2	4	40
329.001.00067	SC	15NOV94	-7, .	No	No	No	No	Yes	Yes	Yes	No	3	1	4	19
329.001.00070	SC	14FEB95	-8, .	No	Yes	No	No	Yes	Yes	Yes	Yes	5	3	3	28
329.001.00122	SC	13JUN95	-7, -64	No	Yes	No	No	No	Yes	Yes	No	3	3	3	28
	8	16AUG95	58, 1	No	Yes	No	No	No	Yes	Yes	No	3	2	2	21
329.002.00050	SC	10MAR95	-13, .	Yes	No	No	No	Yes	No	Yes	No	3	1	4	19
	5	28APR95	37, .	No	No	No	No	No	No	No	No	0	2	2	12
329.002.00056	SC	24JUN94	-25, .	Yes	Yes	Yes	No	No	Yes	Yes	No	5	3	4	34
329.002.00057	SC	11AUG94	-28, -85	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	3	3	41
	8	03NOV94	57, -1	No	No	No	No	No	No	No	No	0	2	2	4
	16	11JAN95	126, 69	No	No	No	No	No	No	No	No	0	2	2	4
329.002.00098	SC	20DEC94	-14, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	3	5	39
	8	02MAR95	59, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	5	36
329.002.00100	SC	16FEB95	-19, -77	No	Yes	Yes	Yes	No	Yes	Yes	Yes	6	4	4	43
	8	04MAY95	59, 1	No	Yes	Yes	No	No	No	No	No	2	2	3	21
	16	06JUL95	122, 64	No	No	Yes	Yes	No	No	Yes	No	3	3	3	25

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.002.00103	SC	11APR95	-9, -65	No	No	Yes	No	No	No	No	No	1	2	3	27
	8	15JUN95	57, 1	No	No	No	No	No	No	No	No	0	3	2	8
	16	10AUG95	113, 57	No	No	No	No	No	No	No	No	0	2	3	13
329.002.00104	SC	28APR95	-6, -62	Yes	Yes	No	No	No	Yes	Yes	Yes	5	2	3	31
	8	29JUN95	57, 1	No	Yes	No	No	Yes	Yes	Yes	Yes	5	2	3	27
	32	02JAN96	244, 188	No	No	No	No	No	No	No	No	0	2	2	20
329.002.00243	SC	27FEB96	-16, .	Yes	Yes	Yes	Yes	No	No	No	No	4	2	3	41
329.002.00244	SC	14MAR96	-7, -64	No	Yes	No	No	No	Yes	No	No	2	2	3	31
	8	16MAY96	57, -1	No	No	No	No	No	Yes	No	No	1	2	2	17
329.002.00321	SC	15MAY96	-8, .	No	Yes	No	No	Yes	Yes	No	No	3	2	3	35
329.002.00322	SC	06JAN97	-3, .	No	No	No	No	No	No	No	No	0	2	3	14
329.003.00073	SC	11JAN95	-8, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	4	49
329.003.00076	SC	24JAN95	-7, -62	Yes	Yes	Yes	No	No	Yes	Yes	No	5	3	4	38
	32	11OCT95	254, 199	No	No	No	No	No	No	No	No	0	2	2	6
329.003.00082	SC	11DEC95	1, .	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	1	3	43
329.003.00088	SC	06FEB95	-22, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	2	3	36
329.003.00090	SC	08MAR95	-6, .	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	2	4	42

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.003.00090	8	16MAY95	64, .	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	2	3	41
329.003.00092	SC	13APR95	-20, -78	No	No	No	No	No	No	No	No	0	3	3	14
	8	30JUN95	59, 1	Yes	Yes	No	No	Yes	Yes	Yes	No	5	1	1	7
	32	02JAN96	245, 187	No	No	No	No	No	No	No	No	0	2	3	10
329.003.00093	SC	08JUN95	-13, -76	Yes	No	No	No	Yes	No	Yes	No	3	3	5	37
	8	22AUG95	63, -1	No	No	Yes	No	No	No	Yes	No	2	2	1	17
	16	03OCT95	105, 42	No	Yes	No	No	Yes	Yes	No	No	3	3	3	31
329.003.00247	SC	05JAN96	-27, -81	Yes	No	Yes	No	Yes	No	Yes	No	4	2	2	38
	8	26MAR96	55, 1	No	No	No	No	No	No	No	No	0	2	2	22
329.003.00249	SC	01MAR96	-6, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	3	40
	8	30APR96	55, .	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	3	4	31
329.003.00289	SC	12FEB96	-16, -72	Yes	Yes	Yes	No	No	Yes	Yes	No	5	3	3	32
	8	24APR96	57, 1	No	No	No	No	No	No	No	No	0	2	2	8
329.003.00290	SC	06MAR96	-5, .	No	Yes	No	No	No	No	Yes	Yes	3	3	5	34
329.003.00314	SC	15OCT96	-7, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	4	48
329.003.00317	SC	12DEC96	-7, .	Yes	Yes	No	No	No	Yes	Yes	Yes	5	5	4	42
	8	11FEB97	55, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	3	34
329.004.00013	SC	05JUL94	-14, -73	Yes	No	Yes	No	Yes	Yes	Yes	No	5	2	3	41

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F: F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.004.00013	8	16SEP94	60, 1	No	No	No	No	No	No	No	No	0	2	2	10
329.004.00014	SC	22NOV94	-7, .	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	7	2	4	37
329.004.00211	SC	24JAN96	-9, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	3	3	23
329.004.00215	SC	12MAR97	-8, .	No	No	Yes	Yes	No	No	No	No	2	3	3	24
329.005.00003	SC	12SEP94	-8, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	3	46
329.005.00006	SC	27OCT94	-8, -68	No	Yes	Yes	No	No	Yes	Yes	Yes	5	2	3	29
	8	03JAN95	61, 1	No	No	No	No	No	No	No	No	0	1	2	6
	24	28APR95	176, 116	No	No	No	No	No	No	Yes	Yes	2	2	3	15
329.005.00007	SC	02NOV94	-7, -70	No	Yes	Yes	No	No	Yes	Yes	Yes	5	3	5	47
	8	11JAN95	64, 1	Yes	Yes	No	No	No	No	Yes	Yes	4	3	2	44
	32	09AUG95	274, 211	No	No	No	Yes	No	No	No	No	1	2	1	18
329.005.00009	SC	07DEC94	-5, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	5	40
	8	07FEB95	58, .	No	No	Yes	Yes	No	No	No	No	2	2	3	22
329.005.00110	SC	04JAN95	-7, .	No	No	No	No	No	No	No	No	0	3	2	10
329.005.00113	SC	20JAN95	-10, .	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	7	4	3	41
329.005.00117	SC	06MAR95	-12, .	No	Yes	No	No	Yes	Yes	Yes	No	4	3	3	38
	8	15MAY95	59, .	Yes	Yes	No	No	No	Yes	Yes	Yes	5	2	2	23

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.005.00118	SC	09MAY95	-8, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	3	4	53
329.005.00153	SC	11JAN96	-14, -70	No	Yes	Yes	No	No	Yes	No	Yes	4	2	3	32
	8	21MAR96	57, 1	No	No	No	No	No	No	No	No	0	3	3	8
	32	04SEP96	224, 168	No	No	No	No	No	No	No	No	0	2	3	17
329.005.00255	SC	26FEB96	-7, .	No	Yes	Yes	Yes	Yes	No	No	No	4	2	3	27
	8	29APR96	57, .	No	No	No	No	No	No	No	No	0	2	2	7
329.005.00256	SC	20FEB96	-14, -70	No	No	No	Yes	Yes	No	No	No	2	2	4	28
	8	30APR96	57, 1	No	No	No	No	No	No	No	No	0	2	3	15
	16	02JUL96	120, 64	No	No	No	Yes	No	No	No	No	1	2	3	18
329.005.00295	SC	21MAR96	-7, .	No	Yes	Yes	No	No	Yes	.	No	3	3	4	33
	8	22MAY96	56, .	Yes	Yes	Yes	No	No	Yes	Yes	No	5	1	3	21
329.005.00297	SC	28MAR96	-22, .	Yes	Yes	Yes	No	No	Yes	Yes	No	5	2	3	31
329.005.00332	SC	05DEC96	-7, .	Yes	Yes	No	No	Yes	No	No	No	3	2	4	26
	8	06FEB97	57, .	Yes	Yes	No	No	No	No	No	No	2	2	3	21
329.005.00335	SC	20FEB97	-8, .	No	No	Yes	No	Yes	Yes	No	No	3	1	4	21
	8	24APR97	56, .	No	No	No	No	No	No	No	No	0	2	2	10
329.006.00040	SC	10FEB95	-6, .	Yes	Yes	No	No	No	Yes	No	No	3	2	4	25
329.006.00041	SC	22MAR95	-14, -78	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	4	3	44

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.006.00041	8	31MAY95	57, -8	Yes	Yes	Yes	Yes	No	Yes	Yes	No	6	2	2	31
	32	21NOV95	231, 167	No	Yes	No	No	No	No	No	No	1	2	1	8
329.007.00139	SC	04MAY95	-4, .	No	No	No	No	Yes	No	No	No	1	3	3	22
329.007.00143	SC	26OCT95	-14, .	No	No	No	No	No	Yes	No	Yes	2	2	2	28
329.007.00146	SC	18JAN96	-7, -60	No	Yes	No	No	No	No	No	No	1	2	3	18
	8	18MAR96	54, 1	No	No	No	No	No	No	No	No	0	1	1	3
	32	09SEP96	229, 176	No	No	No	No	No	No	No	No	0	1	2	5
329.007.00269	SC	04APR96	-7, .	No	Yes	No	No	No	No	No	No	1	2	2	20
	3	02MAY96	22, .	No	No	No	No	No	No	No	No	0	2	2	12
329.007.00270	SC	02MAY96	-7, .	No	No	No	No	No	No	No	No	0	2	3	15
	7	27JUN96	50, .	Yes	No	Yes	No	No	Yes	Yes	No	4	2	3	12
329.007.00307	SC	09MAY96	-7, .	Yes	Yes	No	Yes	Yes	Yes	Yes	No	6	3	3	36
	8	25JUL96	71, .	No	No	No	No	No	No	No	No	0	3	3	32
329.007.00308	SC	27JUN96	-5, .	Yes	Yes	Yes	Yes	No	No	Yes	Yes	6	4	3	27
329.008.00159	SC	06SEP95	-7, -69	Yes	No	Yes	Yes	Yes	Yes	No	No	5	2	2	30
	8	14NOV95	63, 1	No	No	No	No	No	No	No	No	0	2	3	17
329.008.00161	SC	31OCT95	-16, -71	No	Yes	Yes	Yes	Yes	Yes	Yes	No	6	5	4	51
	8	10JAN96	56, 1	No	No	No	No	No	No	No	No	0	3	2	21

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.008.00187	SC	15NOV95	-14, .	Yes	Yes	No	No	Yes	Yes	No	No	4	4	4	45
	8	26JAN96	59, .	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	4	4	43
329.008.00192	SC	14FEB96	-20, .	No	Yes	No	No	No	No	Yes	No	2	1	3	22
329.008.00272	SC	19MAR96	-15, -71	No	No	No	No	Yes	No	No	No	1	1	2	10
	8	29MAY96	57, 1	No	No	No	No	No	No	No	No	0	2	2	4
329.008.00273	SC	19APR96	-28, -91	No	No	No	No	No	No	No	No	0	2	2	24
	8	19JUL96	64, 1	No	No	No	No	No	No	No	No	0	2	2	10
329.009.00127	SC	03APR95	-7, .	Yes	Yes	Yes	No	Yes	Yes	No	Yes	6	2	4	26
329.009.00132	SC	17MAY95	-6, -63	Yes	Yes	No	No	Yes	Yes	Yes	No	5	1	4	35
	8	19JUL95	58, 1	No	No	No	No	No	No	No	No	0	1	1	2
329.009.00134	SC	28JUN95	-8, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	35
	8	29AUG95	55, .	Yes	No	No	No	Yes	No	Yes	No	3	3	3	27
329.009.00137	SC	03OCT95	-7, .	No	No	No	No	No	No	No	No	0	4	5	29
	8	05DEC95	57, .	No	No	No	No	No	No	No	No	0	3	4	29
329.009.00171	SC	31OCT95	-7, .	No	Yes	Yes	No	No	Yes	Yes	No	4	2	5	40
329.009.00172	SC	06NOV95	-7, -64	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	7	2	3	34
	8	09JAN96	58, 1	No	No	Yes	No	.	No	No	No	1	2	4	21
	32	08JUL96	239, 182	No	No	No	No	Yes	No	No	No	1	1	2	11

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.009.00194	SC	28NOV95	-7, -63	No	No	Yes	Yes	No	No	No	No	2	1	4	23
	8	30JAN96	57, 1	Yes	No	No	Yes	No	Yes	No	No	3	1	1	27
	24	04JUN96	183, 127	No	No	No	No	No	Yes	No	No	1	1	1	14
329.009.00195	SC	06DEC95	-9, .	No	No	Yes	Yes	No	No	No	No	2	2	4	26
329.009.00199	SC	10JAN96	-6, .	.	.	.	.	.	.	.	.	.	3	4	39
	8	13MAR96	58, .	No	No	No	No	No	No	No	No	0	2	2	8
329.009.00203	SC	28FEB96	-5, .	No	No	No	No	Yes	No	No	No	1	3	3	29
329.009.00236	SC	17DEC96	-13, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	42
	4	27JAN97	29, .	.	.	.	.	.	.	.	.	.	2	3	29
329.009.00239	SC	11NOV96	-8, -65	Yes	Yes	No	Yes	Yes	Yes	No	No	5	3	3	34
	8	15JAN97	58, 1	No	No	No	Yes	No	No	No	No	1	3	2	14
329.009.00262	SC	07FEB97	-10, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	42
	8	14APR97	57, .	No	No	No	No	No	No	No	No	0	2	3	9
329.009.00264	SC	25OCT96	-7, .	No	No	Yes	No	Yes	No	No	No	2	1	4	21
	7	23DEC96	53, .	No	Yes	No	No	.	No	.	No	1	2	2	11
329.009.00301	SC	06MAR96	-13, -69	No	No	No	No	No	No	No	No	0	2	2	7
	8	14MAY96	57, 1	No	No	No	No	No	No	No	No	0	2	2	4
329.009.00305	SC	01MAY96	-6, -63	No	No	Yes	No	No	No	No	No	1	1	3	13

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Section F = Recreation and Pastimes
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For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F: F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.009.00305	8	03JUL96	58, 1	No	No	No	No	Yes	Yes	No	No	2	2	2	17
	32	10JAN97	249, 192	No	No	No	No	No	No	No	No	0	2	1	6
329.009.00325	SC	21AUG96	-6, -61	Yes	Yes	Yes	Yes	No	Yes	Yes	No	6	2	3	31
	8	21OCT96	56, 1	Yes	Yes	Yes	Yes	No	Yes	No	No	5	3	2	24
	16	16DEC96	112, 57	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	3	3	43
329.009.00326	SC	26AUG96	-10, -63	No	Yes	No	No	No	Yes	No	No	2	3	3	29
	8	28OCT96	54, 1	No	No	No	No	No	No	Yes	No	1	3	3	15
	16	16DEC96	103, 50	No	No	No	No	Yes	No	No	No	1	3	3	27
329.010.00279	SC	08MAR96	-14, -70	Yes	No	.	No	No	No	No	No	1	1	3	21
	8	17MAY96	57, 1	No	No	No	No	No	Yes	No	No	1	3	3	19
	32	06NOV96	230, 174	No	No	No	No	No	No	No	No	0	2	4	20
329.010.00281	SC	19JUL96	-7, -68	No	No	No	No	No	No	No	No	0	1	2	8
	8	25SEP96	62, 1	No	No	No	No	No	No	No	No	0	2	2	7
	24	03JAN97	162, 101	No	Yes	No	No	Yes	No	No	No	2	2	2	28
329.011.00163	SC	18NOV95	-7, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	4	3	38
329.011.00208	SC	22AUG96	-15, -74	Yes	Yes	No	No	No	Yes	Yes	Yes	5	4	4	36
	8	03NOV96	59, -1	No	No	No	No	No	Yes	Yes	Yes	3	2	2	10
329.011.00209	SC	23AUG96	-19, -81	Yes	Yes	No	No	No	No	No	No	2	3	4	20
	8	11NOV96	62, -1	Yes	Yes	No	Yes	Yes	No	No	No	4	3	2	20

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = IMIPRAMINE

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.011.00284	SC	13MAR96	-9, -65	No	Yes	No	No	Yes	Yes	Yes	Yes	5	2	4	44
	8	16MAY96	56, -1	No	No	Yes	Yes	No	No	No	No	2	1	2	6
329.011.00286	SC	15MAY96	-22, -90	No	No	No	No	Yes	No	No	No	1	2	3	22
	8	09AUG96	65, -4	No	No	No	No	No	No	No	No	0	2	2	4
329.012.00026	SC	09NOV95	-19, .	Yes	Yes	Yes	Yes	Yes	Yes	No	No	6	2	5	34
329.012.00219	SC	24MAY96	-7, -67	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	2	3	28
	8	30JUL96	61, 1	No	No	No	No	No	No	No	No	0	1	1	3
	32	24JAN97	239, 179	No	No	No	No	No	No	No	No	0	2	1	4
329.012.00221	SC	18JUN96	-7, -70	No	Yes	No	No	No	No	Yes	No	2	2	4	30
	8	27AUG96	64, 1	No	No	No	No	No	No	No	No	0	2	2	12
329.012.00223	SC	23AUG96	-7, .	No	Yes	No	No	Yes	Yes	Yes	Yes	5	3	3	34
329.012.00227	SC	12DEC96	-6, -75	Yes	Yes	Yes	Yes	No	No	Yes	Yes	6	4	4	30
	8	25FEB97	70, 1	No	No	Yes	No	No	No	Yes	No	2	3	4	25
	32	19AUG97	245, 176	Yes	No	Yes	Yes	No	No	Yes	Yes	5	3	3	25
329.012.00230	SC	20FEB97	-8, -77	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	3	38
	8	08MAY97	70, 1	Yes	Yes	No	No	No	Yes	Yes	Yes	5	3	3	34

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.001.00062	SC	06OCT94	-14, .	No	No	No	No	No	No	No	No	0	2	3	13
329.001.00064	SC	04NOV94	-6, -60	No	No	No	No	No	No	No	No	0	2	3	16
	8	03JAN95	55, 1	No	No	No	No	No	No	No	No	0	2	3	11
329.001.00069	SC	07FEB95	-9, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	3	3	39
	8	13APR95	57, .	No	No	Yes	Yes	No	No	No	No	2	3	2	25
329.001.00071	SC	02FEB95	-21, .	No	No	No	No	Yes	No	Yes	No	2	3	4	21
	8	20APR95	57, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	29
329.001.00123	SC	14DEC95	-21, .	No	Yes	No	No	Yes	Yes	No	Yes	4	3	4	35
329.001.00207	SC	19FEB96	-9, .	Yes	Yes	No	No	No	Yes	Yes	No	4	2	4	25
	8	24APR96	57, .	Yes	No	Yes	No	No	No	No	No	2	3	4	19
329.002.00049	SC	03MAR95	-6, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	3	44
	8	05MAY95	58, .	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	3	3	44
329.002.00059	SC	03NOV94	-7, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	3	31
	8	05JAN95	57, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	3	36
329.002.00060	SC	24JAN95	-7, -63	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	3	4	42
	8	28MAR95	57, 1	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	7	3	3	43
329.002.00097	SC	20DEC94	-14, -72	No	Yes	No	Yes	No	Yes	No	Yes	4	3	4	36
	8	02MAR95	59, 1	Yes	No	No	No	No	Yes	No	No	2	3	3	24

* days relative to start of acute phase, days relative to start of continuation phase
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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.002.00097	32	05SEP95	246, 188	Yes	No	Yes	Yes	Yes	No	No	Yes	5	3	3	21
329.002.00101	SC	20MAR95	-8, -66	No	Yes	Yes	Yes	No	No	Yes	No	4	3	4	39
	8	25MAY95	59, 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	7	2	3	32
329.002.00107	SC	18JAN96	-7, -63	No	Yes	No	No	Yes	Yes	Yes	Yes	5	3	4	40
	8	21MAR96	57, 1	No	No	No	No	No	No	No	No	0	2	3	15
	32	26SEP96	246, 190	No	No	No	No	Yes	Yes	No	No	2	2	2	17
329.002.00241	SC	25JAN96	-12, -68	No	No	No	Yes	No	No	No	No	1	2	5	32
	8	02APR96	57, 1	No	No	No	No	No	No	No	No	0	1	1	10
329.002.00246	SC	01APR96	-17, .	Yes	No	Yes	No	Yes	No	Yes	Yes	5	4	3	39
	8	18JUN96	62, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	4	3	46
329.002.00320	SC	09MAY96	-7, -68	No	Yes	No	Yes	No	No	No	No	2	4	3	22
	8	16JUL96	62, 1	No	Yes	Yes	No	No	No	No	No	2	4	5	25
329.002.00323	SC	04NOV96	-8, -66	Yes	Yes	No	No	No	Yes	No	No	3	3	3	27
	8	09JAN97	59, 1	No	No	No	No	No	No	Yes	No	1	2	2	10
	32	12JUN97	213, 155	No	No	No	No	No	No	No	No	0	2	2	9
329.003.00074	32	11OCT95	260, 204	No	Yes	Yes	No	No	Yes	No	No	3	2	3	18
329.003.00078	SC	11APR95	-15, .	No	Yes	No	No	No	Yes	Yes	Yes	4	2	4	37
	8	21JUN95	57, .	No	Yes	No	No	No	Yes	No	No	2	.	.	24

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.003.00080	SC	22NOV95	-5, .	No	Yes	.	Yes	No	No	.	.	3	3	3	30
329.003.00085	SC	26OCT94	-13, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	4	34
	8	03JAN95	57, .	No	Yes	No	No	No	Yes	No	No	2	1	3	24
329.003.00086	SC	09NOV94	-19, -76	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	5	41
	8	23JAN95	57, -1	No	No	Yes	No	No	No	No	No	1	2	1	20
	32	17AUG95	263, 206	No	No	No	No	No	No	No	No	0	2	3	24
329.003.00094	8	19DEC95	57, .	Yes	Yes	No	No	No	No	No	Yes	3	2	4	37
329.003.00251	SC	19MAR96	-9, .	No	No	No	No	Yes	No	No	No	1	3	4	36
329.003.00252	SC	19MAR96	-22, .	No	Yes	Yes	No	No	No	No	No	2	3	5	24
	8	04JUN96	56, .	Yes	No	No	No	No	No	No	No	1	1	4	19
329.003.00291	SC	01JUL96	-2, -67	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	7	2	4	49
329.003.00315	SC	29OCT96	-14, .	Yes	Yes	No	No	No	Yes	No	No	3	2	3	26
	8	07JAN97	57, .	No	No	No	No	No	No	No	No	0	2	2	5
329.003.00316	SC	05DEC96	-12, .	No	No	Yes	Yes	No	No	No	No	2	2	4	30
	8	11FEB97	57, .	Yes	Yes	Yes	Yes	No	No	Yes	No	5	3	3	33
329.004.00016	SC	01MAR95	-12, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	3	32
	5	19APR95	38, .	Yes	Yes	No	No	Yes	Yes	No	No	4	2	3	31

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.004.00018	SC	19APR95	-14, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	3	5	48
	8	29JUN95	58, .	Yes	No	Yes	Yes	No	No	Yes	No	4	2	2	20
329.004.00020	SC	02NOV95	-7, .	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	7	4	4	34
	2	24NOV95	16, .	No	No	Yes	No	Yes	No	No	No	2	4	4	34
329.004.00213	SC	18JUL96	-15, -69	No	Yes	No	No	No	Yes	No	No	2	3	4	29
	8	24SEP96	54, -1	Yes	No	No	No	No	No	No	No	1	2	3	21
	32	19MAR97	230, 176	No	No	No	No	No	No	No	No	0	2	2	16
329.005.00001	SC	11APR94	-9, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	1	5	25
	8	15JUN94	57, .	No	Yes	Yes	No	Yes	Yes	Yes	No	5	1	4	30
329.005.00005	SC	24OCT94	-8, .	Yes	Yes	Yes	No	Yes	No	No	No	4	2	3	33
329.005.00010	SC	07DEC94	-6, -63	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	3	36
	8	08FEB95	58, 1	No	No	No	No	No	No	No	No	0	2	2	8
	32	09AUG95	240, 183	No	No	Yes	Yes	.	No	No	No	2	2	2	10
329.005.00012	SC	12DEC94	-7, -66	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	43
	8	16FEB95	60, 1	No	No	No	No	No	No	No	No	0	2	3	23
329.005.00111	SC	05JAN95	-6, -62	No	Yes	No	No	.	Yes	.	.	3	3	3	26
	8	08MAR95	57, 1	No	Yes	No	No	No	Yes	Yes	Yes	4	3	3	15
	16	03MAY95	113, 57	No	No	Yes	Yes	No	No	No	No	2	2	2	8
329.005.00114	SC	23JAN95	-8, -65	No	Yes	No	No	No	Yes	No	No	2	2	3	17

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.005.00114	8	29MAR95	58, 1	No	Yes	Yes	No	Yes	Yes	Yes	No	5	3	4	44
	16	17MAY95	107, 50	No	Yes	No	No	No	Yes	Yes	No	3	2	3	18
329.005.00115	SC	27JAN95	-10, -81	No	No	Yes	Yes	No	No	No	No	2	3	3	21
	8	18APR95	72, 1	No	No	No	No	No	No	No	No	0	2	2	5
329.005.00120	SC	22AUG95	-8, .	Yes	Yes	No	No	No	No	Yes	Yes	4	4	4	25
	8	26OCT95	58, .	Yes	Yes	Yes	No	No	Yes	No	Yes	5	4	5	29
329.005.00253	SC	31JAN96	-8, .	Yes	No	Yes	No	No	No	Yes	Yes	4	1	3	24
	8	03APR96	56, .	Yes	No	No	No	No	No	No	No	1	3	4	30
329.005.00254	SC	08FEB96	-7, -62	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	2	4	33
	8	10APR96	56, 1	No	No	Yes	No	No	No	No	No	1	2	3	17
	32	16OCT96	245, 190	No	No	Yes	No	No	No	No	No	1	2	3	11
329.005.00293	SC	06MAR97	-6, .	Yes	Yes	No	No	No	Yes	Yes	Yes	5	2	3	37
	8	07MAY97	57, .	No	No	No	No	No	No	No	No	0	2	3	16
329.005.00298	SC	15MAY96	-7, -63	No	Yes	No	No	Yes	Yes	Yes	No	4	3	5	44
	8	17JUL96	57, 1	Yes	Yes	No	No	Yes	Yes	Yes	No	5	3	4	25
	32	13JAN97	237, 181	Yes	Yes	No	No	No	Yes	Yes	No	4	2	4	22
329.005.00331	SC	14NOV96	-7, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	3	4	40
	8	16JAN97	57, .	No	No	No	No	Yes	No	Yes	Yes	3	3	3	25
329.005.00334	SC	24JAN97	-7, .	Yes	No	Yes	Yes	No	Yes	No	Yes	5	2	3	40

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.005.00334	8	27MAR97	56, .	No	No	No	No	No	No	No	No	0	1	2	5
329.006.00037	SC	20JAN95	-8, .	No	No	No	No	No	No	Yes	No	1	1	1	13
329.006.00042	SC	01DEC95	-6, -63	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	3	38
	8	02FEB96	58, 1	No	No	No	No	No	No	No	No	0	3	3	21
	32	16JUL96	223, 166	No	No	No	No	No	No	Yes	No	1	2	3	19
329.006.00259	SC	22APR96	-32, .	No	No	No	No	No	No	No	No	0	3	3	16
	8	17JUL96	55, .	No	Yes	No	No	No	No	No	No	1	4	3	14
329.007.00141	SC	14SEP95	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	No	No	6	3	4	33
329.007.00144	SC	30NOV95	-7, -63	No	No	No	Yes	Yes	No	Yes	No	3	4	3	23
	8	01FEB96	57, 1	No	No	No	No	No	No	No	No	0	2	3	14
329.007.00266	SC	29FEB96	-7, .	No	No	No	No	No	No	No	Yes	1	3	4	13
	8	02MAY96	57, .	No	No	No	No	No	No	No	No	0	2	3	8
329.007.00267	SC	29FEB96	-7, .	No	Yes	No	No	Yes	Yes	Yes	Yes	5	3	4	25
	8	02MAY96	57, .	No	No	No	No	No	No	No	No	0	3	3	11
329.007.00311	SC	26SEP96	-7, -67	Yes	Yes	No	No	Yes	No	No	No	3	2	3	28
	8	02DEC96	61, 1	Yes	Yes	No	No	No	No	Yes	No	3	2	1	22
329.008.00158	SC	06SEP95	-7, -69	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	7	3	3	32
	8	14NOV95	63, 1	No	No	No	No	No	No	Yes	No	1	3	3	14

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.008.00162	SC	26OCT95	-6, -71	Yes	Yes	No	No	Yes	Yes	Yes	No	5	4	3	48
	8	05JAN96	66, 1	Yes	Yes	Yes	No	Yes	Yes	No	No	5	3	4	39
	32	02JUL96	245, 180	Yes	Yes	Yes	No	No	Yes	No	No	4	2	2	19
329.008.00191	SC	12JAN96	-20, -81	Yes	Yes	No	No	Yes	Yes	No	No	4	3	4	41
	8	02APR96	62, 1	No	No	No	No	No	No	No	No	0	2	3	11
329.009.00128	SC	05APR95	-6, .	No	No	No	No	No	No	No	No	0	3	3	14
329.009.00129	SC	22MAR95	-20, .	Yes	Yes	No	No	Yes	Yes	Yes	No	5	4	3	54
329.009.00135	SC	25SEP95	-7, .	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	4	4	37
329.009.00136	SC	26SEP95	-7, .	Yes	No	Yes	No	Yes	Yes	No	Yes	5	3	3	51
	8	28NOV95	57, .	Yes	Yes	No	No	No	No	No	Yes	3	3	2	23
329.009.00169	SC	25OCT95	-6, -71	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	7	3	4	44
	8	27DEC95	58, -8	No	No	No	No	No	Yes	No	No	1	2	1	12
329.009.00174	SC	14NOV95	-7, -64	No	No	No	No	No	No	No	No	0	3	3	14
	8	17JAN96	58, 1	No	No	No	No	No	No	No	No	0	3	3	11
329.009.00197	SC	20DEC95	-9, -63	No	No	Yes	Yes	Yes	No	Yes	No	4	2	2	13
	8	20FEB96	54, -1	No	No	No	No	Yes	No	No	No	1	2	2	6
	32	20AUG96	236, 182	No	No	No	No	No	No	No	No	0	2	1	6
329.009.00198	SC	19DEC95	-14, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	4	3	54

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.009.00198	8	27FEB96	57, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	4	50
329.009.00200	SC	17JAN96	-6, .	Yes	Yes	No	No	No	Yes	Yes	Yes	5	3	5	46
329.009.00202	SC	14FEB96	-6, .	Yes	No	No	No	Yes	No	No	No	2	3	4	37
329.009.00238	SC	28OCT96	-15, .	Yes	Yes	No	No	Yes	No	Yes	No	4	3	3	39
	8	07JAN97	57, .	No	No	No	No	No	No	No	No	0	3	4	26
329.009.00276	SC	17JAN97	-4, .	No	Yes	No	No	No	Yes	Yes	Yes	4	3	5	46
	8	18MAR97	57, .	Yes	Yes	No	No	Yes	Yes	No	No	4	3	4	46
329.009.00302	SC	20MAR96	-7, .	No	Yes	No	No	No	Yes	No	No	2	2	3	31
329.009.00306	SC	03JUN96	-8, .	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	7	1	4	31
	8	06AUG96	57, .	No	Yes	Yes	Yes	No	No	Yes	Yes	5	1	3	35
329.009.00312	SC	30OCT96	-5, .	No	No	No	No	Yes	Yes	Yes	Yes	4	3	4	39
	8	06JAN97	64, .	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7	.	.	33
329.009.00327	SC	09SEP96	-7, .	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	3	4	53
	5	21OCT96	36, .	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	8	3	5	58
329.009.00330	SC	15OCT96	-6, .	Yes	No	Yes	No	No	No	Yes	No	3	2	4	25
329.010.00183	SC	21NOV95	-12, .	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	7	2	4	40

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

Patient ID	Week	Date	Relative Days*	Sickness Impact Profile Scores: Section F F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Present: Health	QOL	Total
329.010.00263	SC	24JUL96	-16, .	Yes	Yes	Yes	Yes	No	Yes	Yes	No	6	2	3	35
	8	09OCT96	62, .	No	No	Yes	Yes	Yes	No	No	Yes	4	3	2	18
329.010.00277	SC	23FEB96	-7, -63	Yes	Yes	No	No	No	Yes	Yes	Yes	5	3	3	30
	8	26APR96	57, 1	No	No	No	No	Yes	No	No	No	1	2	2	7
	24	07AUG96	160, 104	No	No	No	No	No	No	No	No	0	2	2	4
329.010.00282	SC	19JUL96	-7, .	No	No	No	No	No	No	No	No	0	2	2	8
	8	27SEP96	64, .	No	No	Yes	No	No	No	No	No	1	2	2	6
329.011.00164	SC	15DEC95	-7, .	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	2	4	36
329.011.00210	SC	13SEP96	-15, -81	Yes	No	Yes	No	No	No	Yes	No	3	2	3	23
	8	02DEC96	66, -1	No	No	No	No	No	No	No	No	0	2	2	16
329.011.00285	SC	08MAY96	-10, .	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	7	3	5	49
	8	24JUL96	68, .	Yes	Yes	No	No	No	Yes	Yes	Yes	5	3	3	49
329.011.00287	SC	25JUN96	-8, .	Yes	Yes	No	No	Yes	No	No	No	3	3	3	35
	8	27AUG96	56, .	No	No	No	No	No	No	No	No	0	3	3	17
329.012.00027	SC	23NOV95	-13, .	Yes	Yes	Yes	No	No	Yes	Yes	No	5	4	4	48
329.012.00217	SC	14MAY96	-7, .	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8	4	4	54
329.012.00218	SC	04JUN96	-12, -70	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6	3	4	37
	8	13AUG96	59, 1	No	No	Yes	No	No	No	No	No	1	1	2	8

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
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For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix C.7
Listing of Sickness Impact Profile Scores by Treatment Group, Part IV
Intent-to-Treat Population

Treatment = PLACEBO

				Sickness Impact Profile Scores											
			Relative	Section F									Present		
Patient ID	Week	Date	Days*	F1	F2	F3	F4	F5	F6	F7	F8	Sec. F Total	Health	QOL	Total
329.012.00224	SC	30AUG96	-17, -83	No	No	Yes	Yes	No	No	No	No	2	2	2	18
	8	20NOV96	66, -1	Yes	No	No	No	No	No	No	No	1	1	2	13
329.012.00225	SC	19NOV96	-7, -71	Yes	Yes	No	No	Yes	No	Yes	No	4	2	3	23
	8	29JAN97	65, 1	No	No	No	No	No	No	No	No	0	2	3	12
	32	30JUL97	247, 183	No	No	No	No	No	No	No	No	0	2	2	5

* days relative to start of acute phase, days relative to start of continuation phase
Section F = Recreation and Pastimes
Section and Overall totals were computed by converting yes/no answers to yes=1 and no=0, then summing the items.
For Present Health and Present Quality of Life scores: 1 = Very Good, 2 = Good, 3 = Fair, 4 = Poor, 5 = Very Poor

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Appendix D: Patient Data Listings of Adverse Experiences

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329 DEP Appendix D.2 Listing of Adverse Experiences by Treatment Group and Patient Intent-to-Treat Population 672

PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abdominal Pain	"STOMACH ACHE"	329.005.00119	23OCT95	105, 46, -36	5 Days	40	5	MOD	NO	PBU	No	No
	ABDOMINAL PAIN(PRESENT PREVIOUSLY)	329.010.00278	22MAR96	43, -14,-197	5 Days	40	CON	SEV	NO	PBU	Yes	No
	CRAMPS (ABDOMINAL)	329.007.00294	07APR97	39, ., -3	02:00 Hrs	30	CON	MOD	NO	UNR	Yes	No
	DISCOMFORT ACROSS ALL OF ABDOMEN	329.012.00025	06NOV95	14, ., -59	02:00 Hrs	20	1	MOD	NO	PBU	No	No
	STOMACH ACHE	329.001.00063	09NOV94	2, ., -46	8 Days	20	5	MIL	NO	PSR	No	No
			30NOV94	23, ., -25	Not Stated	20	CON	MIL	NO	PSR	No	No
		329.005.00008	10DEC94	25, -31,-117	3 Days	20	CON	MOD	NO	UNR	No	No
		329.005.00119	20JUL95	10, -50,-131	4 Days	20	2	MIL	NO	PBU	No	No
		329.005.00258	21MAR96	10, ., -47	02:00 Hrs	20	1	MOD	NO	PBU	No	No
			05APR96	25, ., -32	4 Days	20	4	MOD	NO	PBU	No	No
		329.005.00299	31JUL96	54, -7,-110	3 Days	20	2	MOD	NO	PSR	Yes	No
		329.007.00309	27OCT96	105, 53,-150	3 Days	20	CON	MIL	NO	UNR	No	No
		329.009.00130	13SEP95	149, 93, -33	Not Stated	20		MIL	NO	PBU	Yes	No
	STOMACH ACHES	329.002.00102	05SEP95	146, 92,-106	36 Days	40	1	MOD	NO	REL	No	No
		329.002.00106	03AUG95	8, ., -40	10 Mins	20	10	MIL	NO	REL	No	No
	STOMACH ACHES INTERMITTENT AM AND LUNCH	329.004.00015	08DEC94	1, -57,-202	12 Days	20	6	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abdominal Pain	STOMACH PAIN	329.002.00319	09JUL96	71, 15,-174	16:00 Hrs	30	1	MIL	NO	UNR	No	No
		329.004.00017	11NOV95	235, 179, -3	Not Stated	20	CON	MIL	NO	UNR	No	No
Allergic Reaction	ALLERGIES	329.003.00250	29APR96	47, -11, -28	24:00 Hrs	40		MIL	NO	UNR	Yes	No
	CONGESTION-NASAL DUE TO ALLERGIES	329.004.00015	09JUN95	184, 127, -19	Not Stated	20	CON	MOD	NO	UNR	No	No
	ITCHY EYES-DUE TO ALLERGIES	329.004.00015	09JUN95	184, 127, -19	Not Stated	20	CON	MOD	NO	UNR	No	No
	SEASONAL ALLERGIES	329.009.00303	29APR96	28, -29,-237	1 Days	20	CON	MIL	NO	UNR	No	No
Asthenia	DECREASED ENERGY/TIRED	329.008.00271	07MAY96	58, -7,-197	Not Stated	40	CON	MIL	NO	PSR	No	No
	EXTREME SLEEPINESS/FATIGUE	329.005.00008	29DEC94	44, -12, -98	11 Days	40	CON	SEV	DCR	REL	No	No
	FATIGUE	329.002.00319	01MAY96	2, -55,-243	202 Days	20	CON	MIL	NO	REL	No	No
		329.004.00015	08DEC94	1, -57,-202	15 Days	20	CON	MIL	NO	REL	No	No
			22DEC94	15, -43,-188	11 Days	20	CON	MOD	NO	REL	No	No
		329.005.00119	11JUL95	1, -59,-140	4 Days	20	CON	MOD	NO	PSR	No	No
		329.009.00170	27JUN96	234, 177, -11	11 Days	20	CON	MOD	NO	PSR	No	Yes
		329.009.00173	01JAN96	43, -21, -57	Not Stated	30	CON	MOD	NO	PSR	No	No
		329.012.00025	16NOV95	24, ., -49	Not Stated	20	CON	MOD	NO	REL	No	No
	FATIGUE NEW	329.004.00015	02FEB95	57, -1,-146	43 Days	20	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Asthenia	FATIGUE WITH DIZZINESS AND DROWSINESS [FATIGUE WITH DROWSINESS]	329.005.00011	28JAN95	47, -10,-109	Not Stated	40	CON	MIL	NO	PSR	No	No
	TIRED	329.003.00075	14JUN95	141, 85, -99	2 Days	20		MIL	NO	UNR	No	No
		329.003.00089	10MAR95	4, ., -56	Not Stated	20	CON	MIL	NO	PSR	No	No
	TIREDNESS INCREASED FATIGUE	329.005.00011	19DEC94	7, -50,-149	10 Days	20	4	MIL	NO	PSR	No	No
	VERY TIRED	329.006.00039	22MAR95	43, -19, -49	7 Days	20	CON	SEV	NO	PSR	No	No
Back Pain	BACK PAIN	329.005.00151	06SEP95	1, -57,-238	1 Days	20	1	MOD	NO	UNR	Yes	No
			19OCT95	44, -14,-195	02:00 Hrs	20	1	MIL	NO	UNR	Yes	No
	BACKACHE	329.005.00336	28MAR97	25, ., -33	2 Days	20	CON	MIL	NO	UNR	No	No
			20APR97	48, ., -10	4 Days	20	CON	MIL	NO	UNR	Yes	No
		329.007.00294	21MAR97	22, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
	NECK PAIN	329.007.00268	26MAY96	56, -4,-206	5 Days	30	CON	MOD	NO	UNR	Yes	No
Chest Pain	CHEST PAIN	329.002.00319	09JUL96	71, 15,-174	16:00 Hrs	30	1	MIL	NO	UNR	No	No
		329.005.00002	19JUN94	26, -31,-121	06:30 Hrs	20	CON	MOD	NO	PSR	No	No
	CHEST PAIN-APPROXIMATELY 3 OCCASIONS-INTENSE JAB THEN REMITS	329.006.00038	27MAR95	41, ., -16	3 Days	20	3	SEV	NO	PSR	No	No
Chills	SHIVERING AND SHAKING	329.004.00017	28MAR95	7, -50,-231	12 Days	20	CON	MIL	NO	PSR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Appendix D.1

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Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Fever	FEVER	329.004.00017	29AUG95	161, 105, -77	18:00 Hrs	30		MOD	NO	UNR	Yes	No
		329.005.00112	24JAN95	-2, -57, -94	3 Days	0	CON	MOD	NO	UNR	Yes	No
		329.007.00309	04DEC96	143, 91,-112	3 Days	20	CON	MIL	NO	UNR	Yes	No
Headache	HEADACHE	329.001.00206	10MAR96	19, ., -39	2 Days	20	CON	MIL	NO	PBU	No	No
		329.002.00099	03APR95	33, -23,-222	02:00 Hrs	20	CON	MIL	NO	PSR	Yes	No
		329.002.00319	18NOV96	203, 147, -42	04:00 Hrs	30	1	MOD	NO	PBU	Yes	No
		329.003.00089	14MAR95	8, ., -52	8 Days	20	CON	MIL	NO	PSR	Yes	No
			17APR95	42, ., -18	24:00 Hrs	20		MOD	NO	UNR	Yes	No
		329.003.00091	25MAR95	2, -53,-243	15 Mins	20		MIL	NO	PBU	No	No
		329.004.00015	20DEC94	13, -45,-190	03:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			10JAN95	34, -24,-169	01:00 Hrs	20	1	SEV	NO	PBU	Yes	No
			17JAN95	41, -17,-162	02:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			14FEB95	69, 12,-134	01:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			24FEB95	79, 22,-124	01:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			05JUN95	180, 123, -23	2 Days	20	CON	MOD	NO	UNR	No	No
		329.004.00019	06JUN95	7, ., -8	09:00 Hrs	20	1	MOD	NO	PSR	Yes	No
		329.004.00214	08NOV96	36, -25, -52	2 Days	30	CON	MIL	DCR	REL	Yes	No
			15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	Yes	No
		329.005.00002	20MAY94	-5, -61,-151	03:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
			17JUL94	54, -3, -93	4 Days	40	3	MOD	NO	PSR	Yes	No
		329.005.00004	24OCT94	15, -45, -88	02:30 Hrs	20	CON	MIL	NO	PBU	No	No

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Appendix D.1

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Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.005.00004	29DEC94	81, 22, -22	2 Days	40	CON	MOD	NO	PBU	No	No
		329.005.00008	10DEC94	25, -31,-117	3 Days	20	CON	MOD	NO	UNR	No	No
		329.005.00109	20MAR95	81, 28, -57	3 Days	20	4	MOD	NO	UNR	Yes	No
		329.005.00112	24JAN95	-2, -57, -94	3 Days	0	CON	MOD	NO	UNR	Yes	No
		329.005.00116	12APR95	65, 7, -90	1 Days	20	3	MOD	NO	PBU	Yes	No
		329.005.00119	17JUL95	7, -53,-134	02:00 Hrs	20		MOD	NO	PSR	Yes	No
			20AUG95	41, -19,-100	01:00 Hrs	40	2	MOD	NO	PBU	No	No
		329.005.00152	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No	No
		329.005.00257	14AUG96	157, 101, -82	8 Days	30	2	MIL	NO	PBU	Yes	No
		329.005.00258	21MAR96	10, ., -47	4 Days	20	2	MOD	NO	PBU	No	No
			05APR96	25, ., -32	4 Days	20	3	MOD	NO	PBU	No	No
		329.005.00299	31JUL96	54, -7,-110	5 Days	20	2	MOD	NO	PSR	Yes	No
			03SEP96	88, 28, -76	03:00 Hrs	20	4	MOD	NO	PBU	No	No
			23OCT96	138, 78, -26	02:00 Hrs	30	1	MOD	NO	PBU	Yes	No
			19NOV96	165, 105, 1	04:00 Hrs	20	1	MOD	NO	PBU	No	No
		329.005.00300	12NOV96	55, ., -2	02:00 Hrs	20	CON	MOD	NO	UNR	No	No
		329.005.00333	24JAN97	2, ., -31	03:20 Hrs	20	CON	MIL	NO	UNR	Yes	No
			26JAN97	4, ., -29	02:30 Hrs	20	CON	MIL	NO	UNR	No	No
			13FEB97	22, ., -11	8 Days	20	7	MOD	NO	PSR	Yes	No
			24FEB97	33, ., 0	03:00 Hrs	20	CON	MOD	NO	PBU	Yes	No
		329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.006.00260	23JUL96	6, -53,-148	45 Mins	20	1	MIL	NO	UNR	Yes	No
			24JUL96	7, -52,-147	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No
			27JUL96	10, -49,-144	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			28JUL96	11, -48,-143	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			29JUL96	12, -47,-142	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			30JUL96	13, -46,-141	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			11AUG96	25, -34,-129	45 Mins	20	1	MIL	NO	PBU	Yes	No
			20AUG96	34, -25,-120	30 Mins	30	1	MIL	NO	PBU	Yes	No
			26AUG96	40, -19,-114	40 Mins	30	1	MOD	NO	PBU	Yes	No
			02SEP96	47, -12,-107	30 Mins	30	1	MIL	NO	PBU	Yes	No
			06SEP96	51, -8,-103	45 Mins	30	1	MOD	NO	PBU	Yes	No
			08SEP96	53, -6,-101	45 Mins	30	1	SEV	NO	PBU	Yes	No
			11SEP96	56, -3, -98	30 Mins	30	1	MOD	NO	PBU	Yes	No
			16SEP96	61, 3, -93	02:00 Hrs	30	1	SEV	NO	PBU	Yes	No
			08OCT96	83, 25, -71	01:00 Hrs	30	1	MIL	NO	PBU	Yes	No
			05NOV96	111, 53, -43	01:00 Hrs	30	1	MIL	NO	PBU	No	No
		329.006.00261	22JAN97	58, -1, -97	01:00 Hrs	30	1	MOD	NO	PBU	Yes	No
		329.007.00145	30APR96	111, 55,-115	16 Days	40	CON	SEV	DCR	PSR	Yes	No
		329.007.00268	26MAY96	56, -4,-206	5 Days	30	CON	MOD	NO	UNR	Yes	No
		329.007.00310	17DEC96	83, 23,-188	3 Days	20	CON	SEV	NO	PBU	No	No
			14MAR97	170, 110,-101	10 Days	20	CON	MOD	NO	PBU	Yes	No
		329.009.00235	17MAR97	90, 36, -40	29 Days	20	CON	MIL	NO	PSR	No	No
		329.010.00182	28DEC95	10, ., -22	1 Days	20	CON	MIL	NO	PSR	Yes	No
		329.010.00280	25JUN96	40, -16, -34	60 Mins	30	1	MIL	NO	PSR	Yes	No
			27JUN96	42, -14, -32	60 Mins	40	1	MIL	NO	PSR	Yes	No

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.011.00283	25FEB96	18, -40, -40	01:00 Hrs	20	1	MIL	NO	PBU	No	No
			11MAR96	33, -25, -25	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
		329.012.00231	18APR97	43, -19,-122	2 Days	20	CON	MOD	NO	PBU	No	No
			24APR97	49, -13,-116	02:00 Hrs	20	CON	MOD	NO	PBU	Yes	No
			28APR97	53, -9,-112	Not Stated	30		MIL	NO	PBU	Yes	No
	HEADACHE (CHANGE IN SEVERITY)	329.007.00309	05DEC96	144, 92,-111	04:00 Hrs	20	CON	SEV	NO	PBU	No	No
	HEADACHE (DAILY)	329.008.00271	07MAY96	58, -7,-197	6 Days	40		MIL	NO	PSR	Yes	No
	HEADACHE UPON RISING	329.005.00299	14JUN96	7, -54,-157	27 Days	20		MOD	NO	PSR	No	No
	HEADACHE(WORSENING FROM BASELINE)	329.009.00304	21MAY96	43, -14,-167	8 Days	30	CON	MOD	NO	PSR	No	No
	HEADACHES	329.001.00072	21MAR95	2, ., -30	3 Days	20	2	MIL	NO	PSR	No	No
		329.003.00075	08FEB95	15, -42,-225	Not Stated	20	CON	MIL	NO	PBU	No	No
		329.005.00011	20DEC94	8, -49,-148	15 Days	20	14	MOD	NO	PSR	Yes	No
	HEADACHES (DAILY)	329.007.00268	01OCT96	184, 125, -78	38 Days	30	35	MIL	NO	PSR	Yes	No
		329.007.00309	14JAN97	184, 132, -71	30 Days	20	24	MOD	NO	PBU	Yes	No
	HEADACHES (DAILY, 1-2X /DAY)	329.007.00294	04MAR97	5, ., -37	Not Stated	20		MOD	NO	PSR	Yes	No
	HEADACHES (INCREASED FREQUENCY)	329.007.00309	24SEP96	72, 20,-183	19 Days	20	20	MOD	NO	PBU	Yes	No

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Intent-to-Treat Population

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHES 1 DAILY	329.004.00015	11DEC94	4, -54,-199	7 Days	20	3	MIL	NO	PSR	Yes	No
	HEADACHES-MORE SEVERE THAN USUAL	329.006.00039	24APR95	76, 15, -16	5 Days	30	3	SEV	NO	PBU	Yes	No
	MILD HEADACHE	329.007.00310	17OCT96	22, -39,-249	03:00 Hrs	20	CON	MIL	NO	PSR	No	No
	MODERATE HEADACHE	329.012.00231	28APR97	53, -9,-112	Not Stated	30		MOD	NO	PSR	Yes	No
Infection	"FLU" HEADACHE, SORE THROAT AND WEAKNESS, FEVER, EARACHE	329.007.00310	05OCT96	10, -51,-261	12 Days	20	CON	MOD	NO	PBU	No	No
	COLD AND FLU STUFFY NOSE/NAUSEA/VOMITING DIARRHEA	329.005.00109	09FEB95	42, -12, -96	4 Days	20	CON	MOD	NO	UNR	No	No
	FLU	329.003.00248	02APR96	33, ., -30	10 Days	40	CON	MIL	NO	UNR	No	No
		329.007.00142	01DEC95	45, ., -3	8 Days	40	1	MOD	NO	UNR	Yes	No
	FLU (COUGH, HEAD CONGESTION, LOW-GRADE FEVER)	329.007.00309	12DEC96	151, 99,-104	11 Days	20	CON	MOD	NO	UNR	No	No
	FLU SYMPTOMS - FEVER, HEADACHES, MUSCLE ACHES	329.002.00319	06DEC96	221, 165, -24	6 Days	30	1	MOD	NO	UNR	No	No
	MONONUCLEOSIS	329.010.00278	01SEP96	206, 150, -34	Not Stated	40	CON	SEV	NO	PBU	Yes	No
	NAUSEA VOMITING DIARRHEA (FLU)	329.005.00112	13MAR95	47, -9, -46	2 Days	20	CON	SEV	NO	UNR	No	No

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Infection	NAUSEA,VOMITING,DIARRHEA (STOMACH FLU)	329.005.00116	06MAR95	28, -31,-127	24:00 Hrs	20	CON	SEV	NO	UNR	No	No
	POSSIBLE STREP THROAT	329.007.00310	17MAR97	173, 113, -98	12 Days	20	CON	MOD	NO	UNR	Yes	No
	REPORT OF SORE THROAT.POSITIVE CULTURE,THROAT.BETA HEMOLYTIC STREP,GROUP A.	329.002.00058	16NOV94	58, -1, -61	3 Days	40	CON	MIL	NO	UNR	Yes	No
	SCABIES ON BOTH ARMS	329.006.00261	18FEB97	85, 27, -70	44 Days	30	CON	MOD	NO	UNR	No	No
	SORE THROAT AND EAR INFECTION DIAGNOSIS:STREP THROAT	329.005.00151	15OCT95	40, -18,-199	12 Days	20	CON	SEV	NO	UNR	Yes	No
	STOMACH FLU WITH NAUSEA,VOMITING AND DIARRHEA	329.005.00008	27NOV94	12, -44,-130	3 Days	20	CON	SEV	NO	UNR	No	No
	STOMACH FLU-NAUSEA,VOMITING AND DIARRHEA	329.005.00008	16DEC94	31, -25,-111	4 Days	30	CON	SEV	NO	UNR	No	No
	TONSILLITIS (STREP PHARYNGITIS)	329.009.00201	01APR96	56, ., -3	Not Stated	30	CON	MIL	NO	UNR	Yes	No
Trauma	FOREIGN OBJECT IN EYE	329.005.00151	06FEB96	154, 97, -85	3 Days	30	CON	MOD	NO	UNR	Yes	No
	HEADACHE DUE TO ACCIDENT	329.007.00268	26MAY96	56, -4,-206	5 Days	30	CON	MOD	NO	UNR	Yes	No
	MOTOR VEHICLE ACCIDENT	329.002.00102	02AUG95	112, 58,-140	1 Days	40	1	MIL	NO	UNR	No	No

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Treatment Group=PAROXETINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Trauma	NECK PAIN DUE TO ACCIDENT	329.007.00268	26MAY96	56, -4,-206	13 Days	30	CON	MOD	NO	UNR	Yes	No
	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENED) [SPRAIN]	329.001.00063	05NOV94	-3, ., -50	12 Days	0	CON	MIL	NO	UNR	No	No
	PATIENT ACCIDENTALLY THROWN FROM 3 WHEELER STRIKING HEAD AND A NUMBER OF ABRASIONS	329.007.00268	26MAY96	56, -4,-206	5 Mins	30	1	SEV	NO	UNR	Yes	No
	SUPERFICIAL SCRATCHES	329.006.00039	25FEB95	18, -44, -74	12 Days	20	CON	MIL	NO	PBU	No	No

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Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Arrhythmia	IRREGULAR PULSE	329.003.00248	22FEB96	-8, ., -70	Not Stated	0	CON	MIL	NO	UNR	No	No
	SINUS ARRHYTHMIA (PER EKG)	329.009.00235	17MAR97	90, 36, -40	Not Stated	20	CON	MIL	NO	UNR	No	No
Av Block	PR PROLONGATION CARDIAC CONDUCTION DELAY	329.012.00226	20DEC96	18, ., 0	4 Days	20	CON	MOD	STP	PSR	No	No
Hypertension	HYPERTENSION	329.007.00145	14MAY96	125, 69,-101	17 Days	20	CON	MOD	DCR	PSR	No	No
Migraine	MIGRAINES	329.008.00188	20FEB96	48, ., -7	04:00 Hrs	40	2	MOD	NO	UNR	No	No
Palpitation	CHEST PALPITATIONS	329.005.00002	19JUN94	26, -31,-121	06:30 Hrs	20	CON	MOD	NO	PSR	No	No
	HEART PALPITATIONS	329.002.00099	30JUN95	121, 66,-134	63 Days	40	3	MOD	NO	PSR	No	No
Postural Hypotension	ORTHOSTATIC HYPOTENSION	329.009.00304	21MAY96	43, -14,-167	30 Mins	30	CON	MIL	NO	PSR	No	No
	POSTURAL HYPOTENSION	329.005.00008	12NOV94	-4, -59,-145	2 Mins	0	2	MIL	NO	PSR	No	No
Syncope	BLACKNESS IN FRONT OF EYES, LIGHTHEADED, SWEATING {PRE-SYNCOPAL EPISODE/HEAT EXPOSURE}	329.007.00268	01AUG96	123, 64,-139	20 Mins	40	CON	MIL	NO	UNR	No	No
	FAINTED	329.005.00299	17JUN96	10, -51,-154	1 Mins	20	1	MOD	NO	PSR	No	No
Tachycardia	ELEVATED PULSE	329.009.00235	06JAN97	20, -35,-110	36 Days	20	CON	MIL	NO	REL	No	No
	HEART RACING	329.003.00075	06MAY95	102, 46,-138	12 Days	20	CON	MIL	NO	PSR	No	No
		329.003.00077	20APR95	46, -14, -48	3 Days	30	3	MIL	NO	PSR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Vasodilatation	FEELING HOT	329.008.00271	06MAR96	-5, -69,-259	61 Days	0		MIL	NO	PSR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Constipation	CONSTIPATION	329.003.00089	21MAR95	15, ., -45	7 Days	20		MIL	NO	PSR	No	No
		329.004.00017	13APR95	23, -34,-215	12 Days	20	CON	MOD	NO	REL	No	No
			25APR95	35, -22,-203	28 Days	20	CON	MIL	NO	REL	No	No
		329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
		329.007.00268	19NOV96	233, 174, -29	02:00 Hrs	30	1	MOD	NO	UNR	Yes	No
		329.009.00131	20MAY95	19, -38, -99	3 Days	20	1	MOD	NO	PSR	Yes	No
		329.009.00170	07JUL96	244, 187, -1	Not Stated	20	CON	MIL	NO	UNR	No	No
		329.009.00196	20DEC95	3, ., -67	Not Stated	20	7	MIL	NO	PBU	No	No
Decreased Appetite	ANOREXIA	329.001.00063	10NOV94	3, ., -45	Not Stated	20	CON	MIL	NO	PSR	No	No
	APPETITE DECREASED	329.001.00072	28MAR95	9, ., -23	Not Stated	20	CON	MIL	NO	PSR	No	No
	APPETITE SUPPRESSION	329.003.00075	05APR95	71, 15,-169	98 Days	20	CON	MIL	NO	PSR	No	No
	DECREASED APPETITE	329.009.00196	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PBU	No	No
		329.009.00324	16DEC96	50, ., -23	31 Days	20	CON	MIL	NO	PSR	No	No
	LOSS OF APPETITE	329.009.00170	09NOV95	3, -55,-242	43 Days	20	CON	MIL	NO	PSR	No	No
			21DEC95	45, -13,-200	14 Days	40	CON	MOD	DCR	PSR	No	No
	REDUCED APPETITE	329.008.00271	18MAR96	8, -57,-247	24 Days	20	CON	MIL	NO	REL	No	No
	SLIGHT DECREASE APPETITE	329.001.00205	09FEB96	3, ., -5	Not Stated	20	CON	MIL	NO	PSR	No	No
Diarrhea	DIARRHEA	329.001.00063	09NOV94	2, ., -46	14 Days	20	3	MIL	NO	PSR	No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Diarrhea	DIARRHEA	329.002.00105	03AUG95	8, ., -14	8 Days	20	4	MIL	NO	PSR	No	No
		329.005.00008	10DEC94	25, -31,-117	3 Days	20	CON	MOD	NO	UNR	No	No
		329.005.00152	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No	No
		329.005.00333	21FEB97	30, ., -3	08:00 Hrs	20	CON	SEV	NO	UNR	Yes	No
		329.007.00268	03APR96	3, -57,-259	8 Days	20	CON	MIL	NO	PSR	No	No
	LOOSE STOOLS	329.009.00133	29JUN95	17, ., -28	Not Stated	20		MOD	NO	PSR	Yes	No
Dry Mouth	DRY MOUTH	329.001.00065	21NOV94	5, ., -9	Not Stated	20	CON	MIL	NO	REL	No	No
		329.001.00068	10FEB95	3, ., -69	Not Stated	20	CON	MIL	NO	PSR	No	No
		329.002.00106	03AUG95	8, ., -40	03:00 Hrs	20	CON	MIL	NO	REL	No	No
		329.002.00319	01MAY96	2, -55,-243	202 Days	20	CON	MIL	NO	REL	No	No
		329.003.00075	25JAN95	1, -56,-239	4 Days	20	CON	MIL	NO	PSR	No	No
		329.003.00077	16APR95	42, -18, -52	10 Days	30		MIL	NO	PSR	No	No
		329.003.00089	21MAR95	15, ., -45	Not Stated	20	CON	MIL	NO	PSR	No	No
		329.003.00313	18MAY96	2, ., -10	Not Stated	20	CON	MIL	NO	PSR	No	No
		329.005.00008	20NOV94	5, -51,-137	140 Days	20	CON	MIL	NO	PSR	No	No
		329.005.00116	10FEB95	4, -55,-151	152 Days	20	CON	MOD	NO	REL	No	No
		329.005.00300	24SEP96	6, ., -51	27 Days	20	CON	MOD	NO	REL	No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dry Mouth	DRY MOUTH	329.005.00300	21OCT96	33, ., -24	10 Days	20	CON	MIL	NO	REL	No	No
		329.005.00336	09MAR97	6, ., -52	39 Days	20	CON	MIL	NO	REL	No	No
		329.008.00271	06APR96	27, -38,-228	11 Days	20	CON	MIL	NO	PBU	No	No
		329.008.00275	08MAY96	1, -55,-222	Not Stated	20	CON	MIL	NO	PSR	No	No
			21JUL96	75, 20,-148	06:00 Hrs	30	1	MIL	NO	REL	No	No
			12AUG96	97, 42,-126	9 Days	30	3	MIL	NO	REL	No	No
			03SEP96	119, 64,-104	2 Days	30	3	MIL	NO	REL	No	No
			04NOV96	181, 126, -42	26:00 Hrs	30	2	MIL	NO	REL	No	No
		329.009.00196	03JAN96	17, ., -53	6 Days	20	CON	MIL	NO	PSR	No	No
		329.009.00235	30DEC96	13, -42,-117	43 Days	20	CON	MIL	NO	PSR	No	No
		329.010.00278	29MAR96	50, -7,-190	6 Days	40	CON	MIL	NO	REL	No	No
		329.012.00228	20MAR97	2, ., -2	4 Days	20	CON	MIL	NO	PBU	No	No
		329.012.00231	20MAR97	14, -48,-151	41 Days	20	CON	MIL	NO	PBU	No	No
Dyspepsia	HEARTBURN	329.009.00196	27JAN96	41, ., -29	Not Stated	30	CON	MIL	NO	PBU	Yes	No
	HEARTBURN ON AN EMPTY STOMACH WHEN TAKING MEDS.	329.002.00102	09MAY95	27, -28,-225	7 Days	30	7	MIL	NO	REL	No	No
	STOMACH UPSET	329.001.00206	10MAR96	19, ., -39	2 Days	20	CON	MIL	NO	PBU	No	No
	UPSET STOMACH	329.004.00214	09NOV96	37, -24, -51	2 Days	30	CON	MIL	DCR	REL	Yes	No
		329.005.00116	08FEB95	2, -57,-153	6 Days	20	10	MOD	NO	PBU	No	No

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Appendix D.1

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Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dyspepsia	UPSET STOMACH AND HEARTBURN	329.003.00077	12MAR95	7, -53, -87	08:30 Hrs	20	CON	MIL	NO	PBU	No	No
	UPSET STOMACH {WHEN TAKES MEDICATIONS AT BEDTIME}	329.005.00116	04APR95	57, -2, -98	99 Days	20	CON	MIL	NO	PSR	No	No
Esophagitis	BURNING ACHE IN UPPER ESOPHAGUS REGION	329.006.00260	05AUG96	19, -40,-135	5 Mins	20	3	MOD	NO	PSR	No	No
	BURNING ACHE IN UPPER ESOPHAGUS REGION-BRIEF	329.006.00260	07AUG96	21, -38,-133	45 Mins	20	1	MOD	NO	PSR	No	No
Gastrointestinal Disorder	FOOD POISONING	329.007.00310	16NOV96	52, -9,-219	2 Days	20	CON	MOD	NO	UNR	Yes	No
	NAUSEA AND REFLUX {ESOPHAGEAL}	329.003.00075	15FEB95	22, -35,-218	24:00 Hrs	20	CON	MIL	NO	PSR	No	No
Gingivitis	ABSCESSED TOOTH	329.007.00309	26SEP96	74, 22,-181	1 Days	20	CON	SEV	NO	UNR	Yes	No
Increased Appetite	INCREASED APPETITE	329.001.00068	01MAR95	22, ., -50	29 Days	20	CON	MIL	NO	PSR	No	No
		329.003.00081	19DEC95	9, ., -50	16 Days	20	CON	MIL	NO	PSR	No	No
		329.005.00116	15FEB95	9, -50,-146	162 Days	20	CON	MOD	NO	PSR	No	No
		329.009.00170	01APR96	147, 90, -98	85 Days	30	CON	MIL	NO	PSR	No	No
			30JUN96	237, 180, -8	9 Days	20	CON	MOD	NO	PSR	No	No
Nausea	NAUSEA	329.001.00063	30NOV94	23, ., -25	Not Stated	20	CON	MIL	NO	PSR	No	No
		329.001.00065	18NOV94	2, ., -12	Not Stated	20	4	MOD	NO	REL	No	No

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Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nausea	NAUSEA	329.001.00121	06APR95	3, -54,-151	27 Days	20	CON	MIL	NO	PSR	No	No
		329.002.00099	18APR95	48, -8,-207	7 Days	40	21	MIL	NO	PSR	No	No
		329.003.00075	08MAR95	43, -14,-197	128 Days	20	CON	MIL	INC	PSR	No	No
			15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU	No	No
		329.003.00077	21APR95	47, -13, -47	3 Days	30	3	MIL	NO	PSR	No	No
			02MAY95	58, -2, -36	35 Days	30	2	MIL	NO	PSR	No	No
		329.003.00089	10MAR95	4, ., -56	Not Stated	20	CON	MIL	NO	PSR	No	No
		329.003.00091	26MAR95	3, -52,-242	10 Mins	20		MIL	NO	PBU	No	No
		329.004.00017	23MAR95	2, -55,-236	4 Days	20	CON	SEV	DCR	REL	No	No
			27MAR95	6, -51,-232	5 Days	0	CON	MIL	NO	REL	No	No
			06NOV95	230, 174, -8	7 Days	20	CON	MOD	NO	UNR	Yes	No
		329.004.00214	15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	Yes	No
			23DEC96	81, 21, -7	06:00 Hrs	20	3	MOD	NO	PSR	No	No
		329.005.00152	27OCT95	2, ., -3	4 Days	20	CON	SEV	STP	REL	No	No
		329.007.00268	27OCT96	210, 151, -52	10 Days	30	CON	MOD	NO	PBU	Yes	No
		329.007.00309	27OCT96	105, 53,-150	3 Days	20	CON	MIL	NO	UNR	No	No
			10MAR97	239, 187, -16	Not Stated	30	CON	MIL	NO	UNR	No	No
		329.009.00130	23MAY95	36, -21,-146	3 Days	20	2	MIL	NO	PSR	No	No
		329.009.00133	29JUN95	17, ., -28	Not Stated	20	CON	MOD	NO	PSR	No	No
		329.009.00170	27JUN96	234, 177, -11	12 Days	20	CON	SEV	NO	REL	Yes	Yes

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nausea	NAUSEA	329.009.00196	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PSR	No	No
		329.009.00201	07MAR96	31, ., -28	1 Days	20	CON	MIL	NO	PBU	No	No
		329.009.00204	26MAR96	8, -49,-203	22 Days	20	CON	MIL	NO	PSR	No	No
		329.009.00235	27JAN97	41, -14, -89	50 Days	20	CON	MIL	NO	PSR	No	No
		329.009.00324	29OCT96	2, ., -71	21 Days	20	CON	MIL	NO	PSR	No	No
		329.012.00025	06NOV95	14, ., -59	02:00 Hrs	20	1	MOD	NO	PBU	No	No
		329.012.00220	13SEP96	89, 29, -70	04:00 Hrs	30	1	MIL	NO	PBU	No	No
		329.012.00226	12DEC96	10, ., -8	12 Days	20	CON	MIL	NO	PBU	No	No
		329.012.00231	25MAY97	80, 19, -85	10 Days	30	4	MIL	NO	PBU	No	No
	NAUSEA (FOR 10 MINUTES DAILY BEFORE BREAKFAST)	329.002.00099	30JUN95	121, 66,-134	63 Days	40	25	MIL	NO	PSR	No	No
	NAUSEA DUE TO RIDES AT AMUSEMENT PARK	329.007.00268	29APR96	29, -31,-233	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No
	NAUSEATED	329.002.00099	04MAR95	3, -53,-252	11 Days	20	CON	MIL	NO	PSR	No	No
	NAUSEOUS	329.003.00250	15MAR96	2, -56, -73	12 Days	20	CON	MIL	NO	PBU	No	No
Peptic Ulcer Hemorrhage	BLEEDING ULCER {PEPTIC}	329.005.00109	07MAY95	129, 76, -9	4 Days	20	CON	SEV	NO	UNR	Yes	Yes
Tooth Disorder	ORTHODONTIC DISCOMFORT	329.005.00258	01APR96	21, ., -36	03:30 Hrs	20	1	MOD	NO	UNR	Yes	No
			08APR96	28, ., -29	02:40 Hrs	20	1	MOD	NO	UNR	Yes	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Tooth Disorder	TOOTHACHE	329.005.00112	26FEB95	32, -24, -61	10:30 Hrs	20	CON	MOD	NO	UNR	No	No
		329.006.00260	06AUG96	20, -39,-134	30 Mins	20	1	SEV	NO	UNR	Yes	No
	TOOTHACHE (CUTTING WISDOM TEETH)	329.007.00309	26AUG96	43, -10,-212	17 Days	20	CON	MOD	NO	UNR	Yes	No
	TOOTHACHE PAIN	329.006.00260	25JUL96	8, -51,-146	09:00 Hrs	20	1	MOD	NO	UNR	Yes	No
	WISDOM TOOTH EXTRACTION {TOOTH DISORDER}	329.009.00133	14JUL95	32, ., -13	03:00 Hrs	30	CON	MIL	NO	UNR	Yes	No
Vomiting	NAUSEA AND VOMITING	329.005.00109	10MAY95	132, 79, -6	2 Days	20	CON	SEV	NO	PSR	No	No
		329.005.00119	23OCT95	105, 46, -36	5 Days	40	5	MOD	NO	PBU	No	No
		329.005.00152	27OCT95	2, ., -3	4 Days	20	8	SEV	STP	REL	No	No
	VOMITING	329.001.00065	21NOV94	5, ., -9	1 Mins	20	1	MIL	NO	REL	No	No
		329.004.00017	08NOV95	232, 176, -6	5 Days	20	3	MOD	NO	UNR	No	No
		329.005.00152	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No	No
		329.009.00170	01JUL96	238, 181, -7	6 Days	20	CON	SEV	NO	REL	Yes	No
		329.009.00201	07MAR96	31, ., -28	1 Days	20		MIL	NO	UNR	No	No

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Hemic and Lymphatic System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Anemia	ANEMIA	329.003.00248	23APR96	54, ., -9	Not Stated	30	CON	MIL	NO	PBU	No	No
Thrombocythemia	INCREASED PLATELET COUNT	329.009.00131	27JUN95	57, 1, -61	29 Days	20	CON	MIL	NO	PBU	No	No
Thrombocytopenia	THROMBOCYTOPENIA	329.007.00145	30MAY96	141, 85, -85	29 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

---------- Treatment Group=PAROXETINE Body System=Metabolic and Nutritional Disorders ----------

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Weight Gain	WEIGHT GAIN	329.005.00151	28NOV95	84, 27,-155	156 Days	20	CON	MOD	NO	PSR	No	No
		329.005.00257	03JUN96	85, 29,-154	Not Stated	30	CON	MOD	NO	PSR	No	No
		329.007.00268	30SEP96	183, 124, -79	95 Days	30	CON	MOD	NO	PSR	Yes	No
	WEIGHT GAIN {10 LBS}[WEIGHT GAIN]	329.009.00304	30JUL96	113, 57, -97	Not Stated	30	CON	MIL	NO	PSR	No	No
	WEIGHT GAIN {11LBS}[WEIGHT GAIN]	329.009.00201	02APR96	57, ., -2	Not Stated	20	CON	MOD	NO	PSR	No	No
Weight Loss	WEIGHT LOSS	329.001.00121	11APR95	8, -49,-146	22 Days	20	CON	MIL	NO	PSR	No	No
		329.009.00170	21DEC95	45, -13,-200	14 Days	40	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Musculoskeletal System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Arthralgia	LEFT KNEE PAIN	329.007.00310	14NOV96	50, -11,-221	Not Stated	20	CON	MOD	NO	UNR	Yes	No
Myalgia	CRAMPS IN LEFT LEG	329.005.00116	08MAR95	30, -29,-125	2 Days	20	CON	MOD	NO	UNR	No	No
	MUSCLE ACHE	329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
	MUSCLE PAIN	329.007.00268	07JUL96	98, 39,-164	124 Days	30	CON	MIL	NO	UNR	Yes	No
	PAIN IN NECK MUSCLES	329.007.00310	07OCT96	12, -49,-259	9 Days	20	CON	MOD	NO	PBU	Yes	No
Myasthenia	MUSCLE WEAKNESS	329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
Tendinous Disorder	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENED) [TENDONITIS]	329.001.00063	05NOV94	-3, ., -50	12 Days	0	CON	MIL	NO	UNR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abnormal Dreams	INCREASED DREAMING	329.009.00324	25NOV96	29, ., -44	Not Stated	20	CON	MIL	NO	PSR	No	No
	NIGHTMARES	329.009.00324	11NOV96	15, ., -58	15 Days	20	CON	MIL	NO	PSR	No	No
	VIVID DREAMS	329.005.00333	10FEB97	19, ., -14	11 Days	20	10	MOD	NO	PSR	No	No
Agitation	AGITATION	329.009.00170	09JUL96	246, 189, 1	12:00 Hrs	20	CON	MOD	NO	PSR	No	Yes
		329.009.00201	03APR96	58, ., -1	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	FIDGETY/PSYCHOMOTOR AGITATION	329.007.00268	16SEP96	169, 110, -93	17 Days	40	CON	MIL	DCR	PSR	No	No
	["HYPER"{AGITATION}]	329.009.00130	19MAY95	32, -25,-150	26 Days	20	3	MOD	NO	PSR	No	No
Amnesia	"FORGETFUL"	329.002.00099	30JUN95	121, 66,-134	63 Days	40	3	MIL	NO	PBU	No	No
Anxiety	ANXIETY	329.004.00017	23MAR95	2, -55,-236	4 Days	20	CON	SEV	DCR	REL	No	No
	ANXIETY ATTACKS	329.008.00188	24FEB96	52, ., -3	30 Mins	40	1	MIL	NO	PBU	No	No
Concentration Impaired	ATTENTION DEFICIT HYPERACTIVITY DISORDER	329.009.00240	26MAR97	72, ., 21	Not Stated	0	CON	MOD	NO	UNR	Yes	No
	DECREASED CONCENTRATION	329.008.00271	11MAY96	62, -3,-193	4 Days	40	CON	MIL	NO	PSR	No	No
Depression	MORE DEPRESSED	329.006.00039	22MAR95	43, -19, -49	7 Days	20	CON	SEV	NO	PSR	No	No
	WORSENING OF DEPRESSION	329.009.00240	02MAR97	48, ., -3	Not Stated	30	CON	SEV	STP	UNR	Yes	Yes
		329.009.00329	12NOV96	35, ., -35	22 Days	20	CON	MOD	NO	PBU	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Depression	WORSENING OF DEPRESSION HOSPITALIZED	329.001.00065	30NOV94	14, ., 0	Not Stated	20	CON	SEV	STP	PSR	No	Yes
Dizziness	COLD CLAMMY LIGHTHEADEDNESS [LIGHTHEADEDNESS]	329.008.00271	05APR96	26, -39,-229	15 Mins	20	1	MIL	DCR	PSR	No	No
	CONSTANT DIZZINESS (DAILY)	329.002.00099	28JUN95	119, 64,-136	93 Days	40	CON	MOD	NO	PSR	No	No
	DIZZINESS	329.001.00063	10NOV94	3, ., -45	5 Mins	20	1	MIL	NO	PSR	No	No
		329.001.00065	18NOV94	2, ., -12	Not Stated	20	4	MIL	NO	REL	No	No
		329.002.00102	05SEP95	146, 92,-106	36 Days	40	1	MOD	NO	REL	No	No
		329.003.00075	08MAR95	43, -14,-197	15 Days	20	CON	MOD	INC	PSR	No	No
			01JUL95	158, 102, -82	10 Days	20	CON	MIL	NO	PBU	No	No
			15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU	No	No
		329.003.00081	28DEC95	18, ., -41	14 Days	20	CON	MIL	NO	PBU	No	No
		329.003.00248	26MAR96	26, ., -37	17 Days	30	CON	MIL	NO	PSR	No	No
		329.003.00250	15MAR96	2, -56, -73	5 Mins	20	2	MIL	NO	PBU	No	No
		329.004.00015	18FEB95	73, 16,-130	31 Days	20	CON	MIL	NO	PBU	No	No
			05JUN95	180, 123, -23	2 Days	20	CON	MOD	NO	UNR	No	No
		329.004.00017	06NOV95	230, 174, -8	5 Days	20	CON	MIL	NO	UNR	No	No
		329.004.00214	15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	No	No
			23DEC96	81, 21, -7	06:00 Hrs	20	3	MOD	NO	PSR	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dizziness	DIZZINESS	329.005.00011	02JAN95	21, -36,-135	34 Days	20		MIL	NO	REL	No	No
		329.005.00299	05NOV96	151, 91, -13	8 Days	20	CON	MOD	NO	PSR	No	No
		329.005.00336	10MAR97	7, ., -51	13 Days	20	2	MIL	NO	REL	No	No
		329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
		329.007.00309	17JUL96	3, -50,-252	2 Days	20	2	MIL	NO	PSR	No	No
		329.008.00275	25JUN96	49, -7,-174	9 Days	40	3	MIL	NO	REL	No	No
			19JUL96	73, 18,-150	5 Days	30	3	MIL	NO	REL	No	No
			10AUG96	95, 40,-128	3 Mins	30	1	MIL	NO	REL	No	No
			08SEP96	124, 69, -99	3 Days	30	2	MIL	NO	REL	No	No
		329.012.00220	25JUN96	9, -52,-150	3 Days	20	CON	MOD	NO	REL	No	No
		329.012.00231	25MAY97	80, 19, -85	10 Days	30	4	MIL	NO	PBU	No	No
	DIZZINESS ARISING FROM LAYING SITTING OR SOMETIMES WHEN SITTING	329.002.00099	28MAR95	27, -29,-228	28 Days	20	78	MOD	NO	PSR	No	No
	DIZZINESS IN AM	329.009.00329	14OCT96	6, ., -64	10 Days	20	CON	MIL	NO	REL	No	No
	DIZZINESS UPON RISING	329.005.00299	14JUN96	7, -54,-157	27 Days	20		MOD	NO	PSR	No	No
	DIZZINESS WHEN ARISING SUDDENLY	329.002.00099	14MAR95	13, -43,-242	11 Days	20	33	MOD	NO	PSR	No	No
	DIZZINESS WHEN STANDING	329.003.00089	14MAR95	8, ., -52	24:00 Hrs	20	CON	MIL	NO	PSR	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dizziness	DIZZINESS"FELT LIKE FAINTING"	329.003.00091	01APR95	9, -46,-236	01:30 Hrs	20		MOD	NO	PSR	Yes	No
	DIZZY	329.001.00121	23MAY95	50, -7,-104	20 Mins	30	1	MIL	NO	PBU	No	No
		329.002.00099	04MAR95	3, -53,-252	30 Mins	20	CON	MIL	NO	PSR	No	No
	DIZZY GETTING OUT OF BED OR AFTER LYING DOWN A LONG TIME	329.004.00019	03JUN95	4, ., -11	Not Stated	20		MIL	NO	REL	No	No
	FATIGUE WITH DIZZINESS AND DROWSINESS [DIZZINESS]	329.005.00011	28JAN95	47, -10,-109	Not Stated	40	CON	MIL	NO	PSR	No	No
	GIDDINESS	329.005.00336	14MAR97	11, ., -47	4 Days	20	4	MIL	NO	PSR	No	No
			27MAR97	24, ., -34	3 Days	20	CON	MIL	NO	PSR	No	No
	LIGHT-HEADED (X2 MINUTES)	329.010.00280	10JUL96	55, -1, -19	2 Mins	40	1	MIL	NO	PSR	No	No
	LIGHTHEADED	329.001.00065	18NOV94	2, ., -12	Not Stated	20	4	MIL	NO	REL	No	No
		329.008.00271	03APR96	24, -41,-231	15 Mins	20	2	MIL	DCR	PSR	No	No
	LIGHTHEADED {WHEN STANDING}	329.008.00271	11MAY96	62, -3,-193	Not Stated	40	CON	MIL	NO	PSR	No	No
	LIGHTHEADEDNESS	329.008.00275	05JUN96	29, -27,-194	3 Days	30	2	MIL	NO	REL	No	No
Drug Dependence	POSITIVE CANNABIS	329.005.00002	20MAY94	-5, -61,-151	1 Days	0	1	MIL	NO	UNR	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Drug Dependence	POSITIVE URINE DRUG SCREEN CANNABINOIDS	329.005.00109	25MAY95	147, 94, 9	1 Days	20	1	SEV	NO	UNR	No	No
Emotional Lability	ATTEMPTED SUICIDE {INTENTIONAL}	329.006.00038	12APR95	57, ., 0	1 Days	20	1	SEV	STP	UNR	No	Yes
	INTENTIONAL OVERDOSE {TYLENOL OVERDOSE TOOK 80 PILLS}	329.002.00058	19JAN95	122, 64, 3	1 Days	40	CON	MOD	STP	PBU	No	Yes
	OVERDOSE {INTENTIONAL}	329.003.00250	19APR96	37, -21, -38	21 Days	40	CON	MOD	NO	UNR	No	Yes
			27MAY96	75, 18, 0	01:00 Hrs	30	1	SEV	STP	UNR	No	Yes
	SELF-MUTILATION	329.004.00015	07JAN95	31, -27,-172	30 Mins	20	1	MIL	NO	UNR	No	No
	SUICIDAL IDEATION	329.004.00015	18FEB95	73, 16,-130	03:00 Hrs	20	1	MIL	NO	UNR	No	No
		329.005.00333	28FEB97	37, ., 4	103 Days	20	CON	SEV	NO	UNR	No	Yes
	SUPERFICIAL CUTS RISK TO SELF	329.003.00313	28MAY96	12, ., 0	6 Days	20	CON	SEV	STP	PBU	No	Yes
	TYLENOL OVERDOSE {INTENTIONAL}	329.002.00245	10APR96	14, ., -4	1 Days	20	1	SEV	STP	UNR	No	Yes
	[OVERDOSE{WITH BAYER EXTRA STRENGTH}[INTENTIONAL]	329.005.00011	17MAY95	156, 100, 0	1 Days	30	1	SEV	STP	UNR	Yes	Yes
Euphoria	ELATION AND EXPANSIVE MOOD	329.003.00089	04APR95	29, ., -31	Not Stated	20	CON	SEV	STP	PSR	No	Yes
Hallucinations	AUDITORY HALLUCINATIONS	329.003.00313	28MAY96	12, ., 0	6 Days	20	CON	SEV	STP	PBU	No	Yes

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Number of Episodes [No. Epi]: CON = Continuous
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Hostility	AGGRESSIVE ASSAULTIVE BEHAVIOR	329.009.00201	03APR96	58, ., -1	Not Stated	20	CON	SEV	STP	PSR	Yes	Yes
	ALLEGATIONS OF SEXUAL AGGRESSION	329.002.00055	25JUL94	32, -24,-124	1 Days	30		MIL	NO	UNR	No	No
	ANGRY(PATIENT NOTICED)	329.006.00038	15MAR95	29, ., -28	8 Days	20	CON	MIL	NO	PSR	No	No
	NEEDED 6 STITCHES TO HAND AFTER BREAKING PICTURES (DUE TO ANGER) RESULTED IN HOSPITALIZATION TO PREVENT AGGRESSION AGAINST SELF	329.001.00065	30NOV94	14, ., 0	1 Days	20	CON	MOD	STP	PBU	No	Yes
	OPPOSITIONAL BEHAVIOR (PHYSICALLY AND VERBALLY FIGHTING WITH MOTHER)	329.005.00300	18OCT96	30, ., -27	7 Days	20	6	SEV	NO	PBU	No	No
			25OCT96	37, ., -20	Not Stated	20		MOD	NO	PBU	No	No
	OPPOSITIONAL DEFIANT DISORDER	329.002.00106	15SEP95	51, ., 3	16 Days	40	CON	SEV	NO	PBU	No	Yes
	PHYSICAL FIGHT {AGGRESSION}	329.005.00119	28JUL95	18, -42,-123	10 Mins	20	1	MIL	NO	PBU	No	No
Hyperkinesia	AKATHISIA	329.007.00145	02MAY96	113, 57,-113	29 Days	30	CON	MOD	DCR	REL	No	No
	HYPERACTIVE	329.004.00214	08OCT96	5, -56, -83	01:00 Hrs	20	5	MIL	NO	PSR	No	No
	HYPERACTIVITY	329.003.00075	13JUL95	170, 114, -70	70 Days	20	CON	MIL	NO	PBU	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Hypertonia	STIFF NECK	329.007.00310	14MAR97	170, 110,-101	10 Days	20	CON	MOD	NO	UNR	Yes	No
		329.008.00271	07APR96	28, -37,-227	30 Mins	20	3	MIL	NO	PBU	No	No
Insomnia	AWAKENING (MIDDLE OF NIGHT)	329.004.00214	12OCT96	9, -52, -79	15 Mins	20	2	MIL	NO	PSR	No	No
	INITIAL AND MIDDLE INSOMNIA	329.012.00025	24OCT95	1, ., -72	Not Stated	20	CON	MOD	NO	PSR	No	No
	INITIAL INSOMNIA	329.009.00201	28FEB96	23, ., -36	Not Stated	20	CON	MOD	NO	PSR	No	No
		329.012.00228	20MAR97	2, ., -2	4 Days	20	CON	MIL	NO	PBU	No	No
	INITIAL INSOMNIA (INCREASE 2 HOURS)	329.002.00099	24MAY95	84, 29,-171	02:00 Hrs	40	39	SEV	NO	PBU	No	No
	INITIAL INSOMNIA MOST NIGHTS INCREASE 2 HOURS	329.002.00099	13JUN95	104, 49,-151	33 Days	40	10	MOD	NO	PSR	No	No
	INSOMNIA	329.003.00077	24MAY95	80, 21, -14	Not Stated	30	CON	SEV	DCR	PSR	No	No
		329.004.00017	27MAR95	6, -51,-232	5 Days	0	CON	MIL	NO	PSR	No	No
		329.009.00173	15JAN96	57, -7, -43	Not Stated	20	CON	MOD	NO	PSR	No	No
		329.009.00324	11NOV96	15, ., -58	8 Days	20	CON	MIL	NO	PSR	No	No
	INSOMNIA (INITIAL)	329.009.00196	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PBU	No	No
		329.009.00235	03FEB97	48, -7, -82	8 Days	20	CON	MIL	NO	UNR	No	No
	INSOMNIA(NO SLEEP)	329.004.00017	24MAR95	3, -54,-235	3 Days	20	CON	SEV	DCR	REL	No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Insomnia	MIDDLE INSOMNIA	329.001.00068	15FEB95	8, ., -64	Not Stated	20	CON	MOD	NO	PSR	No	No
		329.009.00170	23NOV95	17, -41,-228	6 Days	20	CON	MIL	NO	PSR	No	No
			28NOV95	22, -36,-223	37 Days	20	CON	MOD	NO	PSR	No	No
	RESTLESS AT NIGHT	329.002.00099	05MAR95	4, -52,-251	10 Days	20	2	MIL	NO	PSR	No	No
	SLEEP PROBLEMS-EXAMPLE WAKES UP TOO EARLY	329.003.00089	14MAR95	8, ., -52	Not Stated	20	CON	MIL	NO	PSR	No	No
	TERMINAL INSOMNIA	329.007.00268	09SEP96	162, 103,-100	24 Days	40	12	MOD	DCR	PSR	No	No
	TROUBLE SLEEPING	329.003.00075	15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU	No	No
	WORSENING OF SLEEP DISTURBANCE	329.009.00240	05MAR97	51, ., 0	Not Stated	30	CON	SEV	NO	PSR	Yes	Yes
Manic Reaction	HOSPITALIZATION RULE-OUT HYPOMANIA	329.004.00017	31AUG95	163, 107, -75	3 Days	30	CON	MIL	NO	UNR	No	Yes
	MANIA AND HYPOMANIA SYMPTOMS	329.001.00205	10FEB96	4, ., -4	Not Stated	20	CON	SEV	STP	PSR	No	No
	MANIA SYMPTOMS	329.001.00063	11DEC94	34, ., -14	Not Stated	20	CON	MOD	STP	PSR	No	No
Myoclonus	GRIMACING FACE WITH BLINKING EYES {TIC}	329.006.00039	22MAR95	43, -19, -49	7 Days	20	CON	MIL	NO	PSR	No	No
	LEG TWITCHES	329.005.00336	19APR97	47, ., -11	4 Days	20	4	MIL	NO	PSR	No	No
	LEG TWITCHES (NIGHTLY)	329.005.00336	29MAR97	26, ., -32	5 Days	20	4	SEV	NO	PSR	No	No
			02APR97	30, ., -28	8 Days	20	7	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervousness	"JITTERINESS"	329.005.00257	21OCT96	225, 169, -14	Not Stated	30	CON	MOD	NO	PSR	No	No
	INCREASED IRRITABILITY	329.008.00271	12MAY96	63, -2,-192	Not Stated	40	CON	MIL	NO	PSR	No	No
	IRRITABLE MOOD	329.006.00039	22MAR95	43, -19, -49	7 Days	20	CON	MOD	NO	PSR	No	No
	JITTERINESS	329.008.00160	20NOV95	20, -47,-261	8 Days	20	1	MIL	NO	UNR	No	No
		329.008.00188	07JAN96	4, ., -51	Not Stated	20	12	MIL	NO	PSR	No	No
	NERVOUS JITTERY TREMULOUS	329.003.00075	25JAN95	1, -56,-239	8 Days	20	CON	MIL	NO	PSR	No	No
	RESTLESSNESS	329.009.00173	29DEC95	40, -24, -60	18 Days	30	CON	MOD	DCR	PSR	No	No
		329.009.00193	01DEC95	4, ., -67	12 Days	20	CON	MIL	NO	PSR	No	No
		329.010.00278	03MAR96	24, -33,-216	5 Days	20	CON	MIL	NO	PSR	No	No
	TEETH CHATTERING(JITTERINESS)	329.003.00075	16MAR95	51, -6,-189	13 Days	20	CON	MIL	NO	REL	No	No
Paranoid Reaction	PARANOIA	329.009.00201	03APR96	58, ., -1	Not Stated	20	CON	MOD	STP	PSR	No	Yes
Paresthesia	TINGLING LEG AND FEET	329.001.00063	10NOV94	3, ., -45	7 Days	20	2	MIL	NO	PSR	No	No
Personality Disorder	BEHAVIOR PROBLEMS-->STOLE MOM'S CAR AND WRECKED IT.	329.005.00008	31JAN95	77, 22, -65	02:00 Hrs	30	1	SEV	NO	PSR	No	No
	SKIPPING SCHOOL TALKING BACK TO MOM {BEHAVIOR PROBLEMS}	329.005.00008	22DEC94	37, -19,-105	47 Days	40	CON	SEV	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Somnolence	DAYTIME SLEEPINESS	329.009.00304	14MAY96	36, -21,-174	15 Days	30	CON	MOD	NO	PSR	No	No
	DROWSINESS	329.003.00075	02MAR95	37, -20,-203	5 Days	20	CON	MIL	DCR	PSR	No	No
		329.012.00025	16NOV95	24, ., -49	20 Days	20	CON	MOD	NO	REL	No	No
	DROWSINESS DURING DAY	329.007.00294	28FEB97	1, ., -41	19 Days	20	CON	MIL	NO	PBU	No	No
	DROWSINESS-SLEEPINESS	329.005.00008	16NOV94	1, -55,-141	17 Days	20	7	MIL	NO	PSR	No	No
			02DEC94	17, -39,-125	160 Days	20	CON	MOD	NO	REL	No	No
	DROWSY	329.009.00170	27JUN96	234, 177, -11	11 Days	20	CON	MOD	NO	PSR	No	Yes
	INCREASED DAYTIME SLEEPINESS SOMNOLENCE	329.009.00173	13DEC95	24, -40, -76	Not Stated	20	CON	MOD	NO	PSR	No	No
	MILD SEDATION	329.002.00242	07MAR96	30, -29, -90	8 Days	30	1	MIL	NO	PSR	No	No
	SEDATION	329.004.00212	09JUN96	7, ., -16	12:00 Hrs	20	1	SEV	NO	PSR	No	No
			10JUN96	8, ., -15	2 Days	20	CON	MIL	NO	PSR	No	No
			12JUN96	10, ., -13	14 Days	20	CON	SEV	NO	PSR	No	No
	SLEEPINESS	329.003.00250	19APR96	37, -21, -38	Not Stated	40	CON	MOD	DCR	PSR	No	No
		329.005.00333	01FEB97	10, ., -23	7 Days	20	CON	SEV	NO	PSR	Yes	No
			21FEB97	30, ., -3	Not Stated	20	CON	SEV	NO	PSR	No	No
	SLEEPINESS (IN AM)	329.005.00300	01OCT96	13, ., -44	11 Days	20	CON	MOD	NO	REL	No	No
			12OCT96	24, ., -33	Not Stated	20	CON	SEV	NO	REL	No	No
	SLEEPINESS IN AM	329.009.00329	14OCT96	6, ., -64	16 Days	20	CON	MIL	NO	REL	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Somnolence	SLEEPINESS WHEN TAKING EVENING MEDS	329.009.00170	21DEC95	45, -13,-200	14 Days	40	CON	MOD	NO	PSR	No	No
	SLEEPY	329.003.00250	15MAR96	2, -56, -73	12 Days	20	CON	MIL	NO	PBU	No	No
	SOMNOLENCE	329.003.00081	19DEC95	9, ., -50	23 Days	20	CON	MIL	NO	PSR	No	No
		329.009.00201	26MAR96	50, ., -9	Not Stated	30	CON	MIL	NO	PSR	No	No
	SOMNOLENCE DAYTIME	329.008.00271	15MAR96	5, -60,-250	52 Days	20	CON	MIL	NO	PSR	No	No
Tremor	"SHAKINESS"	329.011.00283	05MAR96	27, -31, -31	6 Days	20	6	MIL	NO	PSR	No	No
	HAND TREMORS	329.005.00109	20JAN95	22, -32,-116	12 Days	20	CON	MIL	NO	REL	No	No
		329.005.00116	04MAR95	26, -33,-129	29 Days	20	CON	MIL	NO	REL	No	No
		329.005.00336	08MAR97	5, ., -53	4 Days	20	CON	MOD	NO	REL	No	No
			13MAR97	10, ., -48	7 Days	20	CON	MIL	NO	REL	No	No
			04APR97	32, ., -26	13 Days	20	CON	MIL	NO	PSR	No	No
	HANDS TREMBLING INTERMITTENT	329.004.00015	10DEC94	3, -55,-200	14 Days	20	4	MOD	NO	REL	No	No
	SHAKINESS OF WHOLE BODY	329.012.00025	24OCT95	1, ., -72	02:00 Hrs	20	CON	MIL	NO	PSR	No	No
	SHAKY	329.008.00271	14MAY96	65, 1,-190	Not Stated	40	CON	MIL	NO	PSR	No	No
	SHAKY TREMORS	329.009.00170	27JUN96	234, 177, -11	2 Days	20	CON	MOD	NO	PSR	No	Yes
	SUBJECTIVE FEELINGS OF SHAKINESS	329.008.00271	03APR96	24, -41,-231	14 Days	20	3	MIL	DCR	PSR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Tremor	TREMBLING JAW	329.001.00063	10NOV94	3, ., -45	7 Days	20	3	MIL	NO	PSR	No	No
	TREMOR (HANDS, HEAD, TEETH)	329.007.00309	15JUL96	1, -52,-254	47 Days	20	CON	MIL	NO	PSR	No	No
	TREMORS	329.001.00063	11DEC94	34, ., -14	Not Stated	20	3	MIL	NO	PSR	No	No
		329.004.00017	21APR95	31, -26,-207	11 Days	20	CON	MOD	NO	REL	No	No
			02MAY95	42, -15,-196	87 Days	30	CON	SEV	NO	REL	Yes	No
			28JUL95	129, 73,-109	40 Days	30	CON	MOD	NO	REL	No	No
			06SEP95	169, 113, -69	57 Days	30	CON	MIL	NO	REL	No	No
Vestibular Disorder	LEFT INNER EAR INFECTION	329.007.00268	01JUL96	92, 33,-170	10 Days	30	CON	MOD	NO	UNR	Yes	No
Withdrawal Syndrome	MIGRAINE HEADACHE {WITHDRAWAL SYMPTOM}	329.003.00248	29APR96	60, ., -3	6 Days	30	CON	SEV	NO	REL	Yes	Yes

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Asthma	ASTHMA	329.009.00196	29JAN96	43, ., -27	Not Stated	30	CON	SEV	NO	UNR	Yes	No
	EXERCISE INDUCED ASTHMA	329.005.00257	01SEP96	175, 119, -64	Not Stated	30	CON	MOD	NO	UNR	Yes	No
Bronchitis	BRONCHITIS	329.007.00309	13SEP96	61, 9,-194	7 Days	20	CON	MOD	NO	UNR	Yes	No
		329.012.00220	26SEP96	102, 42, -57	37 Days	30	CON	MOD	NO	PBU	Yes	No
	BRONCHITIS WITH COUGH	329.005.00116	04MAR95	26, -33,-129	25 Days	20	CON	SEV	NO	UNR	Yes	No
Cough Increased	COUGH	329.003.00089	02APR95	27, ., -33	Not Stated	20	CON	MIL	NO	UNR	No	No
		329.004.00015	12DEC94	5, -53,-198	5 Days	20	CON	MIL	NO	UNR	Yes	No
			02FEB95	57, -1,-146	34 Days	20	CON	MOD	NO	UNR	Yes	No
		329.005.00116	22APR95	75, 17, -80	16 Days	20	5	MOD	NO	UNR	Yes	No
		329.005.00258	08MAR96	-4, ., -60	8 Days	0	1	MOD	NO	UNR	Yes	No
		329.005.00336	04APR97	32, ., -26	6 Days	20	CON	MOD	NO	UNR	Yes	No
			10APR97	38, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
		329.011.00288	26JUL96	2, ., -41	Not Stated	20	CON	MIL	NO	UNR	Yes	No
	COUGHING	329.004.00017	23MAY95	63, 7,-175	15 Days	30	CON	MOD	NO	UNR	Yes	No
Dyspnea	SHORTNESS OF BREATH	329.005.00333	11FEB97	20, ., -13	3 Days	20	5	MIL	NO	PBU	No	No
		329.008.00160	20NOV95	20, -47,-261	8 Days	20	CON	MIL	NO	UNR	Yes	No
Epistaxis	NOSEBLEED	329.005.00299	12NOV96	158, 98, -6	10 Mins	20	1	MIL	NO	PSR	No	No
Larynx Disorder	LARYNGITIS	329.010.00278	01MAR96	22, -35,-218	4 Days	20	1	MIL	NO	UNR	No	No

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Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Pharyngitis	SORE THROAT	329.001.00063	05DEC94	28, ., -20	9 Days	20	CON	MOD	NO	UNR	Yes	No
		329.001.00068	27MAR95	48, ., -24	2 Days	40	CON	MOD	NO	UNR	Yes	No
		329.003.00091	21SEP95	182, 128, -63	11 Days	40	1	MOD	NO	UNR	Yes	No
		329.004.00015	02FEB95	57, -1,-146	34 Days	20	CON	MOD	NO	UNR	Yes	No
		329.004.00017	09NOV95	233, 177, -5	5 Days	20	CON	MOD	NO	UNR	No	No
		329.005.00004	29DEC94	81, 22, -22	2 Days	40	CON	MOD	NO	UNR	Yes	No
		329.005.00336	04APR97	32, ., -26	6 Days	20	CON	MOD	NO	UNR	Yes	No
		329.007.00310	19DEC96	85, 25,-186	11 Days	20	CON	MOD	NO	UNR	Yes	No
	SORE THROAT SWALLOWING	329.008.00271	06APR96	27, -38,-228	11 Days	20	CON	MIL	NO	PBU	No	No
	THROAT PAIN	329.002.00319	09JUL96	71, 15,-174	16:00 Hrs	30	1	MIL	NO	UNR	No	No
	TONSILLITIS	329.005.00116	24JUN95	138, 80, -17	14 Days	30	CON	SEV	NO	UNR	Yes	No
Respiratory Disorder	COLD SYMPTOMS	329.005.00119	27SEP95	79, 20, -62	4 Days	40	CON	MOD	NO	PBU	Yes	No
	COLD SYMPTOMS (SORE THROAT, COUGH)	329.012.00226	30NOV96	-3, ., -20	24 Days	0	CON	MIL	NO	UNR	No	No
	COLD SYNDROME (URI) {UPPER RESPIRATORY INFECTION}	329.009.00193	10DEC95	13, ., -58	18 Days	20	CON	MOD	NO	UNR	Yes	No
	COLD {SYMPTOMS}	329.003.00091	28APR95	36, -19,-209	5 Days	40	1	MIL	NO	UNR	Yes	No
			20OCT95	211, 157, -34	11 Days	40	CON	MIL	NO	UNR	Yes	No

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Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory Disorder	COLD {SYMPTOMS}	329.004.00214	17OCT96	14, -47, -74	4 Days	20	CON	MIL	NO	UNR	No	No
		329.005.00299	10SEP96	95, 35, -69	Not Stated	20	CON	MOD	NO	UNR	Yes	No
		329.006.00260	08OCT96	83, 25, -71	08:00 Hrs	30	1	MIL	NO	PBU	Yes	No
		329.009.00324	09DEC96	43, ., -30	8 Days	20	CON	MIL	NO	UNR	No	No
	FEVER, COLD SYMPTOMS, SORE THROAT	329.007.00145	21AUG96	224, 168, -2	3 Days	20	CON	MIL	NO	UNR	Yes	No
	HEAD COLD	329.002.00099	16MAR95	15, -41,-240	6 Days	20	CON	MIL	NO	UNR	Yes	No
	RHINITIS-COLD	329.004.00017	14SEP95	177, 121, -61	3 Days	30	CON	MIL	NO	UNR	Yes	No
	SORE THROAT (COLD SYMPTOM)	329.005.00257	18MAR96	8, -49,-231	9 Days	20	CON	MOD	NO	PBU	Yes	No
	STUFFY NOSE (COLD SYMPTOMS)	329.005.00257	18MAR96	8, -49,-231	9 Days	20	CON	MOD	NO	PBU	Yes	No
	UPPER RESPIRATORY ILLNESS	329.007.00309	30AUG96	47, -6,-208	9 Days	20	CON	MOD	NO	UNR	Yes	No
	UPPER RESPIRATORY INFECTION	329.005.00151	22OCT95	47, -11,-192	17 Days	20	CON	MOD	NO	UNR	Yes	No
		329.007.00294	02APR97	34, ., -8	6 Days	20	CON	MIL	NO	UNR	Yes	No
	URI (UPPER RESPIRATORY INFECTION)	329.007.00309	26JUL96	12, -41,-243	21 Days	20	CON	MIL	NO	UNR	No	No

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Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory Disorder	VIRAL UPPER RESPIRATORY INFECTION	329.001.00068	27FEB95	20, ., -52	7 Days	20	CON	MOD	NO	UNR	Yes	No
Rhinitis	"STUFFY" NOSE	329.005.00333	23JAN97	1, ., -32	Not Stated	20	CON	MOD	NO	UNR	No	No
	CONGESTION (NASAL)	329.010.00280	15MAY96	-2, -57, -75	2 Days	0	1	MIL	NO	UNR	Yes	No
	CONGESTION {NOSE}	329.007.00309	04DEC96	143, 91,-112	5 Days	20	CON	MOD	NO	UNR	Yes	No
	NASAL CONGESTION	329.004.00015	11DEC94	4, -54,-199	10 Days	20	CON	MIL	NO	UNR	Yes	No
			02FEB95	57, -1,-146	34 Days	20	CON	MOD	NO	UNR	Yes	No
		329.007.00142	30NOV95	44, ., -4	1 Days	40	1	MIL	NO	UNR	Yes	No
		329.007.00145	01FEB96	22, -35,-204	2 Days	20	1	MIL	NO	UNR	Yes	No
		329.007.00310	19DEC96	85, 25,-186	12 Days	20	CON	MOD	NO	UNR	Yes	No
		329.009.00201	07APR96	62, ., 3	3 Days	20	CON	MOD	NO	UNR	Yes	No
	RHINITIS	329.004.00017	09NOV95	233, 177, -5	5 Days	20	CON	MOD	NO	UNR	No	No
	STUFFY NOSE	329.002.00099	29MAR95	28, -28,-227	16:00 Hrs	20	CON	MIL	NO	UNR	Yes	No
		329.005.00336	10APR97	38, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
Sinusitis	COLD-SINUS SYMPTOMS	329.006.00038	22FEB95	8, ., -49	10 Days	20	CON	MIL	NO	UNR	No	No
	SINUS CONGESTION	329.007.00310	05OCT96	10, -51,-261	25 Days	20	CON	MOD	NO	PBU	Yes	No
		329.009.00240	11FEB97	29, ., -22	14 Days	20	CON	MIL	NO	UNR	No	No
	SINUS INFECTION	329.005.00257	24MAR96	14, -43,-225	7 Days	20		MOD	NO	PBU	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Sinusitis	SINUS INFECTION	329.005.00257	14APR96	35, -22,-204	37 Days	20	CON	MOD	NO	PBU	Yes	No
		329.009.00130	04SEP95	140, 84, -42	10 Days	20	CON	MOD	NO	PBU	Yes	No
		329.009.00196	29JAN96	43, ., -27	Not Stated	30	CON	MOD	NO	PBU	Yes	No
	SINUSITIS	329.009.00130	25APR95	8, -49,-174	10 Days	20	CON	MOD	NO	PBU	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Skin and Appendages

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Acne	ACNE	329.010.00280	16JUN96	31, -25, -43	Not Stated	20	CON	MIL	NO	PSR	No	No
	ACNE WORSE	329.001.00121	12APR95	9, -48,-145	21 Days	20	CON	MIL	NO	PBU	No	No
	ACNE-FACIAL	329.009.00131	30MAY95	29, -28, -89	Not Stated	20	CON	MOD	NO	PSR	Yes	No
Contact Dermatitis	POISON IVY	329.005.00116	17JUN95	131, 73, -24	26 Days	30	CON	SEV	STP	UNR	Yes	No
Fungal Dermatitis	RINGWORM	329.007.00140	13OCT95	29, -27, -40	21 Days	20	CON	MIL	NO	UNR	No	No
Photosensitivity	SUNBURN	329.007.00310	01MAY97	218, 158, -53	8 Days	20	CON	MOD	NO	UNR	Yes	No
	SUNBURN,APPROPRIATE TO DEGREE OF EXPOSURE(BEACH)	329.002.00055	13JUL94	20, -36,-136	3 Days	20	1	MIL	NO	UNR	No	No
Rash	BILATERAL ERYTHEMATOUS EYELIDS	329.009.00240	11FEB97	29, ., -22	8 Days	20	CON	MIL	NO	UNR	No	No
	BLOTCHES (RED) ON LEGS	329.005.00333	10FEB97	19, ., -14	3 Days	20	CON	MOD	NO	PSR	No	No
	RASH	329.009.00324	27DEC96	61, ., -12	20 Days	20	CON	MOD	STP	REL	No	No
	RASH ON ARMS (RED, DRY, ITCHY)	329.004.00214	01DEC96	59, -2, -29	10:00 Hrs	20	CON	MIL	NO	PBU	No	No
Skin Disorder	COLD, CLAMMY LIGHTHEADEDNESS [COLD, CLAMMY]	329.008.00271	05APR96	26, -39,-229	15 Mins	20	1	MIL	DCR	PSR	No	No
Sweating	SWEATING INCREASED	329.009.00133	07JUL95	25, ., -20	Not Stated	20	CON	MOD	NO	PSR	No	No

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Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Skin and Appendages

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urticaria	HIVES - BOTH ARMS BOTH LEGS AND STOMACH AREA (QUESTIONABLE)	329.005.00002	13JUN94	20, -37,-127	2 Days	20	CON	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Special Senses

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abnormal Vision	BLURRED VISION	329.005.00299	24OCT96	139, 79, -25	6 Days	30	CON	MIL	NO	PBU	No	No
			05NOV96	151, 91, -13	8 Days	20	CON	MOD	NO	PSR	No	No
		329.012.00220	25JUN96	9, -52,-150	2 Days	20	CON	MIL	NO	REL	No	No
Conjunctivitis	CONJUNCTIVITIS BILATERAL	329.004.00015	08DEC94	1, -57,-202	11 Days	20	CON	MOD	NO	UNR	Yes	No
			03JAN95	27, -31,-176	12 Days	20	CON	MOD	NO	UNR	Yes	No
	DRY ITCHY EYES	329.008.00271	07APR96	28, -37,-227	2 Days	20	CON	MIL	NO	PSR	No	No
	ITCHY EYES	329.012.00231	23APR97	48, -14,-117	4 Days	20	CON	MIL	NO	PBU	No	No
Ear Pain	EARACHE	329.007.00309	06JAN97	176, 124, -79	8 Days	20	CON	MIL	NO	UNR	Yes	No
	RIGHT EARACHE	329.001.00063	05DEC94	28, ., -20	9 Days	20	CON	MOD	NO	UNR	Yes	No
Otitis Externa	SWIMMER'S EAR	329.005.00257	31JUL96	143, 87, -96	3 Days	30	CON	MOD	NO	PBU	Yes	No
Otitis Media	EAR INFECTION	329.007.00268	10APR96	10, -50,-252	5 Days	20	CON	MOD	NO	UNR	Yes	No
	EAR INFECTION/ACHE	329.005.00116	04MAR95	26, -33,-129	25 Days	20	CON	SEV	NO	UNR	Yes	No
	LEFT EAR INFECTION	329.007.00268	21JUN96	82, 23,-180	9 Days	30	CON	MOD	NO	UNR	Yes	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Urogenital System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Albuminuria	PROTEIN IN URINE	329.005.00151	31JAN96	148, 91, -91	92 Days	30	CON	MOD	NO	PBU	No	No
Amenorrhea	AMENORRHEA	329.003.00075	01FEB95	8, -49,-232	161 Days	20	CON	MOD	NO	PSR	No	No
Breast Enlargement	INCREASE IN BREAST SIZE {FEMALE}	329.008.00160	27NOV95	27, -40,-254	Not Stated	20	CON	MIL	NO	PSR	No	No
Cystitis	BLADDER INFECTION	329.012.00222	18JUL96	21, -43, -65	4 Days	20	CON	MIL	NO	UNR	Yes	No
Dysmenorrhea	DYSMENORRHEA	329.009.00170	07JUL96	244, 187, -1	Not Stated	20	CON	MIL	NO	UNR	Yes	No
	MENSTRUAL CRAMPS	329.004.00015	17APR95	131, 74, -72	30 Mins	20	1	MOD	NO	UNR	Yes	No
		329.005.00116	28MAY95	111, 53, -44	3 Days	20	CON	SEV	NO	UNR	Yes	No
		329.007.00309	16AUG96	33, -20,-222	4 Days	20	CON	MOD	NO	UNR	Yes	No
	PREMENSTRUAL CRAMPS	329.004.00015	29JAN95	53, -5,-150	02:00 Hrs	20	1	MOD	NO	UNR	Yes	No
Female Genital Disorders	ANORGASMIA {FEMALE}	329.003.00075	25JAN95	1, -56,-239	57 Days	20	CON	SEV	DCR	REL	No	No
			23MAR95	58, 2,-182	56 Days	20	CON	MIL	NO	REL	No	No
Haematuria	RBC IN URINE (PT MENSTRUATING WHEN SAMPLE TAKEN)	329.005.00257	21OCT96	225, 169, -14	Not Stated	30	CON	MOD	NO	UNR	No	No
Urinary Casts	COURSE GRANULAR CASTS HYALINE CAST IN URINE	329.005.00151	31JAN96	148, 91, -91	92 Days	30	CON	MOD	NO	PBU	No	No
Urinary Tract Infection	YEAST INFECTION (SQUAMOUS EPITHELIAL CELLS IN URINE)	329.005.00257	15OCT96	219, 163, -20	Not Stated	30	CON	MOD	NO	PBU	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PAROXETINE Body System=Urogenital System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urinary Tract Infection	[URINARY INFECTION QUESTIONABLE]	329.012.00025	19DEC95	57, ., -16	9 Days	40	CON	MIL	NO	UNR	No	No
Urine Abnormality	ABNORMAL URINALYSIS	329.010.00280	21AUG96	97, 42, 23	Not Stated	0	CON	MIL	NO	UNR	No	No
	ABNORMAL URINE ROUTINE & MICROSCOPIC(URINALYSIS	329.005.00258	07MAY96	57, ., 0	Not Stated	30	CON	MOD	NO	PBU	No	No
	CLOUDY URINE ON URINALYSIS	329.001.00068	05APR95	57, ., -15	Not Stated	40	CON	MIL	NO	UNR	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abdominal Pain	STOMACH ACHE	329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
		329.002.00322	21JAN97	13, ., -33	02:00 Hrs	100	1	MOD	NO	PBU	No	No
		329.003.00092	22DEC95	234, 176, -27	02:00 Hrs	200	1	MIL	NO	PBU	No	No
		329.005.00255	05MAR96	2, ., -69	04:00 Hrs	50	1	MOD	NO	PBU	No	No
		329.009.00194	19DEC95	15, -42,-169	181 Days	150	CON	MOD	NO	REL	Yes	No
		329.010.00281	18DEC96	146, 85, -32	2 Days	300	CON	MIL	NO	PBU	No	No
		329.011.00208	16SEP96	11, -49, -68	03:00 Hrs	100	1	MIL	NO	UNR	No	No
			20SEP96	15, -45, -64	3 Days	150	6	MIL	NO	PBU	No	No
	STOMACH ACHE FOLLOWING INGESTION OF MEDS	329.002.00103	21APR95	2, -55,-126	21 Days	50	14	MIL	NO	PSR	No	No
	STOMACH ACHE FOLLOWING INGESTION OF STUDY MEDS	329.002.00103	20JUN95	62, 6, -66	52 Days	250	2	MIL	NO	PSR	No	No
	STOMACH ACHE, RE-OCCURRING	329.002.00322	06FEB97	29, ., -17	Not Stated	200		MIL	NO	PSR	No	No
	STOMACH ACHES	329.002.00243	21MAR96	8, ., -15	Not Stated	100	CON	MIL	NO	REL	No	No
	STOMACH CRAMPS	329.003.00092	21MAY95	19, -40,-242	30 Mins	150	2	MIL	NO	PBU	No	No
			10JUN95	39, -20,-222	1 Days	200	1	MOD	NO	PBU	Yes	No
	STOMACH PAIN	329.010.00279	02OCT96	195, 139, -51	6 Days	300	5	MOD	DCR	PBU	No	No
	STOMACH PAINS	329.010.00279	30SEP96	193, 137, -53	02:00 Hrs	300	CON	MIL	NO	PSR	Yes	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abnormal Laboratory Value	TOXIC IMIPRAMINE LEVEL	329.011.00208	07NOV96	63, 4, -16	Not Stated	300		MIL	STP	REL	No	No
Accidental Overdose	TRICYCLIC TOXICITY	329.008.00273	09SEP96	116, 53, 0	8 Days	300		SEV	STP	REL	No	Yes
Allergic Reaction	ALLERGY	329.003.00317	14JAN97	27, ., -43	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
Asthenia	FATIGUE	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	SEV	STP	REL	No	No
		329.008.00272	04APR96	2, -55,-167	Not Stated	50	CON	MIL	NO	PSR	No	No
		329.009.00134	10JUL95	5, ., -61	65 Days	50	CON	MIL	NO	PSR	No	No
		329.009.00137	14NOV95	36, ., -32	22 Days	200	CON	MOD	NO	PSR	No	No
		329.010.00281	05DEC96	133, 72, -45	20 Days	300	CON	MOD	NO	PSR	No	No
			24DEC96	152, 91, -26	30 Days	300	CON	SEV	STP	PSR	No	No
	FEELS MORE TIRED AFTER TAKING MEDS	329.002.00244	22MAR96	2, -56, -82	14 Days	50	CON	MIL	NO	PSR	No	No
	TIRED	329.003.00247	30APR96	90, 36, -21	1 Days	200	1	MIL	NO	UNR	No	No
	TIREDNESS AND DROWSINESS	329.002.00243	14MAR96	1, ., -22	Not Stated	50	CON	MOD	NO	PSR	No	No
	WEAKNESS	329.004.00215	30APR97	42, ., 2	Not Stated	200	CON	MOD	STP	REL	No	No
Back Pain	BACK PAIN	329.005.00153	23JAN96	-2, -58,-237	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	BACKACHE	329.003.00317	07JAN97	20, ., -50	27 Days	150	3	MIL	NO	PSR	No	No
		329.005.00256	17MAR96	13, -44,-122	4 Days	100	CON	MOD	NO	UNR	Yes	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Chest Pain	CHEST PAIN	329.005.00295	15APR96	19, ., -50	2 Days	150	2	MOD	NO	PSR	No	No
		329.007.00139	17MAY95	10, ., -8	8 Days	50	4	MOD	STP	PSR	No	No
		329.009.00195	04JAN96	21, ., -15	19 Days	200	2	MOD	NO	PSR	No	No
	CHEST PAIN WHEN TAKING MEDS	329.009.00127	17APR95	8, ., -39	45 Days	100	CON	MIL	NO	PBU	No	No
	CHEST PAIN, CHEST TIGHTNESS	329.007.00270	19JUN96	42, ., -1	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes
			20JUN96	43, ., 0	05:00 Hrs	200	CON	MIL	STP	PSR	No	No
Chills	CHILLS	329.009.00325	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
	CHILLS / GOOSE BUMPS WHILE EXERCISING (1X)	329.002.00103	08MAY95	19, -38,-109	2 Mins	150	CON	MIL	NO	PSR	No	No
	CHILLS-INCREASED AND DECREASED BACK AND ARMS-NO FEVER	329.005.00117	18MAR95	1, ., -69	31 Days	50	11	MOD	NO	PSR	No	No
	FEELING HOT/COLD	329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
Fever	FEVER	329.002.00050	23MAR95	1, ., -34	6 Days	50	CON	MOD	NO	PBU	Yes	No
		329.005.00256	05MAR96	1, -56,-134	2 Days	50	1	MOD	NO	PBU	No	No
Headache	HEAD PAIN	329.009.00195	02JAN96	19, ., -17	21 Days	200	20	MOD	NO	PSR	No	No
	HEADACHE	329.001.00066	23NOV94	2, ., -20	5 Days	50	2	MIL	NO	PSR	No	No
		329.002.00050	23MAR95	1, ., -34	5 Days	50	CON	MIL	NO	PBU	Yes	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.003.00082	02JAN96	23, ., -15	04:00 Hrs	100	1	MOD	NO	PSR	No	No
			17JAN96	38, ., 0	Not Stated	250	CON	MIL	NO	PSR	No	No
		329.003.00090	16MAR95	3, ., -66	13 Days	50	CON	SEV	DCR	PSR	Yes	No
		329.003.00249	07MAR96	1, ., -61	3 Days	50	2	MIL	NO	PSR	Yes	No
		329.004.00211	23FEB96	22, ., -27	Not Stated	200	CON	MOD	NO	PBU	Yes	No
		329.004.00215	25MAR97	6, ., -34	2 Days	50	1	MIL	NO	UNR	No	No
			01APR97	13, ., -27	30 Days	100	CON	MIL	NO	PSR	No	No
		329.005.00003	23SEP94	4, ., -11	03:00 Hrs	50	1	MOD	NO	PSR	No	No
		329.005.00007	07MAY95	180, 117, -12	03:30 Hrs	250	CON	MOD	NO	UNR	Yes	No
		329.005.00009	16DEC94	5, ., -68	4 Days	50	3	MOD	NO	PSR	Yes	No
			01JAN95	21, ., -52	04:00 Hrs	150	1	SEV	NO	PSR	Yes	No
		329.005.00113	31JAN95	2, ., -30	03:45 Hrs	50	1	SEV	NO	UNR	Yes	No
		329.005.00117	25APR95	39, ., -31	Not Stated	200	CON	SEV	NO	PBU	No	No
		329.005.00118	09JUN95	24, ., -26	02:00 Hrs	200	2	MOD	NO	PBU	No	No
		329.005.00153	10FEB96	17, -40,-219	05:00 Hrs	150	CON	MIL	NO	PBU	Yes	No
			21FEB96	28, -29,-208	03:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
			02MAR96	38, -19,-198	03:30 Hrs	250	CON	MIL	NO	UNR	Yes	No
			21MAR96	57, 1,-179	28 Days	250	3	MOD	NO	UNR	Yes	No
			17APR96	84, 28,-152	57 Days	300	9	MIL	NO	UNR	Yes	No
			12JUN96	140, 84, -96	55 Days	300	3	MIL	NO	UNR	Yes	No
		329.005.00255	04MAR96	1, ., -70	22 Days	50	16	MOD	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.005.00256	05MAR96	1, -56,-134	3 Days	50	1	MOD	NO	PBU	Yes	No
			17MAR96	13, -44,-122	4 Days	100	CON	MOD	NO	UNR	Yes	No
		329.005.00295	18APR96	22, ., -47	03:30 Hrs	200	CON	MIL	NO	PBU	No	No
			05MAY96	39, ., -30	04:30 Hrs	200	CON	MOD	NO	PSR	No	No
		329.005.00297	10MAY96	22, ., -4	02:00 Hrs	150	2	MOD	NO	PSR	Yes	No
		329.005.00335	27FEB97	-1, ., -68	03:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			10MAR97	11, ., -57	03:30 Hrs	100	CON	MIL	NO	UNR	No	No
			17MAR97	18, ., -50	4 Days	150	6	MOD	NO	UNR	No	No
			21MAR97	22, ., -46	6 Days	200	5	MOD	NO	UNR	No	No
			30MAR97	31, ., -37	4 Days	250	3	MOD	NO	UNR	No	No
			11APR97	43, ., -25	04:00 Hrs	200	CON	SEV	NO	PBU	Yes	No
			22APR97	54, ., -14	03:30 Hrs	200	CON	MOD	NO	PBU	Yes	No
		329.006.00041	23AUG95	141, 77,-104	1 Days	300	1	SEV	NO	PBU	Yes	No
		329.007.00270	24JUN96	47, ., 4	2 Days	200	CON	MOD	NO	UNR	No	No
		329.009.00132	18JUN95	27, -31,-140	3 Days	200	CON	MIL	NO	UNR	No	No
		329.009.00137	17NOV95	39, ., -29	4 Days	200		MIL	NO	PSR	No	No
		329.009.00239	18FEB97	92, 35, -55	Not Stated	200	CON	MIL	NO	PSR	No	No
		329.010.00279	01APR96	11, -46,-235	03:00 Hrs	100	1	MOD	NO	PBU	Yes	No
		329.010.00281	03SEP96	40, -22,-138	16:00 Hrs	250	1	MOD	NO	PSR	Yes	No
			18DEC96	146, 85, -32	2 Days	300	CON	MIL	NO	PBU	Yes	No
		329.011.00163	23NOV95	-2, ., -29	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
			28NOV95	4, ., -24	18:00 Hrs	50	1	MOD	NO	PBU	Yes	No

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Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.011.00284	21APR96	31, -26,-107	01:00 Hrs	200	1	MOD	NO	PBU	Yes	No
			07JUN96	78, 22, -60	01:00 Hrs	250	CON	MIL	NO	PBU	Yes	No
		329.012.00230	31MAR97	32, -38, -56	1 Days	200	CON	MIL	NO	PBU	Yes	No
	HEADACHE - AFTER GYM CLASS OR EXERCISE	329.005.00332	16DEC96	5, ., -67	30 Mins	50	CON	MIL	NO	PSR	No	No
	HEADACHE(OCCASIONAL)	329.009.00134	12AUG95	38, ., -28	Not Stated	200		MIL	NO	PSR	Yes	No
	HEADACHES	329.002.00098	21FEB95	50, ., -23	9 Days	250	CON	MOD	DCR	PSR	No	No
		329.003.00090	11APR95	29, ., -40	15 Days	200	CON	MIL	NO	PSR	Yes	No
			26APR95	44, ., -25	9 Days	250	CON	MOD	DCR	PSR	Yes	No
			05MAY95	53, ., -16	1 Days	200	3	MIL	NO	PSR	Yes	No
		329.003.00289	28FEB96	1, -56,-237	85 Days	50		MIL	NO	PBU	No	No
		329.003.00317	19DEC96	1, ., -69	48 Days	50	7	MIL	NO	PSR	Yes	No
		329.004.00013	20JUL94	2, -58,-246	5 Days	50	CON	SEV	NO	REL	No	No
		329.004.00215	01MAY97	43, ., 3	Not Stated	200	CON	SEV	STP	REL	Yes	No
		329.005.00009	22DEC94	11, ., -62	6 Days	100	3	SEV	NO	PSR	Yes	No
		329.005.00255	24MAR96	21, ., -50	9 Days	150	4	MOD	NO	PBU	No	No
		329.005.00295	21MAR96	-7, ., -75	1 Days	0	1	MOD	NO	UNR	Yes	No
		329.007.00307	04JUL96	50, ., 14	Not Stated	0	20	MOD	NO	UNR	No	No
		329.009.00199	13MAR96	58, ., -13	Not Stated	200	5	MIL	NO	PBU	No	No

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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
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Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHES	329.009.00325	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	PBU	Yes	No
	HEADACHES (SEVERE)	329.012.00221	10SEP96	78, 15, -54	06:00 Hrs	200	1	SEV	NO	PBU	Yes	No
	MODERATE HEADACHE	329.012.00227	05JAN97	19, -51,-241	52 Days	100	5	MOD	NO	PSR	No	No
	OCCASIONAL HEADACHE	329.009.00127	12APR95	3, ., -44	Not Stated	50		MIL	NO	PSR	No	No
	SEVERE HEADACHES	329.012.00227	24DEC96	7, -63,-253	07:00 Hrs	50	2	SEV	NO	PSR	No	No
	SOMATIC COMPLAINT HEADACHE	329.005.00255	29APR96	57, ., -14	Not Stated	200		MOD	NO	PSR	No	No
Infection	FLU	329.003.00314	15NOV96	25, ., -52	3 Days	200	1	MIL	NO	UNR	Yes	No
		329.010.00279	01MAY96	41, -16,-205	3 Days	300	CON	MIL	NO	PBU	No	No
	GI VIRUS-NAUSEA,VOMITING AND DIARRHEA	329.005.00007	10DEC94	32, -32,-160	4 Days	200	CON	SEV	NO	UNR	No	No
	INCREASED SWEATING(VIRAL SYNDROME)	329.009.00301	09APR96	22, -35, -75	20 Mins	150	CON	MIL	NO	PBU	No	No
	NAUSEA(VIRAL SYNDROME)	329.009.00301	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No	No
	NAUSEA,VOMITING,DIARRHEA ,FLU	329.005.00007	30DEC94	52, -12,-140	2 Days	250	CON	SEV	NO	UNR	No	No
	STREP THROAT	329.002.00104	21DEC95	232, 176, -27	11 Days	300	1	MOD	NO	UNR	Yes	No
	STREP THROAT/FEVER/SORE THROAT	329.005.00006	26NOV94	23, -38,-152	5 Days	150	CON	SEV	NO	UNR	Yes	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Infection	VOMITING(VIRAL SYNDOME)	329.009.00301	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No	No
Trauma	DIZZINESS - (HIT HEAD DURING FALL)	329.002.00243	17MAR96	4, ., -19	Not Stated	50	CON	MOD	STP	PSR	No	No
	FOOT PAIN{INJURY}	329.007.00269	21APR96	11, ., -4	2 Days	100	CON	MIL	NO	UNR	Yes	No
	MOUTH CUTS	329.004.00211	20MAR96	48, ., -1	Not Stated	200	CON	SEV	STP	REL	Yes	No

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Arrhythmia	ORTHOSTATIC CHANGES [IRREGULAR PULSE]	329.002.00322	13FEB97	36, ., -10	Not Stated	200	CON	MOD	STP	PSR	No	No
Av Block	1ST DEGREE AV BLOCK	329.009.00203	26MAR96	23, ., -10	Not Stated	150	CON	MOD	STP	REL	No	No
	INCREASED PR INTERVAL (PER EKG)	329.009.00262	07MAR97	19, ., -50	11 Days	200	CON	MIL	NO	PSR	No	No
Bradycardia	SINUS BRADYCARDIA PER EKG	329.009.00239	12MAY97	175, 118, 28	Not Stated	0	CON	MIL	NO	PBU	No	No
Bundle Branch Block	PROLONGED QRS DURATION	329.010.00281	18SEP96	55, -7,-123	15 Days	300	CON	MIL	NO	REL	No	No
Electrocardiogram Abnormal	EKG CHANGE	329.005.00335	03APR97	35, ., -33	1 Days	200	CON	MOD	DCR	REL	No	No
	LOW OR NEGATIVE T WAVES	329.007.00269	18APR96	8, ., -7	15 Days	100	CON	MIL	STP	REL	No	No
	NONSPECIFIC T-WAVE ABNORMALITY (PER EKG) BASELINE ARTIFACT	329.009.00264	23DEC96	53, ., -12	Not Stated	200	CON	MIL	NO	PSR	No	No
	POSITIVE/NEGATIVE RIGHT AXIS DEVIATION (EKG)	329.009.00305	10JAN97	249, 192, -12	19 Days	200	CON	MIL	NO	PBU	No	No
Extrasystoles	CARIDAC ARRHYTHMIA [PREMATURE VENTRICULAR CONTRACTIONS]	329.009.00195	08JAN96	25, ., -11	15 Days	150	CON	MOD	STP	REL	No	No
	PVC'S ON EKG [PREMATURE VENTRICULAR CONTRACTIONS]	329.001.00122	27JUN95	8, -50,-174	9 Days	100	CON	MIL	NO	PBU	No	No

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Treatment Group=IMIPRAMINE Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Heart Malformation	POSSIBLE RIGHT ATRIAL ENLARGEMENT (PER EKG)	329.009.00262	17MAR97	29, ., -40	15 Days	200	CON	MIL	NO	PSR	No	No
Hypertension	HIGH BLOOD PRESSURE	329.003.00290	20MAR96	10, ., -2	15 Days	100	CON	MIL	STP	PSR	No	No
	HYPERTENSION	329.012.00223	30SEP96	32, ., -12	Not Stated	200	CON	MOD	NO	UNR	No	Yes
		329.012.00227	25APR97	129, 60,-131	117 Days	300		MOD	NO	PBU	No	No
Migraine	MIGRAINE HEADACHE	329.005.00118	20MAY95	4, ., -46	04:00 Hrs	50	CON	SEV	NO	UNR	No	No
Palpitation	HEART WAS POUNDING	329.005.00113	19FEB95	21, ., -11	30 Mins	150	1	MOD	NO	REL	No	No
	PALPITATIONS	329.005.00153	02FEB96	9, -48,-227	9 Days	100		MIL	NO	PSR	No	No
		329.009.00203	24MAR96	21, ., -12	Not Stated	150	CON	MOD	NO	PSR	No	No
Postural Hypotension	POSTURAL HYPOTENSION	329.009.00134	11AUG95	37, ., -29	33 Days	200	3	MOD	NO	PSR	No	No
	DIZZINESS WHEN STANDING UP ORTHOSTATIC HYPOTENSION	329.003.00247	09FEB96	9, -46,-102	33 Days	100	CON	MIL	NO	PSR	No	No
	DIZZINESS WITH ORTHOSTATIC HYPOTENSION	329.002.00050	30MAR95	8, ., -27	6 Days	100	CON	MIL	STP	PSR	No	No
	DIZZINESS-POSTURAL HYPOTENSION(ONLY IN GYM CLASSES)	329.005.00007	01DEC94	23, -41,-169	14 Days	150	1	MOD	NO	REL	No	No

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Postural Hypotension	MILD OTHOSTATIC STATE (1X) (DUE TO BLOOD DRAW) {ORTHOSTATIC HYPOTENSION}	329.009.00262	14APR97	57, ., -12	5 Mins	200	CON	MIL	NO	PSR	No	No
	ORTHOSTATIC HYPOTENSION	329.002.00243	28MAR96	15, ., -8	Not Stated	150	CON	MIL	NO	PSR	No	No
		329.003.00088	12MAR95	13, ., -28	1 Days	100	1	MIL	NO	PSR	No	No
		329.004.00211	12FEB96	11, ., -38	7 Days	100	CON	MIL	NO	PSR	No	No
			19FEB96	18, ., -31	15 Days	150	CON	MOD	NO	REL	No	No
			05MAR96	33, ., -16	Not Stated	200	CON	MIL	NO	REL	No	No
		329.004.00215	01APR97	13, ., -27	21 Days	100	CON	MOD	NO	REL	No	No
			22APR97	34, ., -6	11 Days	200	CON	MIL	NO	REL	No	No
		329.007.00270	01JUN96	24, ., -19	4 Days	200	5	MIL	NO	PSR	No	No
		329.012.00230	18APR97	50, -20, -38	19 Days	200		MIL	NO	PBU	No	No
	ORTHOSTATIC SYMPTOMS {ORTHOSTATIC HYPOTENSION}	329.003.00073	03FEB95	16, ., -29	Not Stated	150	CON	MOD	NO	PSR	No	No
	POSTURAL HYPOTENSION	329.001.00067	30NOV94	9, ., -13	Not Stated	100	CON	MOD	STP	PSR	No	No
Qt Interval Prolonged	INCREASED QT/{CORRECTED}QTC RATIO	329.009.00134	29AUG95	55, ., -11	15 Days	150	CON	MOD	STP	REL	No	No
	PROLONGED QT-QUANTITATIVE TIP CULTURES	329.009.00203	26MAR96	23, ., -10	Not Stated	150	CON	MOD	STP	REL	No	No

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Treatment Group=IMIPRAMINE Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Qt Interval Prolonged	WIDENED CORRECTED QT {INTERVAL} QRS	329.001.00061	01SEP94	35, ., -13	Not Stated	200	CON	MIL	STP	REL	No	No
Syncope	BLACKOUTS	329.009.00134	11AUG95	37, ., -29	33 Days	200	3	MOD	NO	PSR	No	No
	DIZZINESS WITH SYNCOPE	329.009.00325	01SEP96	6, -50,-118	1 Days	50	CON	MIL	NO	PSR	No	No
	FAINTNESS UPON STANDING	329.001.00070	10MAR95	17, ., -14	Not Stated	150	3	MIL	NO	PSR	No	No
	LIGHTHEADED FAINT SYNCOPE	329.006.00041	22APR95	18, -47,-227	1 Mins	150	1	MIL	NO	PSR	No	No
	SYNCOPE	329.012.00227	23MAR97	96, 27,-164	161 Days	300		MIL	NO	PBU	No	No
Tachycardia	"RACING HEART"	329.005.00003	23SEP94	4, ., -11	12 Days	50	4	MOD	NO	PBU	No	No
	ELEVATED HEART RATE	329.006.00040	01MAR95	14, ., 0	14 Days	50	CON	MOD	STP	REL	No	No
	ELEVATED PULSE	329.009.00239	25NOV96	7, -51,-140	141 Days	100	CON	MIL	NO	REL	No	No
	HEART RACING (BEATS HARD)	329.001.00122	12SEP95	85, 28, -97	30 Days	200	2	MIL	NO	REL	No	No
	HEART RATE INCREASE	329.002.00050	23MAR95	1, ., -34	22 Days	50	CON	MOD	STP	PSR	No	No
	INCREASE IN PULSE(SECONDARY TO ALUPENT)	329.009.00301	23APR96	36, -21, -61	15 Mins	200	CON	MOD	NO	PBU	No	No
	INCREASED HEART RATE	329.001.00066	05DEC94	14, ., -8	Not Stated	100	CON	MOD	STP	REL	No	No
		329.002.00056	02AUG94	15, ., -21	22 Days	150	CON	MIL	STP	PSR	No	No

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Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Tachycardia	INCREASED HEART RATE	329.005.00117	10APR95	24, ., -46	22 Days	200	CON	MOD	NO	PSR	No	No
		329.009.00264	11NOV96	11, ., -54	Not Stated	150	CON	MIL	NO	PSR	No	No
	INCREASED PULSE ON EXERTION	329.005.00153	26FEB96	33, -24,-203	4 Days	250	4	MIL	NO	PSR	No	No
	PULSE {INCREASED} 2 CONSECUTIVE WEEKS	329.001.00070	08MAR95	15, ., -16	Not Stated	150	CON	SEV	STP	REL	No	No
	QUESTIONABLE INCREASED HEART RATE QUESTIONABLE TACHYCARDIA	329.005.00113	19FEB95	21, ., -11	30 Mins	150	1	MOD	NO	REL	No	No
	RACING HEARTBEAT	329.005.00003	30SEP94	11, ., -4	5 Days	100	2	MOD	STP	REL	No	No
	SINUS TACHYCARDIA	329.009.00264	23DEC96	53, ., -12	Not Stated	200	CON	MIL	NO	PSR	No	No
	TACHYCARDIA	329.003.00290	20MAR96	10, ., -2	Not Stated	100	CON	MIL	STP	PSR	No	No
		329.007.00269	18APR96	8, ., -7	15 Days	100	CON	MIL	STP	REL	No	No
		329.009.00134	11AUG95	37, ., -29	33 Days	200		MOD	NO	PSR	No	No
		329.009.00172	14NOV95	2, -56,-249	14 Days	50	2	MIL	NO	PBU	No	No
		329.009.00325	23OCT96	58, 3, -66	27 Days	200		MOD	NO	PSR	No	No
		329.009.00326	30SEP96	26, -28, -89	Not Stated	200	CON	MIL	NO	PSR	No	No
	TACHYCARDIA INCREASED PULSE	329.005.00153	03FEB96	10, -47,-226	8 Days	100		MIL	NO	PSR	No	No

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Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Vasodilatation	FACIAL FLUSHING	329.009.00195	25DEC95	11, ., -25	29 Days	100	CON	MOD	NO	PSR	No	No
	FLUSHED FACE	329.005.00255	11MAR96	8, ., -63	04:00 Hrs	100	1	MOD	NO	PSR	No	No
	FLUSHED FACE-NO HIVES	329.005.00117	18MAR95	1, ., -69	4 Days	50	3	MIL	NO	PSR	No	No
	HOT FLASHES	329.001.00070	01MAR95	8, ., -23	Not Stated	100	2	MIL	NO	PBU	No	No
		329.005.00256	23MAR96	19, -38,-116	3 Days	150	2	MOD	NO	PSR	No	No
	HOT FLASHES(FACIAL FLUSHING)	329.009.00203	24MAR96	21, ., -12	Not Stated	150	CON	MOD	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Constipation	CONSTIPATED	329.004.00014	02DEC94	4, ., -11	Not Stated	50	CON	MOD	NO	REL	No	No
	CONSTIPATION	329.001.00122	05JUL95	16, -42,-166	4 Days	150	CON	MIL	NO	PSR	No	No
			14JUL95	25, -33,-157	19 Days	200	CON	MIL	NO	PSR	No	No
		329.002.00098	02MAR95	59, ., -14	Not Stated	250	CON	MIL	DCR	PSR	No	No
		329.002.00243	04APR96	22, ., -1	Not Stated	150	CON	SEV	NO	PSR	No	No
		329.003.00088	14MAR95	15, ., -26	Not Stated	100	CON	MIL	NO	PSR	No	No
		329.003.00090	26APR95	44, ., -25	6 Days	250	CON	SEV	DCR	PSR	Yes	No
			02MAY95	50, ., -19	Not Stated	200	CON	MOD	NO	PSR	Yes	No
		329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
		329.011.00208	12OCT96	37, -23, -42	13 Days	300	CON	MIL	NO	PSR	No	No
		329.011.00284	22APR96	32, -25,-106	11 Days	200	CON	MIL	NO	PSR	No	No
		329.012.00221	14OCT96	112, 49, -20	19 Days	200	CON	MOD	NO	UNR	Yes	No
Decreased Appetite	DECREASE APPETITE	329.001.00066	23NOV94	2, ., -20	Not Stated	50	CON	MIL	NO	PSR	No	No
	DECREASED APPETITE	329.005.00153	25JAN96	1, -56,-235	42 Days	50	CON	MOD	NO	PSR	No	No
Diarrhea	DIARRHEA	329.005.00117	19MAR95	2, ., -68	3 Days	50	1	MOD	NO	PSR	No	No
		329.007.00146	04JUL96	162, 109, -79	02:00 Hrs	200	CON	MOD	NO	UNR	Yes	No
		329.007.00270	19JUN96	42, ., -1	30 Mins	200	CON	MIL	NO	UNR	No	No
			24JUN96	47, ., 4	2 Days	200	CON	MIL	NO	UNR	No	No

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Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Diarrhea	DIARRHEA	329.009.00172	18JUL96	249, 192, -2	2 Days	50	CON	MIL	NO	PBU	No	No
		329.011.00284	08JUN96	79, 23, -59	03:00 Hrs	250	3	MIL	NO	PBU	No	No
	UPSET STOMACH WITH DIARRHEA	329.005.00335	10MAR97	11, ., -57	2 Days	100	CON	SEV	NO	UNR	No	No
Dry Mouth	DRY MOUTH	329.001.00061	11AUG94	14, ., -34	Not Stated	150	CON	MIL	NO	REL	No	No
		329.001.00070	08MAR95	15, ., -16	Not Stated	150	CON	MIL	NO	REL	No	No
		329.002.00098	10JAN95	8, ., -65	Not Stated	100	CON	MOD	DCR	PSR	No	No
		329.002.00100	14APR95	39, -20, -46	10 Mins	250	12	MIL	NO	PSR	No	No
		329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
		329.002.00104	11MAY95	8, -49,-251	76 Days	100	CON	MOD	NO	REL	No	No
		329.003.00076	01FEB95	2, -54,-238	48 Days	50	CON	MIL	NO	PSR	No	No
		329.003.00082	17JAN96	38, ., 0	Not Stated	250	CON	MIL	NO	PSR	No	No
		329.003.00088	21MAR95	22, ., -19	Not Stated	200	CON	MIL	NO	PSR	No	No
		329.003.00090	28MAR95	15, ., -54	15 Days	100	CON	MIL	NO	PSR	No	No
		329.003.00092	04MAY95	2, -57,-259	146 Days	50	CON	MIL	NO	PSR	No	No
		329.003.00093	20JUN95	-1, -64, -80	106 Days	0	CON	MIL	NO	PSR	No	No
		329.003.00247	10FEB96	10, -45,-101	23 Days	100	CON	MIL	NO	PSR	No	No
			07MAR96	36, -19, -75	15 Days	200	CON	MIL	NO	PSR	No	No

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Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dry Mouth	DRY MOUTH	329.003.00289	11MAR96	13, -44,-225	31 Days	100		MIL	NO	PSR	No	No
		329.003.00290	12MAR96	2, ., -10	24:00 Hrs	50	1	MIL	NO	PBU	No	No
		329.003.00314	14NOV96	24, ., -53	Not Stated	200	1	MIL	NO	PSR	No	No
		329.004.00013	30JUL94	12, -48,-236	Not Stated	100	CON	MOD	NO	REL	No	No
		329.004.00211	05FEB96	4, ., -45	14 Days	50	CON	MIL	NO	PSR	No	No
			19FEB96	18, ., -31	15 Days	150	CON	SEV	NO	REL	No	No
			05MAR96	33, ., -16	14 Days	200	CON	MOD	NO	REL	No	No
			19MAR96	47, ., -2	Not Stated	200	CON	SEV	STP	REL	No	No
		329.004.00215	28MAR97	9, ., -31	Not Stated	100	CON	MOD	NO	REL	No	No
		329.005.00006	09NOV94	6, -55,-169	Not Stated	50	CON	MOD	NO	REL	No	No
		329.005.00007	20DEC94	42, -22,-150	151 Days	250	CON	MOD	NO	REL	No	No
		329.005.00009	16DEC94	5, ., -68	Not Stated	50	CON	MOD	NO	REL	No	No
			09JAN95	29, ., -44	Not Stated	200	CON	MOD	NO	REL	No	No
		329.005.00113	05FEB95	7, ., -25	Not Stated	50	CON	MOD	NO	REL	No	No
		329.005.00256	30MAR96	26, -31,-109	33 Days	200	CON	MOD	NO	PSR	No	No
		329.005.00295	07APR96	11, ., -58	55 Days	100	CON	MOD	NO	REL	No	No
		329.005.00332	03JAN97	23, ., -49	4 Days	200	CON	MIL	NO	REL	No	No
		329.005.00335	08MAR97	9, ., -59	Not Stated	100	CON	MOD	NO	REL	No	No
		329.007.00270	23MAY96	15, ., -28	15 Days	150	CON	MIL	NO	PSR	No	No

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Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dry Mouth	DRY MOUTH	329.007.00307	18MAY96	3, ., -33	39 Days	50	CON	MIL	NO	REL	No	No
		329.008.00159	04OCT95	22, -41,-112	29 Days	200	CON	MIL	NO	PSR	No	No
		329.008.00161	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No
		329.008.00187	30NOV95	2, ., -71	Not Stated	50	CON	MIL	NO	PSR	No	No
		329.008.00192	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU	No	No
		329.009.00134	27JUL95	22, ., -44	48 Days	200	CON	MIL	NO	PSR	No	No
		329.009.00172	05DEC95	23, -35,-228	231 Days	200	CON	MOD	NO	PSR	No	No
		329.009.00199	24JAN96	9, ., -62	15 Days	100	CON	MIL	NO	PSR	No	No
		329.009.00239	09DEC96	21, -37,-126	8 Days	200	CON	MIL	NO	PSR	No	No
			06JAN97	49, -9, -98	10 Days	200	CON	MIL	NO	PSR	No	No
		329.009.00262	24FEB97	8, ., -61	64 Days	100	CON	MIL	NO	REL	No	No
		329.009.00305	14MAY96	8, -50,-253	22 Days	100	CON	MOD	NO	PSR	No	No
			03JUL96	58, 1,-203	35 Days	200	CON	MIL	NO	PSR	No	No
			09SEP96	126, 69,-135	142 Days	200	CON	MIL	NO	PSR	No	No
		329.009.00325	23SEP96	28, -28, -96	8 Days	200	CON	MIL	NO	PSR	No	No
		329.012.00221	30AUG96	67, 4, -65	52 Days	200	CON	MOD	NO	PSR	No	No
		329.012.00227	17JAN97	31, -39,-229	Not Stated	200	CON	MIL	NO	PBU	No	No
		329.012.00230	11MAR97	12, -58, -76	77 Days	100	CON	MOD	NO	PSR	No	No

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Treatment Group=IMIPRAMINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dry Mouth	DRY THROAT, MOUTH	329.002.00244	29MAR96	9, -49, -75	61 Days	100	CON	MOD	NO	PSR	No	No
	SEVERE DRY MOUTH	329.012.00227	25APR97	129, 60,-131	128 Days	300	CON	SEV	NO	PSR	No	No
Dyspepsia	GI UPSET	329.005.00256	11JUL96	129, 73, -6	Not Stated	50	CON	MOD	NO	UNR	Yes	No
	HEARTBURN	329.003.00090	02MAY95	50, ., -19	Not Stated	200	CON	MIL	NO	PSR	Yes	No
		329.003.00314	04DEC96	44, ., -33	48:00 Hrs	200	1	MIL	NO	UNR	No	No
		329.005.00009	09JAN95	29, ., -44	03:00 Hrs	200	1	MOD	NO	PBU	No	No
		329.005.00297	24APR96	6, ., -20	04:00 Hrs	50	CON	MOD	NO	UNR	No	No
		329.008.00192	30MAR96	26, ., -12	Not Stated	200	CON	MIL	DCR	PSR	No	No
		329.012.00230	14MAR97	15, -55, -73	74 Days	150		MIL	NO	PBU	Yes	No
	INDIGESTION	329.003.00090	26APR95	44, ., -25	6 Days	250	CON	MOD	DCR	PSR	No	No
			02MAY95	50, ., -19	Not Stated	200	CON	MIL	NO	PSR	Yes	No
		329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	PSR	No	No
	UPSET STOMACH	329.005.00006	26NOV94	23, -38,-152	64 Days	150	CON	MOD	NO	UNR	Yes	No
		329.007.00146	22MAR96	58, 5,-183	04:00 Hrs	200	CON	MOD	NO	PBU	Yes	No
	UPSET STOMACH/INDIGESTION	329.005.00009	17DEC94	6, ., -67	Not Stated	50	6	MIL	NO	PSR	No	No
Dysphagia	DIFFICULTY SWALLOWING 1 HOUR DURATION AFTER AWAKENING	329.001.00061	28AUG94	31, ., -17	Not Stated	200	3	MIL	NO	PSR	No	No

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dysphagia	DIFFICULTY SWALLOWING PILL	329.009.00239	16DEC96	28, -30,-119	8 Days	200	CON	MIL	NO	REL	No	No
	LUMP IN THE THROAT	329.004.00014	29NOV94	1, ., -14	11 Days	50	7	MOD	NO	REL	No	No
Esophagitis	ESOPHAGEAL IRRITATION	329.004.00215	09APR97	21, ., -19	3 Days	150	CON	MIL	NO	PSR	No	No
Gastritis	GASTRITIS	329.005.00117	27APR95	41, ., -29	Not Stated	200	CON	MOD	NO	PBU	Yes	No
Gastroenteritis	BACTERIAL GASTROENTERITIS	329.004.00211	21MAR96	49, ., 0	3 Days	200	CON	SEV	STP	UNR	Yes	No
Gastrointestinal Disorder	NAUSEA,VOMITING HEADACHES,DIARRHEA(GASTROINTESTINAL ILLNESS)	329.003.00073	23FEB95	36, ., -9	Not Stated	250	CON	MOD	NO	UNR	No	No
	STOMACH PROBLEMS	329.003.00092	22OCT95	173, 115, -88	2 Days	0		MOD	DCR	PBU	Yes	No
Increased Appetite	CRAVINGS:CEREALS,PASTAS, CARBOHYDRATES	329.005.00006	24NOV94	21, -40,-154	41 Days	150	CON	MOD	NO	PSR	No	No
	INCREASED APPETITE	329.001.00122	11OCT95	114, 57, -68	Not Stated	200	CON	MOD	NO	REL	No	No
Nausea	INFREQUENTLY NAUSEA	329.008.00187	10DEC95	12, ., -61	Not Stated	100	CON	MIL	NO	PSR	No	No
	NAUSEA	329.001.00066	23NOV94	2, ., -20	13 Days	50	CON	MIL	NO	PSR	No	No
		329.001.00070	23FEB95	2, ., -29	Not Stated	50	CON	MIL	NO	PSR	No	No
		329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
		329.002.00243	21MAR96	8, ., -15	Not Stated	100	CON	MIL	NO	REL	No	No

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Treatment Group=IMIPRAMINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nausea	NAUSEA	329.004.00014	05DEC94	7, ., -8	3 Days	100	1	MOD	NO	PSR	No	No
			07DEC94	9, ., -6	Not Stated	100	18	SEV	NO	PSR	No	No
		329.004.00215	30APR97	42, ., 2	Not Stated	200	CON	SEV	STP	REL	Yes	No
		329.005.00006	26NOV94	23, -38,-152	64 Days	150	CON	MOD	NO	UNR	Yes	No
		329.005.00256	05MAR96	1, -56,-134	3 Days	50	1	MOD	NO	PBU	No	No
		329.005.00295	05MAY96	39, ., -30	02:00 Hrs	200	CON	MIL	NO	PSR	No	No
		329.007.00269	16APR96	6, ., -9	1 Days	50	CON	MIL	NO	PSR	No	No
		329.007.00308	30JUN96	-2, ., -11	01:00 Hrs	0	CON	MIL	NO	PSR	Yes	No
		329.009.00127	24APR95	15, ., -32	38 Days	150		MOD	STP	REL	No	No
		329.009.00132	18JUN95	27, -31,-140	3 Days	200		MIL	NO	UNR	No	No
			24AUG95	94, 37, -73	62 Days	200		MIL	NO	PSR	No	No
		329.009.00172	18JUL96	249, 192, -2	2 Days	50	CON	MIL	NO	PBU	No	No
		329.009.00194	16JAN96	43, -14,-141	153 Days	200	CON	MOD	STP	PSR	No	No
		329.009.00199	17JAN96	2, ., -69	42 Days	50	CON	MOD	NO	PSR	No	No
			28FEB96	44, ., -27	15 Days	250	CON	MIL	NO	PSR	No	No
		329.009.00239	26DEC96	38, -20,-109	5 Days	200	CON	MOD	NO	PBU	No	No
		329.009.00305	14MAY96	8, -50,-253	15 Days	100	CON	MOD	NO	PSR	No	No
			28MAY96	22, -36,-239	23 Days	200	CON	MIL	NO	PSR	No	No
			02JUL96	57, -1,-204	1 Days	200	CON	MOD	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nausea	NAUSEA	329.009.00325	06SEP96	11, -45,-113	11 Days	100	CON	MIL	NO	PSR	No	No
			23SEP96	28, -28, -96	8 Days	200	CON	MIL	NO	PSR	No	No
		329.009.00326	14OCT96	40, -14, -75	4 Days	200	CON	MIL	NO	PSR	No	No
		329.010.00279	01OCT96	194, 138, -52	03:00 Hrs	300	CON	MIL	NO	PSR	No	No
			02OCT96	195, 139, -51	6 Days	300	5	MOD	DCR	PBU	No	No
		329.011.00163	28NOV95	4, ., -24	18:00 Hrs	50	1	MIL	NO	PBU	No	No
			17DEC95	23, ., -5	5 Days	150	CON	MIL	NO	PBU	No	No
			22DEC95	28, ., 0	Not Stated	200	CON	MOD	STP	PSR	No	No
			23DEC95	29, ., 1	Not Stated	200	CON	MOD	STP	PSR	No	No
		329.011.00284	21MAR96	-1, -57,-138	13 Days	0	4	MIL	NO	PSR	No	No
		329.012.00230	18APR97	50, -20, -38	7 Days	200		MOD	NO	UNR	No	No
			07MAY97	69, -1, -19	14:00 Hrs	250	CON	MIL	NO	UNR	Yes	No
	NAUSEA WHEN TAKING PM MEDS	329.009.00203	05MAR96	2, ., -31	Not Stated	50	CON	MIL	NO	PSR	No	No
	RETCHING	329.004.00014	05DEC94	7, ., -8	Not Stated	100	21	MOD	STP	PSR	No	No
	SOMATIC COMPLAINT NAUSEA	329.005.00255	29APR96	57, ., -14	Not Stated	200		MOD	NO	PSR	No	No
Tooth Disorder	MOLAR ERUPTING	329.010.00279	07AUG96	139, 83,-107	02:00 Hrs	300	CON	MOD	NO	UNR	Yes	No
	PAIN DUE TO WISDOM TOOTH EXTRACTION	329.005.00117	08MAY95	52, ., -18	8 Days	200	CON	MOD	NO	UNR	Yes	No
	PAIN RE: 4 IMPACTED WISDOM TEETH EXTRACTED UNDER GENERAL ANESTHETIC	329.012.00230	18APR97	50, -20, -38	1 Days	200	CON	MOD	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Ulcerative Stomatitis	MOUTH SORES	329.004.00211	20MAR96	48, ., -1	Not Stated	200	CON	SEV	STP	REL	Yes	No
		329.010.00279	03OCT96	196, 140, -50	Not Stated	300	CON	MOD	NO	PBU	No	No
Vomiting	EMESIS	329.006.00041	22AUG95	140, 76,-105	1 Days	300	2	MIL	NO	UNR	No	No
	NAUSEA AND VOMITING DURING DOWN TITRATION	329.002.00104	10JAN96	252, 196, -7	6 Days	100	1	MOD	NO	PSR	No	No
	NAUSEA, VOMITING	329.002.00057	06OCT94	29, -29,-100	20 Mins	250	CON	MIL	NO	UNR	No	No
	NAUSEATED AND VOMITING	329.005.00117	07APR95	21, ., -49	Not Stated	150	CON	SEV	NO	PBU	No	No
	VOMITING	329.003.00073	04MAR95	45, ., 0	Not Stated	250	CON	SEV	STP	PSR	Yes	No
		329.004.00215	30APR97	42, ., 2	Not Stated	200	CON	SEV	STP	REL	Yes	No
		329.005.00295	15MAY96	49, ., -20	30 Mins	250	CON	MOD	NO	PBU	No	No
		329.007.00308	30JUN96	-2, ., -11	01:00 Hrs	0	CON	MIL	NO	PSR	No	No
		329.009.00132	19JUN95	28, -30,-139	06:00 Hrs	200		MIL	NO	UNR	No	No
		329.009.00239	26DEC96	38, -20,-109	5 Days	200	CON	MOD	NO	PBU	Yes	No
		329.011.00163	22DEC95	28, ., 0	4 Days	200	4	MOD	STP	PSR	No	No
	VOMITING WHEN FORGOT DOSE	329.002.00104	25JUL95	83, 27,-176	1 Days	300	1	MOD	NO	REL	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Hemic and Lymphatic System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Anemia	ANEMIA	329.003.00289	11OCT96	227, 171, -11	Not Stated	150	CON	MIL	NO	UNR	No	No
Eosinophilia	EOSINOPHILS ELEVATED	329.005.00255	29APR96	57, ., -14	Not Stated	200	CON	MOD	NO	PBU	No	No
Leukocytosis	NEUTROPHILS, SEGS {INCREASED}	329.005.00009	07DEC94	-5, ., -77	1 Days	0	1	MIL	NO	UNR	No	No
Leukopenia	LOW NEUTROPHILS	329.011.00284	16MAY96	56, -1, -82	Not Stated	250	CON	MOD	NO	PBU	No	No
	LOW WHITE CELL COUNT	329.011.00284	16MAY96	56, -1, -82	Not Stated	250	CON	MOD	NO	PBU	No	No
	LYMPHOCYTES {DECREASED}	329.005.00009	07DEC94	-5, ., -77	1 Days	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Metabolic and Nutritional Disorders

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dehydration	DEHYDRATION	329.005.00007	18MAY95	191, 128, -1	8 Days	250	CON	SEV	STP	PBU	Yes	No
Hyperglycemia	GLUCOSE ELEVATED	329.005.00009	08FEB95	59, ., -14	1 Days	250	1	SEV	NO	UNR	No	No
Thirst	INCREASED THIRST	329.002.00244	29MAR96	9, -49, -75	61 Days	100	CON	MOD	NO	PBU	No	No
		329.009.00203	24MAR96	21, ., -12	Not Stated	150	CON	MIL	NO	PSR	No	No
Weight Gain	WEIGHT GAIN	329.001.00122	11OCT95	114, 57, -68	Not Stated	200	CON	MOD	NO	REL	No	No
Weight Loss	WEIGHT LOSS	329.009.00195	27DEC95	13, ., -23	13 Days	150	CON	MIL	NO	PSR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Musculoskeletal System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Arthralgia	JOINT PAINS	329.004.00215	30APR97	42, ., 2	Not Stated	200	CON	MIL	STP	REL	Yes	No
Myalgia	LEFT KNEE MUSCLE SPASMS	329.007.00146	18SEP96	238, 185, -3	06:00 Hrs	50	CON	MIL	NO	UNR	Yes	No
	LEG CRAMPS AND ACHES	329.005.00007	28JAN95	81, 18,-111	Not Stated	250	CON	MOD	NO	PSR	Yes	No
	MUSCLE SPASMS IN RIBS	329.012.00227	09MAY97	143, 74,-117	11:00 Hrs	300	CON	MOD	NO	PBU	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abnormal Dreams	INCREASED DREAMING	329.009.00194	07DEC95	3, -54,-181	34 Days	50		MOD	NO	PSR	No	No
		329.009.00325	30SEP96	35, -21, -89	11 Days	200	CON	MIL	NO	PSR	No	No
	NIGHTMARES	329.004.00215	25APR97	37, ., -3	7 Days	200	CON	MOD	STP	REL	No	Yes
		329.005.00007	02APR95	145, 82, -47	15 Days	250	10	SEV	NO	UNR	No	No
		329.009.00172	18DEC95	36, -22,-215	52 Days	200		MOD	NO	PSR	No	No
		329.009.00194	07DEC95	3, -54,-181	13 Days	50	1	MOD	NO	PSR	No	No
Agitation	AGITATION	329.009.00264	11NOV96	11, ., -54	8 Days	150	CON	MOD	NO	PSR	No	No
	INCREASE AGITATION	329.001.00070	28FEB95	7, ., -24	Not Stated	100	CON	MIL	NO	PBU	No	No
Amnesia	MORE FORGETFUL	329.001.00122	11JUL95	22, -36,-160	15 Days	200	CON	MIL	NO	PSR	No	No
Anxiety	ANXIETY	329.007.00146	14JUL96	172, 119, -69	04:00 Hrs	200	CON	MIL	NO	UNR	Yes	No
Concentration Impaired	DECREASE CONCENTRATION	329.001.00061	30JUL94	2, ., -46	27 Days	50	CON	MOD	NO	REL	No	No
			01SEP94	35, ., -13	Not Stated	200	CON	MIL	NO	PBU	No	No
Convulsion	SEIZURE	329.005.00007	24MAY95	197, 134, 5	5 Mins	250	CON	SEV	STP	UNR	Yes	No
Depersonalization	"SPACEY" 1X	329.002.00244	23MAR96	3, -55, -81	02:00 Hrs	50	7	MIL	NO	PSR	No	No
Depression	MAJOR DEPRESSION	329.012.00223	29SEP96	31, ., -13	Not Stated	200	CON	MOD	NO	UNR	No	Yes
Dizziness	DIZZINESS	329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
		329.002.00104	24MAY95	21, -36,-238	133 Days	150	CON	MIL	NO	REL	No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dizziness	DIZZINESS	329.002.00322	11JAN97	3, ., -43	Not Stated	50	CON	MOD	STP	PBU	No	No
		329.003.00076	06AUG95	188, 133, -52	66 Days	200	CON	MIL	NO	PBU	No	No
		329.003.00088	14MAR95	15, ., -26	764 Days	100	CON	MIL	NO	PBU	No	No
		329.003.00090	28MAR95	15, ., -54	29 Days	100	CON	MIL	NO	PSR	No	No
			09MAY95	57, ., -12	Not Stated	200	CON	MIL	NO	PSR	No	No
		329.003.00093	08AUG95	49, -15, -31	20 Mins	300	1	MIL	NO	PBU	No	No
		329.003.00249	15APR96	40, ., -22	1 Mins	300	1	MIL	NO	PSR	No	No
		329.003.00314	17DEC96	57, ., -20	Not Stated	200	CON	MIL	NO	PSR	No	No
		329.004.00013	20JUL94	2, -58,-246	5 Days	50	CON	MOD	NO	REL	No	No
		329.004.00211	19FEB96	18, ., -31	18 Days	150	CON	MIL	NO	REL	No	No
		329.004.00215	04APR97	16, ., -24	2 Days	150	CON	MIL	NO	REL	No	No
			25APR97	37, ., -3	Not Stated	200	CON	MOD	STP	REL	No	Yes
		329.005.00003	27SEP94	8, ., -7	10 Days	100	CON	MOD	NO	PSR	No	No
		329.005.00110	15JAN95	5, ., -4	5 Mins	50	CON	MIL	NO	PSR	No	No
		329.005.00113	06FEB95	8, ., -24	Not Stated	50	9	MIL	NO	REL	No	No
		329.005.00295	04MAY96	38, ., -31	2 Days	200	4	MIL	NO	PSR	No	No
		329.005.00335	01MAR97	2, ., -66	4 Days	50	CON	MIL	NO	REL	No	No
			05MAR97	6, ., -62	01:00 Hrs	50	CON	SEV	NO	REL	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dizziness	DIZZINESS	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
		329.008.00159	24OCT95	42, -21, -92	9 Days	250		MIL	NO	REL	No	No
		329.009.00127	24APR95	15, ., -32	38 Days	150		MOD	NO	REL	No	No
		329.009.00134	11AUG95	37, ., -29	33 Days	200	CON	MOD	STP	REL	No	No
		329.009.00172	03DEC95	21, -37,-230	233 Days	150	CON	MOD	NO	PSR	No	No
		329.009.00195	04JAN96	21, ., -15	19 Days	200	CON	MOD	NO	PSR	No	No
		329.009.00199	17JAN96	2, ., -69	Not Stated	50	CON	MOD	NO	PSR	No	No
		329.009.00236	20JAN97	22, ., -19	Not Stated	200	CON	MOD	STP	REL	No	No
		329.009.00301	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No	No
		329.009.00305	14MAY96	8, -50,-253	15 Days	100	CON	MOD	NO	PSR	No	No
			28MAY96	22, -36,-239	71 Days	200	CON	MIL	NO	PSR	No	No
			09SEP96	126, 69,-135	142 Days	200	CON	MIL	NO	PSR	No	No
		329.009.00325	01SEP96	6, -50,-118	16 Days	50	CON	MOD	NO	PSR	No	No
			17SEP96	22, -34,-102	Not Stated	200	CON	MIL	NO	PSR	No	No
		329.009.00326	14OCT96	40, -14, -75	4 Days	200	CON	MIL	NO	PSR	No	No
		329.011.00163	28NOV95	4, ., -24	18:00 Hrs	50	1	MIL	NO	PBU	No	No
		329.012.00221	02AUG96	39, -25, -93	8 Days	200	5	MOD	NO	PBU	No	No
		329.012.00230	12MAR97	13, -57, -75	3 Days	100	2	MIL	NO	PBU	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dizziness	DIZZINESS (ORTHOSTATIC)	329.003.00249	16APR96	41, ., -21	2 Mins	300		MIL	NO	PSR	No	No
	DIZZINESS (WHEN GOING FROM SIT TO STAND)	329.002.00103	10AUG95	113, 57, -15	16 Days	250		MIL	NO	PSR	No	No
	DIZZINESS IN GYM CLASS X1	329.005.00332	20DEC96	9, ., -63	5 Mins	100	CON	MIL	NO	PSR	No	No
	DIZZINESS ORTHOSTATIC	329.003.00317	07JAN97	20, ., -50	29 Days	150	4	MIL	NO	PSR	No	No
	DIZZINESS UPON GETTING UP SUDDENLY	329.001.00061	06AUG94	9, ., -39	20 Days	100	CON	MIL	NO	REL	No	No
	DIZZINESS UPON STANDING	329.005.00256	04APR96	31, -26,-104	13 Days	250	4	MIL	NO	REL	No	No
	DIZZINESS UPON STANDING {1-2X/DAILY}	329.002.00244	29MAR96	9, -49, -75	24 Days	100	48	MOD	NO	PSR	No	No
	DIZZINESS WHEN GETTING OUT OF BED IN AM	329.005.00006	11NOV94	8, -53,-167	25 Days	50	CON	MIL	NO	REL	No	No
	DIZZINESS WHEN WAKING UP IN AM	329.003.00247	10FEB96	10, -45,-101	32 Days	100		MIL	NO	PSR	No	No
	DIZZINESS"OFF AND ON"	329.002.00100	14APR95	39, -20, -46	15 Mins	250	15	MIL	NO	PSR	No	No
	DIZZY	329.001.00066	02DEC94	11, ., -11	5 Mins	100	1	MIL	NO	PSR	No	No
		329.003.00082	03JAN96	24, ., -14	Not Stated	150	CON	MIL	NO	PSR	No	No
	FAINTNESS	329.001.00067	30NOV94	9, ., -13	Not Stated	100	CON	MOD	STP	PSR	No	No
	LIGHT HEADED	329.003.00314	24OCT96	3, ., -74	13 Days	50	CON	MIL	NO	PSR	No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dizziness	LIGHT HEADEDNESS	329.003.00249	20MAR96	14, ., -48	14 Days	150	CON	MIL	NO	PSR	No	No
	LIGHT-HEADEDNESS	329.005.00118	23MAY95	7, ., -43	23 Days	50	5	MIL	NO	PSR	No	No
	LIGHTHEADED	329.005.00153	25JAN96	1, -56,-235	29 Days	50	7	MIL	NO	PSR	No	No
	LIGHTHEADEDNESS	329.008.00192	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU	No	No
	ORTHOSTATIC CHANGES [DIZZINESS]	329.002.00322	13FEB97	36, ., -10	Not Stated	200	CON	MOD	STP	PSR	No	No
Drug Dependence	CANNABIS USE	329.012.00227	18JAN97	32, -38,-228	1 Days	200	1	MIL	NO	UNR	No	No
Emotional Lability	OVERDOSE {INTENTIONAL}	329.012.00221	03NOV96	132, 69, 0	19:30 Hrs	200	CON	SEV	STP	UNR	No	Yes
	SELF MUTILATION	329.012.00223	29SEP96	31, ., -13	Not Stated	200	CON	MOD	NO	UNR	No	Yes
	SUICIDAL IDEATION	329.005.00113	02MAR95	32, ., 0	1 Days	200	CON	MOD	STP	UNR	No	No
		329.012.00223	24SEP96	26, ., -18	10 Days	200	1	MOD	NO	UNR	No	No
	SUICIDAL THREAT WITH SCISSORS	329.005.00295	19APR96	23, ., -46	1 Days	200	1	MOD	NO	PBU	No	No
Euphoria	MILD ELATION AND DISINHIBITION	329.012.00221	24JUL96	30, -34,-102	13 Days	250	CON	MIL	DCR	PSR	No	No
Hallucinations	VISUAL HALLUCINATIONS	329.004.00215	25APR97	37, ., -3	7 Days	200	CON	SEV	STP	REL	No	Yes
Hostility	HOMICIDAL TENDENCIES TOWARDS PARENTS	329.005.00295	18MAY96	52, ., -17	04:30 Hrs	250	CON	SEV	STP	PSR	No	No
	INTENSE ANGER	329.008.00161	24DEC95	39, -17, -17	30 Mins	200	2	MOD	NO	PSR	No	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Hostility	PSYCHIATRIC HOSPITALIZATION FOLLOWING ASSAULTIVE BEHAVIOR	329.002.00321	02JUN96	11, ., -1	Not Stated	50	1	SEV	STP	UNR	No	Yes
Hyperkinesia	AKATHISIA	329.009.00326	30SEP96	26, -28, -89	18 Days	200	CON	MIL	NO	PSR	No	No
	SENSATION OF RESTLESSNESS IN LEGS NO OBSERVABLE TREMORS	329.002.00057	27SEP94	20, -38,-109	45 Mins	150	CON	MIL	NO	PBU	No	No
Hypertonia	STIFF NECK	329.004.00211	23FEB96	22, ., -27	18 Days	200	CON	MIL	NO	PBU	No	No
Hypesthesia	NUMBNESS IN HANDS AND ARMS WHEN AWAKES	329.001.00122	18JUL95	29, -29,-153	30 Days	200	CON	MIL	NO	PBU	No	No
Insomnia	DECREASED SLEEP (INITIAL, MIDDLE)	329.009.00264	11DEC96	41, ., -24	6 Days	200	CON	MIL	NO	PSR	No	No
	INITIAL INSOMNIA	329.009.00127	17APR95	8, ., -39	45 Days	100	CON	MOD	NO	PSR	No	No
		329.009.00172	10JUN96	211, 154, -40	29 Days	200	CON	MIL	NO	PBU	No	No
		329.009.00194	27FEB96	85, 29, -99	64 Days	200	CON	MIL	NO	PSR	No	No
	INSOMNIA	329.003.00289	13MAR96	15, -42,-223	129 Days	150		MIL	NO	PBU	No	No
		329.003.00314	23OCT96	2, ., -75	3 Days	50	3	MOD	NO	PSR	No	No
		329.006.00041	16AUG95	134, 70,-111	8 Days	300	6	MOD	NO	UNR	No	No
		329.012.00221	15AUG96	52, -12, -80	39 Days	200		MOD	NO	UNR	Yes	No

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Insomnia	INSOMNIA (FREQUENT AWAKENING)	329.003.00079	11MAY95	9, ., -8	Not Stated	100	CON	MOD	NO	PSR	No	No
	INSOMNIA MIDDLE	329.001.00061	18AUG94	21, ., -27	Not Stated	200	7	MIL	NO	REL	No	No
	MIDDLE INSOMNIA	329.001.00070	22FEB95	1, ., -30	16 Days	50	CON	MIL	NO	PBU	No	No
		329.009.00236	15JAN97	17, ., -24	6 Days	150	CON	MIL	NO	PSR	No	No
		329.009.00239	30DEC96	42, -16,-105	8 Days	200	CON	MIL	NO	PSR	Yes	No
	POOR SLEEP	329.008.00161	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No
	TERMINAL INSOMNIA	329.001.00070	11MAR95	18, ., -13	Not Stated	150	CON	MIL	NO	PBU	No	No
		329.012.00227	07FEB97	52, -18,-208	Not Stated	200		MIL	INC	PBU	No	No
	TROUBLE GETTING TO SLEEP AND EARLY AWAKENING	329.008.00159	29OCT95	47, -16, -87	8 Days	250	CON	MIL	NO	PSR	No	No
Myoclonus	MUSCLE TWITCH RIGHT EYE	329.001.00122	14JUL95	25, -33,-157	19 Days	200	CON	MIL	NO	PSR	No	No
	RIGHT KNEE TWITCH	329.001.00122	14JUL95	25, -33,-157	62 Days	200	CON	MIL	NO	REL	No	No
Nervousness	INCREASED IRRITABILITY	329.005.00117	15APR95	29, ., -41	Not Stated	200	CON	MOD	NO	PBU	No	No
	IRRITABILITY	329.004.00215	25APR97	37, ., -3	7 Days	200	CON	SEV	STP	REL	No	Yes
	IRRITABLE EDGY BURNT SELF WITH CIGARETTE	329.003.00247	16MAR96	45, -10, -66	11 Days	200	1	MIL	DCR	PSR	No	No
	IRRITABLE MOOD	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervousness	IRRITABLE MOOD	329.006.00041	16APR95	12, -53,-233	3 Days	100	1	MOD	NO	UNR	No	No
	RESTLESSNESS	329.008.00161	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No
Neurosis	OBSESSIVE THOUGHTS	329.005.00006	27FEB95	116, 56, -59	Not Stated	300	CON	MOD	STP	PBU	No	No
Somnolence	DAYTIME DROWSINESS	329.009.00127	12APR95	3, ., -44	Not Stated	50	CON	MIL	NO	PSR	No	No
	DAYTIME SEDATION	329.009.00236	20JAN97	22, ., -19	Not Stated	200	CON	MOD	STP	REL	No	No
	DAYTIME SOMNOLENCE	329.009.00239	09DEC96	21, -37,-126	22 Days	200	CON	MIL	NO	PSR	No	No
		329.009.00262	24FEB97	8, ., -61	8 Days	100	CON	MIL	NO	PSR	No	No
		329.009.00264	08NOV96	8, ., -57	25 Days	100	CON	MOD	NO	PSR	No	No
			16DEC96	46, ., -19	Not Stated	200	CON	MOD	NO	PSR	No	No
	DROWSINESS	329.003.00092	17MAY95	15, -44,-246	16 Days	150	CON	MIL	NO	PSR	No	No
		329.008.00192	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU	No	No
		329.008.00272	24JUL96	113, 57, -56	Not Stated	200	CON	MIL	NO	REL	No	No
	HYPERSOMNIA	329.001.00067	30NOV94	9, ., -13	Not Stated	100	5	MIL	NO	PSR	No	No
	HYPERSOMNOLENCE	329.009.00134	10JUL95	5, ., -61	65 Days	50	CON	MOD	NO	PSR	No	No
	SEDATION	329.008.00187	22DEC95	24, ., -49	Not Stated	200	CON	MOD	NO	REL	No	No
	SLEEPINESS	329.004.00013	20JUL94	2, -58,-246	3 Days	50	2	MIL	NO	REL	No	No
	SOMNOLENCE	329.009.00137	25OCT95	16, ., -52	42 Days	150	CON	MOD	NO	PSR	No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Somnolence	SOMNOLENCE	329.009.00172	29NOV95	17, -41,-234	6 Days	150	CON	MOD	NO	PSR	No	No
Thinking Abnormal	"STRANGE THOUGHTS"	329.010.00279	23APR96	33, -24,-213	2 Days	250	1	MIL	NO	PBU	No	No
	RACING THOUGHTS	329.009.00172	22DEC95	40, -18,-211	13 Days	200		MIL	NO	PBU	No	No
Tremor	"SHAKINESS"	329.005.00255	05MAR96	2, ., -69	4 Days	50	CON	MOD	NO	PSR	No	No
	(WORSENING) ENTIRE BODY SHAKES AND SHAKY HAND	329.002.00243	22MAR96	9, ., -14	Not Stated	100	CON	MOD	NO	PSR	No	No
	HAND TREMORS	329.001.00061	25AUG94	28, ., -20	Not Stated	200	4	MIL	NO	REL	No	No
		329.001.00070	23FEB95	2, ., -29	Not Stated	50	CON	MIL	NO	PSR	No	No
		329.001.00122	08AUG95	50, -8,-132	120 Days	200	CON	MOD	NO	REL	No	No
		329.005.00007	20DEC94	42, -22,-150	6 Days	250	CON	MIL	NO	REL	No	No
			26DEC94	48, -16,-144	3 Days	300	CON	MOD	DCR	REL	No	No
			29DEC94	51, -13,-141	142 Days	250	CON	MIL	NO	REL	No	No
		329.005.00009	12JAN95	32, ., -41	Not Stated	250	CON	MIL	NO	REL	No	No
			15JAN95	35, ., -38	10 Days	250	CON	MIL	NO	REL	No	No
			24JAN95	44, ., -29	8 Days	300	CON	SEV	DCR	REL	No	No
		329.005.00113	06FEB95	8, ., -24	Not Stated	50	CON	MIL	NO	REL	No	No
		329.005.00255	05APR96	33, ., -38	19 Days	250	CON	MOD	DCR	REL	No	No
		329.005.00335	01MAR97	2, ., -66	4 Days	50	CON	MIL	NO	REL	No	No
			05MAR97	6, ., -62	12:00 Hrs	50	CON	SEV	NO	REL	No	No
			06MAR97	7, ., -61	14 Days	50	CON	MOD	NO	REL	No	No
			01APR97	33, ., -35	5 Days	250	CON	MOD	NO	REL	No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Tremor	HAND TREMORS	329.005.00335	06APR97	38, ., -30	4 Days	200	CON	MIL	NO	REL	No	No
	RIGHT KNEE TREMOR	329.001.00122	14JUL95	25, -33,-157	62 Days	200	CON	MIL	NO	REL	No	No
	SHAKINESS	329.005.00003	27SEP94	8, ., -7	10 Days	100	CON	MOD	NO	PSR	No	No
	SHAKING	329.002.00098	14FEB95	43, ., -30	Not Stated	250	CON	MOD	DCR	PSR	No	No
	TREMBLING OF HANDS	329.004.00013	07AUG94	20, -40,-228	4 Days	150	2	MIL	NO	REL	No	No
	TREMORS	329.004.00211	19FEB96	18, ., -31	22 Days	150	CON	MIL	NO	PSR	No	No
		329.007.00307	30MAY96	15, ., -21	25 Days	150	CON	MIL	NO	REL	No	No

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PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Cough Increased	COUGH	329.009.00262	15MAR97	27, ., -42	2 Days	200	CON	MIL	NO	PBU	Yes	No
		329.009.00325	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
	COUGHING	329.002.00050	23MAR95	1, ., -34	12 Days	50	CON	MIL	NO	PBU	Yes	No
Dyspnea	SHORTNESS OF BREATH	329.007.00139	17MAY95	10, ., -8	8 Days	50	CON	MIL	STP	PSR	No	No
		329.007.00270	19JUN96	42, ., -1	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes
		329.009.00325	01SEP96	6, -50,-118	16 Days	50	CON	MIL	NO	PSR	No	No
	SHORTNESS OF BREATH (WITH EXERCISE)	329.008.00187	07JAN96	40, ., -33	Not Stated	200	CON	MIL	NO	PSR	No	No
Epistaxis	NOSEBLEEDS	329.005.00117	14APR95	28, ., -42	15 Mins	200	2	MIL	NO	PBU	No	No
Pharyngitis	PHARYNGITIS	329.012.00227	06JAN97	20, -50,-240	36 Days	150	CON	MOD	NO	PBU	Yes	No
	SORE THROAT	329.002.00050	23MAR95	1, ., -34	6 Days	50	CON	MOD	NO	PBU	Yes	No
		329.003.00079	17MAY95	15, ., -2	Not Stated	100	CON	MIL	NO	PBU	Yes	No
		329.003.00092	01MAY95	-2, -60,-262	16 Days	0	CON	MIL	NO	UNR	No	No
		329.004.00215	25MAR97	6, ., -34	5 Days	50	CON	MIL	NO	UNR	Yes	No
		329.005.00118	20MAY95	4, ., -46	4 Days	50	CON	MOD	NO	UNR	Yes	No
		329.005.00255	14APR96	42, ., -29	4 Days	300	CON	MIL	NO	PBU	No	No
		329.005.00256	28MAR96	24, -33,-111	5 Days	200	CON	MOD	NO	UNR	Yes	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Pharyngitis	SORE THROAT	329.006.00041	16APR95	12, -53,-233	3 Days	100	1	MOD	NO	PBU	Yes	No
		329.009.00171	14NOV95	8, ., 0	Not Stated	50	CON	MIL	NO	PBU	No	No
		329.011.00163	30NOV95	6, ., -22	20:00 Hrs	50	CON	MIL	NO	UNR	Yes	No
		329.011.00284	30MAR96	9, -48,-129	4 Days	100	CON	MIL	NO	UNR	Yes	No
		329.012.00227	10FEB97	55, -15,-205	11 Days	200	CON	MIL	NO	PBU	No	No
	SORE THROAT 1 HOUR DURATION AFTER AWAKENING	329.001.00061	28AUG94	31, ., -17	Not Stated	200	3	MIL	NO	PSR	No	No
Respiratory Disorder	CHEST CONGESTION AND COUGH	329.005.00118	19MAY95	3, ., -47	6 Days	50	CON	MOD	NO	UNR	Yes	No
	COLD - RUNNY NOSE, CONGESTION	329.010.00279	08MAY96	48, -9,-198	4 Days	300	CON	MIL	NO	PBU	No	No
	COLD SYMPTOMS	329.006.00041	22AUG95	140, 76,-105	3 Days	300	CON	MOD	NO	UNR	Yes	No
		329.007.00146	20JUL96	178, 125, -63	3 Days	200	CON	MIL	NO	UNR	Yes	No
	COLD SYNDROME UPPER RESPIRATORY TRACT INFECTION(URI)	329.009.00194	02JAN96	29, -28,-155	15 Days	200	CON	MIL	NO	UNR	Yes	No
	COLD {COMMON}	329.003.00317	14JAN97	27, ., -43	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
	COLD {SYMPTOMS}	329.003.00247	05MAR96	34, -21, -77	3 Days	200	CON	MOD	NO	UNR	Yes	No
		329.003.00249	23APR96	48, ., -14	8 Days	300		MIL	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory Disorder	COMMON COLD	329.004.00014	24NOV94	-5, ., -19	6 Days	0	1	MIL	NO	UNR	Yes	No
		329.012.00227	05MAY97	139, 70,-121	18 Days	300	CON	MIL	NO	UNR	Yes	No
	HEAD COLD	329.009.00239	06JAN97	49, -9, -98	10 Days	200	CON	MIL	NO	UNR	No	No
	HEADCOLD AND NASAL CONGESTION	329.005.00297	14APR96	-5, ., -30	3 Days	0	CON	MOD	NO	UNR	Yes	No
Rhinitis	CONGESTION BACK OF THROAT	329.001.00122	07OCT95	110, 53, -72	8 Days	200	CON	MIL	NO	UNR	No	No
	NASAL CONGESTION	329.009.00325	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
	RHINITIS	329.004.00215	26MAR97	7, ., -33	4 Days	50	CON	MIL	NO	UNR	Yes	No
	RUNNY NOSE	329.011.00209	30SEP96	20, -43, -80	4 Days	150	CON	MIL	NO	UNR	Yes	No
Sinusitis	SINUS CONGESTION	329.009.00171	14NOV95	8, ., 0	Not Stated	50	CON	MIL	NO	PBU	No	No
		329.009.00239	18FEB97	92, 35, -55	28 Days	200	CON	MIL	NO	UNR	Yes	No
	SINUSITIS	329.007.00307	02JUN96	18, ., -18	6 Days	150	CON	MIL	NO	UNR	Yes	No
			23JUL96	69, ., 33	Not Stated	0	CON	MOD	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Skin and Appendages

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Acne	ACNE	329.007.00143	15NOV95	7, ., -16	Not Stated	50	CON	MOD	STP	PSR	No	No
		329.010.00279	15JUN96	86, 30,-160	Not Stated	300	CON	MOD	NO	PBU	Yes	No
	INCREASED ACNE (FACE,CHEST,BACK)	329.008.00187	30NOV95	2, ., -71	Not Stated	50	CON	MIL	NO	PSR	No	No
Contact Dermatitis	POISON IVY	329.007.00270	17MAY96	9, ., -34	3 Days	100	CON	MOD	NO	UNR	Yes	No
		329.010.00279	09JUL96	110, 54,-136	11 Days	300	CON	MIL	NO	UNR	Yes	No
			23AUG96	155, 99, -91	51 Days	300	CON	MOD	NO	UNR	Yes	No
Dry Skin	DRY FINGERTIPS	329.009.00239	17MAR97	119, 62, -28	Not Stated	200	CON	MIL	NO	PSR	Yes	No
Fungal Dermatitis	RINGWORM	329.007.00270	30MAY96	22, ., -21	17 Days	200	CON	MIL	NO	UNR	Yes	No
Maculopapular Rash	MORBILLIFORM "MEASLES LIKE" ERUPTION, GENERALIZED SIMILAR TO TRICYCLIC RASH, ON TRUNK, BACK, EXTREMITIES, CHEST, BUTTOCKS, TORSO/FRONT AND BACK, AND LOWER NECK	329.007.00307	16JUN96	32, ., -4	10 Days	200	CON	MOD	STP	REL	Yes	Yes
	RASH{FINE MACULAR ON FACE,INSIDE ELBOWS,BACK}	329.009.00171	10NOV95	4, ., -4	Not Stated	50	CON	SEV	STP	PBU	No	No
Pruritus	ITCHING-WITHOUT HIVES	329.005.00117	19MAR95	2, ., -68	3 Days	50	1	MIL	NO	PSR	No	No
Rash	ITCHING AND RASH TO RIGHT FOREARM AND BOTH CALVES	329.002.00243	17MAR96	4, ., -19	6 Days	50	CON	MOD	NO	UNR	Yes	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Skin and Appendages

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Rash	RASH	329.011.00163	21NOV95	-4, ., -31	Not Stated	0	CON	MIL	NO	UNR	Yes	No
	RASH-BILATERAL FOREARMS	329.005.00007	10NOV94	2, -62,-190	5 Days	50	CON	MOD	STP	PBU	Yes	No
	RED SPOTS / BLOTCHES ON SKIN ARMS, THROAT, CHEST	329.002.00103	11MAY95	22, -35,-106	35 Days	200		MIL	NO	PSR	No	No
Sweating	EPISODIC CALOR AND PERSPIRATION	329.008.00187	10DEC95	12, ., -61	Not Stated	100	CON	MIL	NO	PSR	No	No
	INCREASED SWEATING	329.009.00134	27JUL95	22, ., -44	48 Days	200	CON	MIL	NO	PSR	No	No
	NIGHT SWEATS	329.009.00194	02APR96	120, 64, -64	76 Days	200	CON	MIL	NO	PSR	No	No
	SWEATINESS	329.005.00003	22SEP94	3, ., -12	6 Days	50	CON	MOD	NO	PSR	No	No
	SWEATING	329.004.00013	20JUL94	2, -58,-246	3 Days	50	CON	MIL	NO	REL	No	No
		329.005.00153	16FEB96	23, -34,-213	13 Days	200	5	MIL	NO	PSR	No	No
		329.009.00195	25DEC95	11, ., -25	29 Days	100	CON	MOD	NO	PSR	No	No
Urticaria	HIVES-BILATERAL FOREARMS	329.005.00007	10NOV94	2, -62,-190	5 Days	50	CON	MOD	NO	PBU	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Special Senses

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abnormal Vision	BLURRED VISION	329.003.00088	14MAR95	15, ., -26	Not Stated	100	CON	MIL	NO	PSR	No	No
		329.005.00113	06FEB95	8, ., -24	Not Stated	50	10	MIL	NO	REL	No	No
		329.005.00255	15APR96	43, ., -28	8 Days	250	15	SEV	DCR	REL	No	No
		329.009.00305	03JUL96	58, 1,-203	35 Days	200	CON	MIL	NO	PSR	No	No
	BLURRED VISION WHEN READING LONG TIME	329.001.00066	02DEC94	11, ., -11	Not Stated	100	3	MIL	NO	PSR	No	No
	BLURRED VISION WHEN STANDS QUICKLY	329.002.00103	08JUN95	50, -7, -78	36 Days	250	10	MIL	NO	PSR	No	No
	VISUAL BRIGHT SPOTS	329.004.00013	20JUL94	2, -58,-246	5 Days	50	8	MIL	NO	REL	No	No
Ear Pain	EARACHE	329.003.00314	20DEC96	60, ., -17	24:00 Hrs	250	1	MIL	NO	UNR	Yes	No
		329.009.00262	03MAR97	15, ., -54	5 Days	150	CON	MIL	NO	PBU	No	No
Eye Disorder	EYE INFECTION (LEFT AND RIGHT EYE)	329.009.00262	10FEB97	-7, ., -75	57 Days	0	CON	MOD	NO	UNR	Yes	No
Keratoconjunctivitis	IRRITATION IN EYES (DRY EYES)	329.009.00325	09SEP96	14, -42,-110	8 Days	150	CON	MIL	NO	PSR	No	No
Mydriasis	EYE DILATION	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
Photophobia	LIGHT SENSITIVITY	329.008.00187	18DEC95	20, ., -53	Not Stated	150	CON	MIL	NO	REL	No	No
Taste Perversion	BAD TASTE	329.003.00088	10MAR95	11, ., -30	21 Days	100	CON	MIL	NO	PSR	No	No
		329.003.00090	16MAR95	3, ., -66	5 Days	50	CON	MIL	DCR	PSR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Special Senses

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Taste Perversion	BITTER TASTE IN MOUTH	329.008.00187	30NOV95	2, ., -71	Not Stated	50	CON	MIL	NO	PSR	No	No
Tinnitus	RINGING IN EARS	329.009.00172	03DEC95	21, -37,-230	30 Days	150		MIL	NO	PSR	No	No
	RINGING IN EARS-5-10 MINUTES IN A.M.	329.004.00013	03AUG94	16, -44,-232	8 Days	150	7	MIL	NO	REL	No	No

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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Urogenital System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Cystitis	FEELING BLADDER FULL AFTER URINATING	329.012.00230	01MAY97	63, -7, -25	28 Days	200	CON	MIL	NO	PBU	Yes	No
Dysmenorrhea	MENSTRUAL CRAMPS	329.003.00249	13APR96	38, ., -24	3 Days	300		MIL	NO	UNR	Yes	No
		329.003.00289	24APR96	57, 1,-181	Not Stated	200	6	MIL	NO	UNR	No	No
		329.005.00009	20JAN95	40, ., -33	5 Days	300	CON	SEV	NO	UNR	No	No
		329.005.00153	31JAN96	7, -50,-229	12:00 Hrs	50	CON	MOD	NO	UNR	Yes	No
		329.005.00256	20MAR96	16, -41,-119	2 Days	100	CON	MOD	NO	UNR	Yes	No
Dysuria	DYSURIA	329.011.00284	09JUN96	80, 24, -58	2 Days	250	3	MOD	NO	PBU	No	No
Haematuria	[URINE OCCULT BLOOD]	329.005.00009	07DEC94	-5, ., -77	1 Days	0	1	MIL	NO	UNR	No	No
Nocturia	NOCTURIA	329.006.00041	24MAY95	50, -15,-195	8 Days	250	CON	MIL	NO	PSR	No	No
Polyuria	POLYURIA	329.004.00014	05DEC94	7, ., -8	1 Days	100		MIL	NO	PSR	No	No
Pyuria	URINALYSIS - WBC'S {INCREASED}	329.005.00006	28APR95	176, 116, 1	Not Stated	50		MIL	NO	UNR	No	No
Unintended Pregnancy	POSITIVE PREGNANCY TEST RESULT	329.005.00110	21JAN95	11, ., 2	1 Days	100	CON	SEV	STP	UNR	No	No
	PREGNANCY NAUSEA VOMITING	329.002.00057	10DEC94	94, 37, -35	Not Stated	300	CON	MOD	STP	UNR	No	No
Urinary Frequency	INCREASED URINATION	329.009.00137	17OCT95	8, ., -60	8 Days	100	CON	MIL	NO	PBU	No	No
Urinary Retention	URINARY RETENTION	329.003.00088	14MAR95	15, ., -26	Not Stated	100	CON	SEV	STP	REL	No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=IMIPRAMINE Body System=Urogenital System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urinary Retention	URINARY RETENTION	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
		329.009.00172	09JAN96	58, 1,-193	8 Days	200	CON	MOD	NO	PBU	No	No
Urination Impaired	DIFFICULTY INITIATING URINATION	329.002.00104	04MAY95	1, -56,-258	8 Days	50	2	MIL	NO	REL	No	No
	HARD TO INITIATE URINATION	329.009.00172	09JAN96	58, 1,-193	8 Days	200	CON	MOD	NO	PBU	No	No
	URINARY HESITANCY	329.002.00050	30MAR95	8, ., -27	6 Days	100	CON	MIL	STP	PSR	No	No
Vaginal Moniliasis	YEAST INFECTION (VAGINAL)	329.005.00255	19APR96	47, ., -24	5 Days	250	CON	MOD	NO	PBU	Yes	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abdominal Pain	ABDOMINAL PAIN	329.007.00311	09OCT96	7, -54,-197	01:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
	STOMACH ACHE	329.001.00064	23NOV94	14, -41,-138	03:00 Hrs	0	1	MIL	NO	PSR	No	No
			01DEC94	22, -33,-130	8 Days	0	2	MIL	NO	PSR	No	No
		329.002.00097	23MAR95	80, 22,-181	20 Mins	0	3	MIL	NO	PSR	No	No
		329.005.00254	28FEB96	14, -42,-244	03:00 Hrs	0	CON	MOD	NO	UNR	No	No
	STOMACH ACHE HEADACHE {SIMULTANEOUS} [STOMACH ACHE]	329.010.00263	08SEP96	31, ., -41	10 Mins	0	1	MIL	NO	PSR	No	No
	STOMACH ACHE,NO VOMITING	329.007.00267	16MAY96	71, ., 15	04:00 Hrs	0	CON	MOD	NO	PBU	No	No
	STOMACH ACHES	329.004.00213	03AUG96	2, -53,-239	8 Days	0	CON	MIL	NO	PSR	No	No
			11AUG96	10, -45,-231	192 Days	0	CON	MOD	NO	UNR	Yes	No
	STOMACH ACHES (IF TAKES MEDS WITHOUT FOOD)	329.002.00246	20MAY96	33, ., -39	Not Stated	0		MIL	NO	PSR	No	No
	STOMACH ACHES IN AM	329.009.00202	08MAR96	18, ., -18	12 Days	0	CON	MOD	NO	PSR	No	No
	STOMACH CRAMPS	329.001.00207	03MAR96	5, ., -53	23:00 Hrs	0	CON	MIL	NO	UNR	No	No
		329.004.00016	28MAR95	16, ., -22	3 Days	0	CON	MOD	NO	UNR	Yes	No
	STOMACH CRAMPS (SINCE STARTING BIAXIN)	329.001.00207	24APR96	57, ., -1	3 Days	0	CON	MIL	NO	UNR	No	No
	STOMACH CRAMPS(VIRAL)	329.009.00202	22FEB96	3, ., -33	3 Days	0	CON	MIL	NO	PBU	No	No
	STOMACH PAINS	329.003.00291	09JUL96	7, -59,-113	01:00 Hrs	0	2	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Allergic Reaction	"PUFFY",ITCHY,WATERY EYES {ALLERGIES}	329.005.00111	04MAR95	53, -4, -57	9 Days	0	CON	SEV	NO	PBU	No	No
	COUGHING DUE TO ALLERGIES	329.004.00016	30MAR95	18, ., -20	Not Stated	0	CON	MIL	NO	UNR	Yes	No
	HEADACHES DUE TO ALLERGIES	329.004.00016	24MAR95	12, ., -26	Not Stated	0	CON	MOD	NO	UNR	Yes	No
	RHINITIS, SNEEZING, ITCHY EYES (POLLEN ALLERGY)	329.004.00018	12MAY95	10, ., -63	7 Days	0	CON	MOD	NO	UNR	Yes	No
	SNEEZING DUE TO ALLERGIES	329.004.00016	24MAR95	12, ., -26	Not Stated	0	CON	MOD	NO	UNR	Yes	No
	STUFFED SINUSES DUE TO ALLERGIES	329.004.00016	24MAR95	12, ., -26	Not Stated	0	CON	MOD	NO	UNR	Yes	No
Asthenia	DROP IN ENERGY	329.008.00162	20DEC95	50, -16,-210	8 Days	0	1	MIL	INC	PSR	No	No
	FATIGUE	329.002.00246	25APR96	8, ., -64	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.002.00323	04MAR97	113, 55,-114	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.003.00080	04JAN96	39, ., -36	Not Stated	0	CON	SEV	NO	PBU	No	No
		329.003.00252	25APR96	16, ., -54	20 Days	0	CON	MIL	NO	PSR	No	No
		329.005.00111	31JAN95	21, -36, -89	8 Days	0	CON	MIL	NO	PSR	No	No
		329.009.00198	03JAN96	2, ., -66	Not Stated	0	CON	MOD	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Asthenia	FATIGUE	329.011.00210	24OCT96	27, -40, -40	12 Days	0	CON	MIL	NO	PSR	No	No
	SLIGHTLY TIRED	329.005.00005	03NOV94	3, ., -6	14 Days	0	5	MIL	NO	PSR	No	No
	TIRED	329.005.00254	16MAR96	31, -25,-227	Not Stated	0	CON	MIL	NO	PSR	No	No
	WEAKNESS	329.003.00094	11DEC95	49, ., -24	02:00 Hrs	0	1	MOD	NO	PSR	No	No
			12DEC95	50, ., -23	Not Stated	0	CON	MIL	NO	PBU	No	No
Back Pain	BACK ACHE	329.005.00298	12SEP96	114, 58,-134	3 Days	0	CON	MOD	NO	UNR	No	No
		329.005.00334	19MAR97	48, ., -8	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
		329.010.00263	07SEP96	30, ., -42	06:00 Hrs	0	1	MIL	NO	UNR	No	No
	BACK AND NECK ACHES	329.001.00062	31OCT94	12, ., -15	19 Days	0		MOD	NO	PSR	No	No
	BACK PAIN	329.002.00320	17SEP96	125, 64, -21	Not Stated	0	CON	MOD	NO	UNR	No	No
	BACK PAIN (OLD SOCCER INJURY)	329.005.00298	23JUN96	33, -24,-215	03:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	BACKACHE	329.004.00213	02AUG96	1, -54,-240	8 Days	0	CON	MIL	NO	UNR	No	No
		329.005.00111	07JAN95	-4, -60,-113	39 Days	0	12	MOD	NO	PBU	Yes	No
		329.005.00331	20DEC96	30, ., -27	6 Days	0	CON	MIL	NO	UNR	No	No
			07JAN97	48, ., -9	2 Days	0	CON	MIL	NO	UNR	No	No
		329.005.00334	20FEB97	21, ., -35	04:00 Hrs	0	CON	MOD	NO	UNR	No	No
		329.010.00282	15AUG96	21, ., -58	12 Days	0	CON	MIL	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Back Pain	BACKACHE	329.011.00164	11JAN96	21, ., -15	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	BACKACHES	329.009.00312	06JAN97	64, ., -14	15 Days	0	CON	MIL	NO	PBU	No	No
	NECK SPASM	329.012.00027	21DEC95	16, ., -21	Not Stated	0	CON	MOD	NO	PBU	Yes	No
Chest Pain	CHEST PAIN	329.005.00254	28FEB96	14, -42,-244	03:00 Hrs	0	CON	MIL	NO	UNR	No	No
		329.011.00210	03OCT96	6, -61, -61	20 Mins	0	1	MIL	NO	PBU	No	No
Fever	FEVER	329.003.00086	02JAN95	36, -22,-243	02:00 Hrs	0		MIL	NO	UNR	Yes	No
		329.005.00111	15FEB95	36, -21, -74	6 Days	0	CON	MOD	NO	UNR	Yes	No
		329.009.00276	13MAR97	52, ., -19	6 Days	0	CON	MIL	NO	PBU	Yes	No
	FEVER - 102 DEGREES[FEVER]	329.005.00334	19MAR97	48, ., -8	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
Headache	HEADACHE	329.001.00064	26JAN95	78, 24, -74	6 Days	0	2	MIL	NO	PBU	No	No
		329.001.00123	21FEB96	49, ., 0	Not Stated	0	CON	MOD	NO	PSR	Yes	No
		329.001.00207	18APR96	51, ., -7	8 Days	0	CON	MOD	NO	PBU	Yes	No
		329.002.00049	25MAR95	17, ., -57	3 Days	0	3	MIL	NO	PSR	Yes	No
		329.002.00323	01FEB97	82, 24,-145	4 Days	0	1	MIL	NO	PSR	No	No
		329.003.00094	11DEC95	49, ., -24	02:00 Hrs	0	1	MOD	NO	PSR	No	No
			12DEC95	50, ., -23	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.003.00252	30APR96	21, ., -49	30 Mins	0	5	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.003.00252	18MAY96	39, ., -31	02:00 Hrs	0	1	MOD	DCR	PSR	Yes	No
		329.003.00291	14JUL96	12, -54,-108	01:00 Hrs	0	1	MOD	NO	PSR	No	No
		329.004.00018	24MAY95	22, ., -51	02:00 Hrs	0	1	SEV	NO	UNR	Yes	No
		329.005.00012	24JAN95	37, -23,-128	04:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
		329.005.00111	07JAN95	-4, -60,-113	39 Days	0	12	MOD	NO	PBU	Yes	No
			14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
			16APR95	96, 40, -14	2 Days	0	CON	SEV	NO	UNR	Yes	No
		329.005.00115	12FEB95	7, -65, -68	02:30 Hrs	0	CON	MIL	NO	PSR	No	No
		329.005.00120	14SEP95	16, ., -42	30 Mins	0	1	MIL	NO	UNR	No	No
		329.005.00253	02FEB96	-6, ., -61	04:00 Hrs	0	2	MIL	NO	UNR	Yes	No
			26FEB96	19, ., -37	05:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			27FEB96	20, ., -36	03:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
			23MAR96	45, ., -11	04:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
		329.005.00254	11FEB96	-4, -59,-261	03:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			16FEB96	2, -54,-256	5 Days	0	3	MIL	NO	PSR	No	No
			24FEB96	10, -46,-248	1 Days	0	2	MIL	NO	PBU	No	No
			08MAR96	23, -33,-235	02:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			07APR96	53, -3,-205	02:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			02SEP96	201, 146, -57	02:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
			03SEP96	202, 147, -56	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
		329.005.00293	06APR97	26, ., -31	03:30 Hrs	0	1	MOD	NO	PBU	Yes	No
			19APR97	39, ., -18	01:00 Hrs	0	1	MOD	NO	PBU	Yes	No
			06MAY97	56, ., -1	45 Mins	0	1	MOD	NO	PBU	No	No

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Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.005.00298	06NOV96	169, 113, -79	02:30 Hrs	0	CON	MOD	NO	UNR	No	No
		329.005.00331	21NOV96	1, ., -56	4 Days	0	4	MOD	NO	REL	Yes	No
			23NOV96	3, ., -54	1 Days	0	2	MIL	NO	PSR	No	No
			24NOV96	4, ., -53	1 Days	0	CON	MIL	NO	PSR	No	No
			30NOV96	10, ., -47	2 Days	0	2	MOD	NO	REL	Yes	No
			26DEC96	36, ., -21	02:30 Hrs	0	CON	MOD	NO	UNR	Yes	No
			09JAN97	50, ., -7	02:30 Hrs	0	CON	MIL	NO	PBU	No	No
		329.005.00334	03MAR97	32, ., -24	02:30 Hrs	0	CON	MIL	NO	PBU	Yes	No
			12MAR97	41, ., -15	05:00 Hrs	0	CON	SEV	NO	PBU	Yes	No
		329.006.00037	06FEB95	10, ., -15	Not Stated	0	CON	MOD	NO	REL	No	No
		329.006.00042	23MAR96	108, 51,-130	30 Mins	0	1	MOD	NO	PBU	Yes	No
			24APR96	140, 83, -98	01:30 Hrs	0	1	MOD	NO	PBU	Yes	No
			09JUL96	216, 159, -22	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			11JUL96	218, 161, -20	06:00 Hrs	0	1	SEV	NO	UNR	Yes	No
			13JUL96	220, 163, -18	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
		329.007.00144	14JAN96	39, -18, -18	2 Days	0	1	MIL	NO	PSR	Yes	No
		329.007.00266	08MAR96	2, ., -69	04:00 Hrs	0	1	SEV	NO	PSR	No	No
		329.007.00267	06MAR96	-1, ., -56	01:00 Hrs	0	1	MOD	NO	PSR	No	No
		329.009.00136	04NOV95	33, ., -37	11 Days	0	3	MIL	NO	PBU	Yes	No
		329.009.00174	03DEC95	13, -45, -72	Not Stated	0		MOD	NO	PSR	Yes	No
		329.010.00263	14AUG96	6, ., -66	03:00 Hrs	0	1	MIL	NO	PBU	Yes	No
			17AUG96	9, ., -63	02:00 Hrs	0	1	MIL	NO	PBU	Yes	No
			04SEP96	27, ., -45	15 Mins	0	1	MIL	NO	PBU	No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.010.00277	06AUG96	159, 103, 46	02:00 Hrs	0	1	MIL	NO	UNR	Yes	No
		329.010.00282	02SEP96	39, ., -40	30 Mins	0	1	MOD	NO	PBU	Yes	No
		329.011.00164	11JAN96	21, ., -15	01:00 Hrs	0	1	MIL	NO	PBU	Yes	No
		329.011.00210	03OCT96	6, -61, -61	20 Mins	0	1	MIL	NO	PBU	No	No
	HEADACHE (MODERATE)	329.012.00218	08JUN96	-8, -66,-115	02:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			11JUL96	26, -33, -82	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	HEADACHES	329.001.00123	21JAN96	18, ., -31	8 Days	0	CON	MIL	NO	UNR	No	No
		329.002.00323	30DEC96	49, -10,-178	11 Days	0	CON	MIL	NO	PSR	Yes	No
		329.003.00074	09FEB95	16, -41,-258	01:30 Hrs	0	2	MIL	NO	PSR	No	No
		329.003.00080	03JAN96	38, ., -37	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.004.00018	22JUN95	51, ., -22	Not Stated	0	CON	MOD	NO	PSR	Yes	No
		329.004.00213	04AUG96	3, -52,-238	227 Days	0	CON	MIL	NO	UNR	Yes	No
		329.005.00115	14MAR95	37, -35, -38	02:00 Hrs	0	7	MIL	NO	PSR	No	No
		329.006.00042	28DEC95	22, -36,-216	6 Days	0	7	MIL	NO	UNR	No	No
		329.009.00276	04FEB97	15, ., -56	15 Days	0	CON	MIL	NO	PSR	No	No
	HEADACHES (WORSENING)	329.002.00246	10MAY96	23, ., -49	Not Stated	0		MIL	NO	PSR	Yes	No
	INCREASE HEADACHE	329.009.00238	03DEC96	22, ., -47	Not Stated	0	CON	MOD	NO	PSR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Headache	INCREASE IN HEADACHES	329.009.00312	27DEC96	54, ., -24	Not Stated	0		MOD	NO	PSR	Yes	No
	STOMACH ACHE HEADACHE {SIMULTANEOUS} [HEADACHE]	329.010.00263	08SEP96	31, ., -41	10 Mins	0	1	MIL	NO	PSR	No	No
Infection	CHLAMYDIA	329.005.00253	04MAR96	26, ., -30	9 Days	0	CON	MIL	NO	UNR	Yes	No
	FLU	329.012.00217	13JUN96	24, ., -1	7 Days	0	CON	MOD	STP	UNR	Yes	No
	FLU SYMPTOMS	329.002.00097	16JAN95	14, -45,-247	3 Days	0	CON	MIL	NO	UNR	Yes	No
		329.007.00311	23JAN97	113, 53, -91	2 Days	0	CON	MOD	NO	UNR	Yes	No
	FLU(STOMACH ACHE)	329.009.00174	03DEC95	13, -45, -72	5 Days	0	CON	MIL	NO	UNR	Yes	No
	FLU-NAUSEA,CRAMPS DIARRHEA,STOMACH ACHE	329.005.00010	18JAN95	37, -21,-218	3 Days	0	CON	SEV	NO	UNR	No	No
	SCABIES	329.009.00169	03DEC95	34, -32, -63	13 Days	0	CON	MOD	NO	UNR	Yes	No
	STOMACH FLU-(HEADACHE,NAUSEA/VOMITING AND DIARRHEA)	329.005.00012	31DEC94	13, -47,-152	4 Days	0	CON	SEV	NO	UNR	No	No
	STOMACH VIRUS	329.009.00276	31MAR97	70, ., -1	2 Days	0	CON	MIL	NO	PSR	Yes	No
	STREP THROAT	329.002.00107	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes	No
		329.012.00224	08DEC96	84, 18, -83	11 Days	0	CON	MIL	NO	UNR	Yes	No
	STREP THROAT SORE THROAT AND FEVER	329.005.00114	04FEB95	5, -53, -93	11 Days	0	CON	SEV	NO	UNR	Yes	No

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Appendix D.1

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Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Infection	TOXOPLASMOSIS	329.005.00012	01JUN95	165, 106, 0	Not Stated	0	CON	MOD	STP	UNR	Yes	No
Pain	BODY ACHES	329.001.00123	22JAN96	19, ., -30	7 Days	0	CON	MIL	NO	UNR	No	No
		329.001.00207	18APR96	51, ., -7	7 Days	0	CON	MIL	NO	UNR	No	No
	FACE PAIN	329.005.00111	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
	SIDE ACHE LEFT SIDE	329.010.00263	10SEP96	33, ., -39	01:30 Hrs	0	1	MIL	NO	UNR	Yes	No
Trauma	CAR ACCIDENT (NO INJURIES)	329.002.00246	15MAY96	28, ., -44	1 Days	0	CON	MIL	NO	UNR	No	No
	CHARLEY HORSE LEFT LEG-THIGH	329.005.00298	01OCT96	133, 77,-115	4 Days	0	CON	MOD	NO	UNR	Yes	No
	FACIAL CUTS {LEFT CHEEK}	329.009.00198	18FEB96	48, ., -20	1 Days	0	CON	MOD	NO	UNR	Yes	No
	FALL FROM ROPE RESULTING IN DIZZINESS,HEADACHES, AND FATIGUE	329.002.00246	26MAY96	39, ., -33	5 Days	0		MOD	NO	UNR	No	No
	FOOT/ANKLE (RUN OVER BY CAR INJURY-PAIN)	329.005.00010	13APR96	488, 431, 233	3 Days	0	CON	MOD	NO	UNR	Yes	No
	FRACTURED LEFT INDEX FINGER	329.001.00064	25JAN95	77, 23, -75	35 Days	0	CON	MOD	NO	UNR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Body as a Whole

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Trauma	HEAD INJURY WITH LACERATION TO SCALP (4 STITCHES) NO LOSS OF CONSCIOUSNESS (PUSHED ONTO SUBWAY TRACK)	329.004.00213	05OCT96	65, 11,-176	5 Mins	0	1	MOD	NO	UNR	No	No
	KNEE INJURY (SOCCER RELATED)	329.005.00298	15JUL96	55, -2,-193	3 Days	0	CON	MOD	NO	UNR	Yes	No
	PAIN IN RIGHT LEG (FOLLOWING AUTOMOBILE ACCIDENT)	329.005.00298	16JUN96	26, -31,-222	04:30 Hrs	0	CON	MOD	NO	UNR	Yes	No
	PULLED MUSCLE - LEFT SHIN (SOCCER INJURY)	329.005.00298	17OCT96	149, 93, -99	06:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	SCALP LACERATIONS (TOP OF HEAD)	329.009.00197	17JUN96	172, 118, -76	2 Days	0	CON	MOD	NO	UNR	Yes	No
	SHOULDER TRAUMA	329.002.00320	16JUN96	32, -30,-114	1 Days	0	CON	MOD	NO	UNR	Yes	No
	SPRAINED ANKLE	329.001.00064	04JAN95	56, 2, -96	18 Days	0	CON	MOD	NO	UNR	No	No
	SPRAINED WRIST LEFT	329.012.00225	15JUL97	232, 168, -26	Not Stated	0	CON	MIL	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Angina Pectoris	ANGINA ON EXERTION	329.007.00141	13SEP95	-8, ., -29	30 Days	0	2	MOD	STP	PBU	No	No
Arrhythmia	SINUS ARRHYTHMIA	329.011.00210	24OCT96	27, -40, -40	40 Days	0	2	MIL	NO	PBU	No	No
	SINUS-ARRHYTHMIA	329.003.00291	02OCT96	92, 27, -28	29 Days	0	1	MIL	NO	PBU	No	No
Av Block	SERIAL INCREASE PR INTERVAL	329.009.00238	26NOV96	15, ., -54	15 Days	0	CON	MIL	NO	PSR	No	No
	SINUS ARRHYTHMIA(MOBITZ I)	329.009.00200	06FEB96	15, ., -42	43 Days	0	2	MIL	NO	PBU	No	No
Bradycardia	SINUS BRADYCARDIA	329.009.00330	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR	No	No
Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	329.009.00128	18APR95	8, ., -14	Not Stated	0	CON	MIL	STP	PSR	No	No
Heart Malformation	POSSIBLE LEFT VENTRICULAR HYPERTROPHY	329.009.00330	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR	No	No
Nodal Arrhythmia	JUNCTIONAL ESCAPE PATTERN(EKG)	329.009.00302	03APR96	8, ., -7	Not Stated	0	CON	MIL	NO	PSR	No	No
Palpitation	HEART PALPITATION {ONE TIME ONLY}	329.006.00042	18MAY96	164, 107, -74	1 Mins	0	1	MIL	NO	PBU	No	No
Postural Hypotension	ORTHOSTATIC HYPOTENSION	329.009.00135	30OCT95	29, ., -20	21 Days	0	CON	MIL	NO	PSR	No	No
Supraventricular Extrasystoles	OCCASIONAL PREMATURE ATRIAL COMPLEXES	329.009.00330	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR	No	No
Syncope	FAINT UPON STANDING	329.001.00069	17MAR95	30, ., -32	22 Days	0	CON	MIL	NO	PSR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Cardiovascular System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Tachycardia	ELEVATED HEART RATE	329.005.00005	08NOV94	8, ., -1	2 Days	0	2	MOD	STP	PSR	No	No
Vasodilatation	HOT FLASHES	329.002.00097	25JAN95	23, -36,-238	5 Mins	0	4	MIL	NO	PSR	No	No
		329.009.00306	02JUL96	22, ., -48	50 Days	0	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Constipation	CONSTIPATION	329.003.00074	18FEB95	25, -32,-249	12 Days	0	CON	MIL	NO	PSR	No	No
		329.003.00291	21AUG96	50, -16, -70	Not Stated	0	1	MIL	NO	PBU	No	No
		329.004.00213	08AUG96	7, -48,-234	5 Days	0	2	MIL	NO	PSR	No	No
			10AUG96	9, -46,-232	13 Days	0	CON	MIL	NO	UNR	No	No
		329.009.00174	10DEC95	20, -38, -65	Not Stated	0		MIL	NO	PSR	No	No
Decreased Appetite	ANOREXIA	329.001.00069	18MAR95	31, ., -31	21 Days	0	CON	MIL	NO	PSR	No	No
	APPETITE DOWN	329.008.00191	03FEB96	3, -59,-131	Not Stated	0	CON	MIL	NO	PSR	No	No
	DECREASED APPETITE	329.001.00207	21MAR96	23, ., -35	15 Days	0	CON	MIL	NO	PBU	No	No
		329.009.00276	18MAR97	57, ., -14	Not Stated	0	CON	MIL	NO	PSR	No	No
Diarrhea	DIARRHEA	329.001.00064	23NOV94	14, -41,-138	03:00 Hrs	0	2	MIL	NO	PSR	No	No
			31JAN95	83, 29, -69	2 Days	0	CON	MIL	NO	UNR	No	No
		329.001.00207	03MAR96	5, ., -53	15:00 Hrs	0	3	MOD	NO	UNR	No	No
			06APR96	39, ., -19	13:00 Hrs	0	4	MIL	NO	PBU	No	No
			24APR96	57, ., -1	3 Days	0	CON	MIL	NO	UNR	No	No
		329.004.00213	07AUG96	6, -49,-235	4 Days	0	4	MIL	NO	PSR	No	No
			09FEB97	192, 138, -49	31 Days	0	CON	MIL	NO	UNR	No	No
		329.007.00311	18OCT96	16, -45,-188	02:00 Hrs	0	1	MIL	NO	UNR	No	No
			23JAN97	113, 53, -91	2 Days	0	12	MOD	NO	UNR	Yes	No
		329.009.00135	21OCT95	20, ., -29	1 Days	0	CON	MIL	NO	UNR	No	No
		329.010.00282	19SEP96	56, ., -23	6 Days	0	20	MOD	NO	PSR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Diarrhea	DIARRHEA(VIRAL)	329.009.00202	22FEB96	3, ., -33	3 Days	0	CON	MIL	NO	PBU	No	No
	STOMACH ACHE WITH DIARRHEA	329.005.00298	18MAY96	-4, -60,-251	4 Days	0	CON	SEV	NO	UNR	No	No
Dry Mouth	DRY MOUTH	329.001.00062	04NOV94	16, ., -11	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.002.00246	25APR96	8, ., -64	Not Stated	0	CON	MIL	NO	REL	No	No
		329.002.00320	14JUN96	30, -32,-116	11 Days	0	CON	MIL	NO	PSR	No	No
		329.003.00080	04JAN96	39, ., -36	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.003.00085	22DEC94	45, ., -26	4 Days	0	1	MIL	NO	PSR	No	No
		329.003.00086	01DEC94	4, -54,-275	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.003.00291	28AUG96	57, -9, -63	8 Days	0	CON	MIL	NO	UNR	No	No
		329.004.00018	20JUN95	49, ., -24	21 Days	0	CON	SEV	NO	PSR	No	No
		329.004.00213	14SEP96	44, -11,-197	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.005.00115	08FEB95	3, -69, -72	6 Days	0	CON	MIL	NO	REL	No	No
		329.005.00331	23NOV96	3, ., -54	5 Days	0	CON	MIL	NO	REL	No	No
	DRY MOUTH (1/2 HOUR AFTER TAKING MEDICATION)	329.005.00012	22DEC94	4, -56,-161	13 Days	0	CON	MIL	NO	REL	No	No
Dyspepsia	INDIGESTION(MEXICAN SPICY FOOD)	329.006.00042	31DEC95	25, -33,-213	3 Days	0	3	MOD	NO	UNR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dyspepsia	STOMACH ACIDITY	329.003.00094	24NOV95	32, ., -41	Not Stated	0	CON	MIL	NO	PSR	Yes	No
	STOMACH UPSET	329.001.00069	22MAR95	35, ., -27	17 Days	0	2	MIL	NO	PSR	No	No
	UPSET STOMACH	329.006.00042	07JAN96	32, -26,-206	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	UPSET STOMACH (1/2 HOUR AFTER TAKING MEDICATION)	329.005.00012	22DEC94	4, -56,-161	13 Days	0	CON	MIL	NO	REL	No	No
Gastrointestinal Disorder	FOOD POISONING	329.005.00334	18MAR97	47, ., -9	3 Days	0	CON	SEV	NO	UNR	No	No
Increased Appetite	INCREASED APPETITE	329.001.00062	23OCT94	4, ., -23	Not Stated	0	CON	MOD	NO	PSR	No	No
Nausea	NAUSEA	329.001.00064	31JAN95	83, 29, -69	2 Days	0	CON	MIL	NO	UNR	No	No
		329.001.00069	21FEB95	6, ., -56	02:30 Hrs	0	1	MIL	NO	PSR	No	No
		329.001.00071	04APR95	41, ., -30	23 Days	0	CON	MIL	NO	PSR	No	No
		329.001.00123	22JAN96	19, ., -30	7 Days	0	CON	MIL	NO	UNR	No	No
			21FEB96	49, ., 0	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.003.00252	30APR96	21, ., -49	30 Mins	0	5	MIL	NO	PSR	No	No
		329.004.00018	09MAY95	7, ., -66	5 Days	0	CON	MOD	NO	REL	No	No
		329.004.00020	12NOV95	4, ., -12	3 Days	0	CON	MOD	NO	UNR	No	No
		329.005.00111	15FEB95	36, -21, -74	4 Days	0	CON	MIL	NO	PSR	No	No
			16MAR95	65, 9, -45	2 Days	0	CON	MIL	NO	PBU	No	No
		329.006.00037	15FEB95	19, ., -6	Not Stated	0	CON	MIL	NO	REL	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nausea	NAUSEA	329.006.00042	07JAN96	32, -26,-206	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
		329.007.00266	08MAR96	2, ., -69	04:00 Hrs	0	1	MIL	NO	PSR	No	No
		329.007.00311	18OCT96	16, -45,-188	02:00 Hrs	0	1	MIL	NO	UNR	No	No
		329.009.00135	21OCT95	20, ., -29	2 Days	0	CON	MIL	NO	UNR	No	No
		329.009.00197	20AUG96	236, 182, -12	4 Days	0		MOD	NO	UNR	No	No
		329.009.00198	08JAN96	7, ., -61	13 Days	0	CON	MIL	NO	PSR	No	No
		329.009.00200	20FEB96	29, ., -28	9 Days	0	CON	MIL	NO	PSR	No	No
		329.009.00238	03DEC96	22, ., -47	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.009.00276	04FEB97	15, ., -56	29 Days	0	CON	MIL	NO	PSR	No	No
		329.009.00330	21OCT96	1, ., -14	Not Stated	0	CON	MOD	STP	REL	No	No
	NAUSEA (POST TAKING MEDS)	329.001.00123	05JAN96	2, ., -47	04:30 Hrs	0	2	MIL	NO	PSR	No	No
			29JAN96	26, ., -23	5 Days	0	CON	MIL	NO	PSR	No	No
	NAUSEA AM	329.001.00069	22MAR95	35, ., -27	17 Days	0	2	MIL	NO	PSR	No	No
Tooth Disorder	ORTHODONTIC PAIN	329.006.00042	02JUL96	209, 152, -29	5 Days	0	CON	SEV	NO	UNR	Yes	No
	TEETH PAIN	329.005.00111	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
	TOOTHACHE	329.011.00285	04JUN96	18, ., -57	Not Stated	0	CON	MOD	NO	UNR	Yes	No
		329.012.00224	01OCT96	16, -51,-151	1 Days	0	CON	MIL	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Digestive System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Tooth Disorder	{TOOTH DISORDER}	329.005.00334	29JAN97	-2, ., -57	01:00 Hrs	0	CON	SEV	NO	UNR	No	No
Ulcerative Stomatitis	MOUTH SORES	329.010.00263	06OCT96	59, ., -13	8 Days	0	CON	MIL	NO	UNR	No	No
Vomiting	EMESIS	329.006.00042	07JAN96	32, -26,-206	1 Mins	0	1	MOD	NO	UNR	No	No
	NAUSEA AND VOMITING	329.002.00241	03MAR96	27, -30, -81	3 Days	0	2	MIL	NO	PBU	No	No
	NAUSEA-VOMITING	329.004.00018	01JUN95	30, ., -43	38 Days	0	CON	MIL	NO	PSR	No	No
	VOMITING	329.002.00246	02MAY96	15, ., -57	2 Days	0	2	MIL	NO	PBU	No	No
		329.007.00311	23JAN97	113, 53, -91	2 Days	0	12	MOD	NO	UNR	Yes	No
		329.009.00135	21OCT95	20, ., -29	2 Days	0	CON	MIL	NO	UNR	No	No
		329.009.00197	20AUG96	236, 182, -12	4 Days	0	3	MIL	NO	UNR	No	No
		329.009.00330	01NOV96	12, ., -3	2 Days	0	2	MIL	STP	PSR	No	No
	VOMITING DRY HEAVES	329.005.00111	17APR95	97, 41, -13	20:00 Hrs	0	CON	SEV	NO	UNR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Hemic and Lymphatic System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Anemia	ANEMIA	329.009.00306	03JUN96	-8, ., -77	Not Stated	0	CON	MIL	NO	UNR	Yes	No
Eosinophilia	INCREASED EOSINOPHILS	329.005.00120	22AUG95	-8, ., -65	Not Stated	0	CON	MIL	NO	UNR	No	No
			26OCT95	58, ., 0	Not Stated	0	CON	MIL	NO	UNR	No	No
Lymphadenopathy	SLIGHTLY ENLARGED NON-TENDER LEFT JUGULO-DIGASTRIC NODE	329.012.00225	04APR97	130, 66,-128	59 Days	0	1	MIL	NO	UNR	No	No
	SWOLLEN LYMPH NODES IN NECK	329.001.00071	13MAR95	19, ., -52	4 Days	0	CON	MIL	NO	UNR	No	No
Thrombocythemia	ELEVATED PLATELETS	329.003.00316	11FEB97	57, ., -7	Not Stated	0	CON	MIL	NO	PBU	No	No
Wbc Abnormality	ATYPICAL LYMPHS	329.005.00115	18APR95	72, 1, -3	1 Days	0	1	MIL	NO	PBU	No	No
	ELEVATED ATYPICAL LYMPHS	329.002.00107	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Metabolic and Nutritional Disorders

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Hyperglycemia	INCREASED GLUCOSE	329.005.00120	22AUG95	-8, ., -65	Not Stated	0	CON	MIL	NO	UNR	No	No
			26OCT95	58, ., 0	Not Stated	0	CON	MIL	NO	UNR	No	No
Thirst	INCREASE IN THIRST	329.009.00136	10OCT95	8, ., -62	15 Days	0	CON	MIL	NO	PSR	No	No
		329.009.00200	12FEB96	21, ., -36	3 Days	0	CON	MIL	NO	PSR	No	No
	INCREASED THIRST	329.002.00323	26NOV96	15, -44,-212	10 Days	0	CON	MIL	NO	REL	No	No
Weight Loss	WEIGHT LOSS	329.009.00276	13MAR97	52, ., -19	20 Days	0	CON	MIL	NO	PSR	No	No
	WEIGHT LOSS (12 POUNDS)	329.005.00115	10APR95	64, -8, -11	9 Days	0	CON	SEV	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Musculoskeletal System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Arthralgia	KNEE PAIN (RIGHT KNEE)	329.007.00311	18NOV96	47, -14,-157	5 Days	0	CON	MOD	NO	UNR	Yes	No
	LEFT KNEE PAIN	329.012.00224	03OCT96	18, -49,-149	18:00 Hrs	0	CON	MIL	NO	UNR	No	No
	SHOULDER PAIN IN AM	329.005.00254	18MAR96	33, -23,-225	3 Days	0	3	MOD	NO	UNR	No	No
	SHOULDER PAIN RIGHT SHOULDER	329.010.00263	11SEP96	34, ., -38	12:00 Hrs	0	1	MIL	NO	UNR	No	No
Myalgia	ARM AND LEG MUSCLE ACHES	329.001.00071	21MAR95	27, ., -44	5 Days	0	CON	MIL	NO	PBU	No	No
	MUSCLE ACHE	329.006.00042	07JAN96	32, -26,-206	34:00 Hrs	0	1	MIL	NO	UNR	No	No

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Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abnormal Dreams	NIGHTMARE	329.009.00198	03JAN96	2, ., -66	7 Days	0	6	MOD	NO	PSR	No	No
	VIVID DREAMING	329.009.00238	26NOV96	15, ., -54	8 Days	0	CON	MIL	NO	PSR	No	No
Anxiety	ANXIETY	329.012.00027	21DEC95	16, ., -21	Not Stated	0	CON	MOD	NO	PBU	Yes	No
	TENSION {ANXIOUS FEELING POST CONFRONTATION NON-MEDICATION RELATED}	329.004.00018	28MAY95	26, ., -47	1 Days	0	1	SEV	NO	UNR	Yes	No
Depersonalization	"SPACED OUT" FEELING	329.005.00331	08DEC96	18, ., -39	5 Days	0	CON	MIL	DCR	PSR	No	No
Depression	DEPRESSION (WORSENING)	329.012.00217	19JUN96	30, ., 5	8 Days	0	CON	SEV	NO	UNR	Yes	Yes
	WORSENING OF DEPRESSION	329.001.00123	18FEB96	46, ., -3	Not Stated	0	CON	SEV	STP	REL	No	Yes
Dizziness	DIZZINESS	329.002.00246	23MAY96	36, ., -36	7 Days	0	CON	MIL	NO	PSR	No	No
		329.003.00080	04JAN96	39, ., -36	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.003.00086	12DEC94	15, -43,-264	Not Stated	0	CON	MIL	NO	PBU	No	No
		329.003.00094	11DEC95	49, ., -24	02:00 Hrs	0	1	MOD	NO	PSR	No	No
		329.003.00252	29APR96	20, ., -50	1 Mins	0	1	MIL	NO	PSR	No	No
		329.003.00291	07AUG96	36, -30, -84	8 Days	0	1	MIL	NO	PBU	No	No
		329.005.00010	22DEC94	10, -48,-245	6 Days	0	4	MIL	NO	PSR	No	No
			20JAN95	39, -19,-216	24:00 Hrs	0	CON	MIL	NO	PSR	No	No
		329.005.00331	19DEC96	29, ., -28	5 Mins	0	CON	MIL	NO	PBU	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Dizziness	DIZZINESS	329.009.00330	21OCT96	1, ., -14	Not Stated	0	CON	MOD	STP	REL	No	No
		329.011.00164	24JAN96	34, ., -2	06:00 Hrs	0	7	MIL	NO	PSR	No	No
	DIZZINESS (ESPECIALLY DURING AEROBICS AND HEAVY LIFTING)	329.002.00323	19NOV96	8, -51,-219	37 Days	0	CON	MOD	NO	PSR	No	No
	DIZZINESS (WHEN STANDING)	329.002.00107	25AUG96	214, 158, -44	Not Stated	0	CON	MIL	NO	PSR	No	No
	DIZZINESS (WHEN STANDS QUICKLY)	329.002.00097	23MAR95	80, 22,-181	1 Mins	0	3	MIL	NO	PSR	No	No
	DIZZINESS IN AM	329.005.00331	09DEC96	19, ., -38	4 Days	0	3	MIL	NO	PBU	No	No
	DIZZINESS WHEN RIDING IN ELEVATOR OR ESCALATOR	329.001.00062	10NOV94	22, ., -5	9 Days	0		MIL	NO	UNR	No	No
	DIZZINESS WHEN STANDING UP	329.005.00298	09DEC96	202, 146, -46	3 Days	0	3	MIL	NO	PBU	No	No
	DIZZY	329.009.00197	18JAN96	21, -34,-227	1 Days	0	CON	MIL	NO	PBU	No	No
	DIZZY UPON POSITION CHANGE	329.001.00064	12NOV94	3, -52,-149	6 Days	0	5	MIL	NO	PSR	No	No
	FAINTING	329.002.00320	03SEP96	111, 50, -35	Not Stated	0	CON	MOD	NO	UNR	No	No
	SLIGHT DIZZINESS WHEN TAKING MEDS	329.009.00169	19DEC95	50, -16, -47	Not Stated	0	CON	MOD	NO	PSR	No	No
	SLIGHTLY DIZZY	329.005.00005	03NOV94	3, ., -6	14 Days	0	4	MIL	NO	PSR	No	No

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Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Drug Dependence	POSITIVE MARIJUANA URINE SCREEN (PROTOCOL DEVIATION)	329.002.00101	22JUN95	87, 29, -19	1 Days	0	CON	MOD	NO	UNR	No	No
Emotional Lability	PT. HOSPITALIZED FOR SUICIDAL IDEATION	329.002.00241	23MAY96	108, 52, 0	Not Stated	0	CON	SEV	STP	PBU	Yes	Yes
	SUICIDAL THOUGHTS	329.001.00123	18FEB96	46, ., -3	Not Stated	0	CON	SEV	STP	REL	No	Yes
Euphoria	LAUGHING A LOT {EUPHORIA}	329.005.00120	19SEP95	21, ., -37	17 Days	0	3	MOD	NO	UNR	No	No
Hostility	PT. HOSPITALIZED FOR HOMICIDAL IDEATION	329.002.00241	23MAY96	108, 52, 0	Not Stated	0	CON	SEV	STP	PBU	No	Yes
Hyperkinesia	AKATHISIA	329.007.00266	11MAR96	5, ., -66	46 Days	0	CON	MIL	NO	REL	No	No
Hypertonia	STIFF NECK	329.005.00298	29JUN96	39, -18,-209	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
Hypesthesia	NUMB LEFT UPPER LEG	329.012.00225	20MAR97	115, 51,-143	1 Days	0	1	MIL	NO	PBU	No	No
Insomnia	DIFFICULTY FALLING TO SLEEP	329.012.00224	01JAN97	108, 42, -59	1 Days	0	1	MIL	NO	PBU	Yes	No
	DROP IN SLEEP	329.008.00162	20DEC95	50, -16,-210	8 Days	0	1	MIL	INC	PSR	No	No
	INSOMNIA	329.006.00037	06FEB95	10, ., -15	Not Stated	0	CON	MOD	NO	REL	No	No
	INSOMNIA(WORSENING)	329.004.00018	07MAY95	5, ., -68	20 Days	0	CON	SEV	NO	REL	No	No
	MILD INITIAL INSOMNIA	329.009.00169	12DEC95	43, -23, -54	Not Stated	0	CON	MIL	NO	PSR	No	No
Manic Reaction	HYPOMANIA	329.009.00169	02JAN96	64, -2, -33	Not Stated	0	CON	SEV	STP	REL	No	No

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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Nervous System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervousness	FIDGETINESS	329.005.00331	23NOV96	3, ., -54	10:00 Hrs	0	CON	MIL	NO	PSR	No	No
	IRRITABILITY	329.003.00252	16MAY96	37, ., -33	13 Days	0	CON	MOD	DCR	PSR	No	No
	NERVOUS	329.005.00120	19SEP95	21, ., -37	2 Days	0		MIL	NO	UNR	No	No
			21SEP95	23, ., -35	8 Days	0	CON	MIL	NO	UNR	No	No
	RESTLESS AND JUMPY	329.008.00191	28FEB96	28, -34,-106	Not Stated	0	CON	MIL	NO	PSR	No	No
	RESTLESSNESS	329.009.00198	16JAN96	15, ., -53	8 Days	0	CON	MIL	NO	PSR	No	No
Somnolence	DAYTIME SLEEPINESS	329.009.00169	22NOV95	23, -43, -74	17 Days	0		MIL	NO	PSR	No	No
	FALLING ASLEEP IN THE AFTERNOON	329.002.00323	15NOV96	4, -55,-223	42 Days	0	CON	MOD	NO	PSR	No	No
	SLEEPINESS	329.008.00191	03FEB96	3, -59,-131	Not Stated	0	CON	MOD	NO	PSR	No	No
Tremor	HAND TREMORS	329.001.00123	04FEB96	32, ., -17	Not Stated	0	3	MIL	NO	PSR	No	No
		329.005.00114	01MAR95	30, -28, -68	22 Days	0	CON	MIL	NO	REL	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Asthma	BRONCHOSPASM	329.012.00225	29MAR97	124, 60,-134	11 Days	0	CON	MOD	NO	UNR	Yes	No
	RECURRENT ASTHMA	329.012.00217	15JUN96	26, ., 1	5 Days	0	CON	MOD	NO	UNR	Yes	No
Bronchitis	BRONCHITIS	329.006.00037	06FEB95	10, ., -15	8 Days	0	CON	MOD	NO	UNR	Yes	No
		329.007.00311	17MAR97	166, 106, -38	15 Days	0	CON	MOD	NO	UNR	Yes	No
		329.008.00162	29NOV95	29, -37,-231	11 Days	0	1	MIL	NO	UNR	No	No
	BRONCHITIS SYMPTOMS: CONGESTION, COUGH	329.007.00311	22OCT96	20, -41,-184	12 Days	0	CON	MOD	NO	UNR	Yes	No
	BRONCHITIS WITH BRONCHOSPASMS	329.001.00123	13JAN96	10, ., -39	13 Days	0	CON	MOD	NO	UNR	Yes	No
Cough Increased	CONGESTED COUGH	329.001.00064	24DEC94	45, -10,-107	18 Days	0	CON	MIL	NO	UNR	No	No
	COUGH	329.001.00207	05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No	No
		329.002.00241	09APR96	64, 8, -44	22 Days	0	CON	MOD	NO	UNR	Yes	No
		329.005.00120	12SEP95	14, ., -44	8 Days	0	CON	MOD	NO	UNR	Yes	No
		329.009.00238	23DEC96	42, ., -27	9 Days	0	CON	MIL	NO	UNR	Yes	No
	COUGHING	329.005.00120	23OCT95	55, ., -3	Not Stated	0	CON	MIL	NO	UNR	Yes	No
	DRY COUGH	329.001.00123	07JAN96	4, ., -45	19 Days	0	CON	MOD	NO	UNR	No	No
Dyspnea	SHORTNESS OF BREATH	329.003.00252	21MAY96	42, ., -28	30 Mins	0	1	MIL	DCR	PSR	No	No
Epistaxis	NOSEBLEEDS	329.005.00298	06JAN97	230, 174, -18	7 Days	0	8	SEV	NO	PSR	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Pharyngitis	PHARYNGITIS	329.002.00323	11APR97	151, 93, -76	8 Days	0	1	MIL	NO	UNR	Yes	No
	SORE THROAT	329.001.00069	09MAR95	22, ., -40	8 Days	0	CON	MIL	NO	UNR	No	No
		329.001.00071	13MAR95	19, ., -52	15 Days	0	CON	MOD	NO	UNR	No	No
		329.001.00207	10APR96	43, ., -15	2 Days	0	CON	MIL	NO	UNR	No	No
		329.005.00111	15FEB95	36, -21, -74	6 Days	0	CON	MOD	NO	UNR	Yes	No
			16MAR95	65, 9, -45	2 Days	0	CON	SEV	NO	UNR	Yes	No
			16APR95	96, 40, -14	2 Days	0	CON	SEV	NO	UNR	Yes	No
		329.005.00334	03FEB97	4, ., -52	8 Days	0	CON	MOD	NO	UNR	Yes	No
		329.007.00266	27APR96	52, ., -19	13 Days	0	CON	MOD	NO	UNR	Yes	No
		329.009.00238	23DEC96	42, ., -27	9 Days	0	CON	MIL	NO	UNR	Yes	No
		329.009.00276	20FEB97	31, ., -40	12:00 Hrs	0	CON	MIL	NO	PBU	No	No
			13MAR97	52, ., -19	6 Days	0	CON	MIL	NO	PBU	Yes	No
	TONSILLITIS	329.002.00107	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes	No
Respiratory Disorder	COLD AND CONGESTION	329.010.00263	22SEP96	45, ., -27	8 Days	0	CON	MIL	NO	UNR	Yes	No
	COLD SYMPTOMS	329.003.00080	23DEC95	27, ., -48	12 Days	0	1	MIL	NO	UNR	No	No
		329.012.00224	22SEP96	7, -60,-160	11 Days	0	CON	MIL	NO	UNR	No	No
	COLD SYMPTOMS:STUFFY NOSE, SORE THROAT, FEVER	329.005.00298	08DEC96	201, 145, -47	12 Days	0	CON	MOD	NO	UNR	Yes	No
	COLD {SYMPTOMS}	329.003.00086	12DEC94	15, -43,-264	3 Days	0	CON	MIL	NO	UNR	Yes	No

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Appendix D.1

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Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory Disorder	COLD {SYMPTOMS}	329.003.00086	15MAY95	169, 112,-110	5 Days	0	CON	MIL	NO	UNR	Yes	No
		329.003.00315	18NOV96	7, ., -53	3 Days	0	1	MIL	NO	UNR	Yes	No
	COMMON COLD	329.012.00027	15DEC95	10, ., -27	13 Days	0	CON	SEV	NO	UNR	Yes	No
		329.012.00217	03JUN96	14, ., -11	10 Days	0	CON	MIL	NO	UNR	Yes	No
	RESPIRATORY CONGESTION	329.005.00293	18MAR97	7, ., -50	8 Days	0	CON	MOD	NO	PBU	Yes	No
	UPPER RESPIRATORY CONGESTION	329.001.00069	09MAR95	22, ., -40	12 Days	0	CON	MIL	NO	UNR	No	No
	UPPER RESPIRATORY INFECTION	329.001.00071	13MAR95	19, ., -52	15 Days	0	CON	MOD	NO	UNR	No	No
	UPPER RESPIRATORY INFECTION (COLD)	329.004.00213	12AUG96	11, -44,-230	19 Days	0	CON	MIL	NO	UNR	Yes	No
Rhinitis	CONGESTION {NOSE}	329.009.00238	23DEC96	42, ., -27	9 Days	0	CON	MIL	NO	UNR	Yes	No
	NASAL CONGESTION	329.001.00064	24DEC94	45, -10,-107	18 Days	0	CON	MIL	NO	UNR	No	No
	NASAL STUFFINESS	329.005.00111	16FEB95	37, -20, -73	49 Days	0	CON	SEV	NO	PBU	Yes	No
	NOSE PAIN	329.005.00111	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
	RUNNY NOSE	329.005.00120	12SEP95	14, ., -44	7 Days	0	CON	MIL	NO	UNR	Yes	No
	STUFFY NOSE	329.001.00207	05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No	No
Sinusitis	HEAD CONGESTION	329.001.00207	22MAR96	24, ., -34	4 Days	0	CON	MIL	NO	UNR	No	No
			05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Respiratory System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Sinusitis	SINUS CONGESTION	329.005.00298	30JUN96	40, -17,-208	2 Days	0	CON	MOD	NO	UNR	Yes	No
			28AUG96	99, 43,-149	8 Days	0	CON	MOD	NO	UNR	No	No
		329.007.00311	26DEC96	85, 25,-119	2 Days	0	CON	MIL	NO	UNR	Yes	No
	SINUS HEADACHE	329.006.00042	07JAN96	32, -26,-206	5 Days	0	CON	MOD	NO	UNR	No	No
	SINUS HEADACHE AND CONGESTION	329.005.00298	02JUN96	12, -45,-236	4 Days	0	CON	MOD	NO	UNR	Yes	No
	SINUS INFECTION	329.001.00207	18APR96	51, ., -7	15 Days	0	CON	MOD	NO	UNR	Yes	No
		329.005.00111	17APR95	97, 41, -13	Not Stated	0	CON	SEV	STP	UNR	Yes	No
		329.005.00331	17DEC96	27, ., -30	11 Days	0	CON	SEV	NO	UNR	Yes	No
	SINUS STUFFINESS	329.005.00111	16FEB95	37, -20, -73	49 Days	0	CON	SEV	NO	PBU	Yes	No
	SINUSITIS	329.007.00311	23OCT96	21, -40,-183	31 Days	0	CON	MIL	NO	UNR	Yes	No
	TOOTHACHE/QUESTIONABLE SINUS INFECTION	329.005.00115	23FEB95	18, -54, -57	26 Days	0	CON	SEV	NO	UNR	Yes	No

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Skin and Appendages

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Acne	ACNE	329.005.00293	26MAR97	15, ., -42	Not Stated	0	CON	MIL	NO	UNR	No	No
Contact Dermatitis	CONTACT DERMATITIS LOWER AND UPPER HIP	329.009.00136	10OCT95	8, ., -62	15 Days	0	CON	MIL	NO	PBU	No	No
Herpes Zoster	VARICELLA	329.002.00246	12JUN96	56, ., -16	5 Days	0		MOD	NO	UNR	No	No
Maculopapular Rash	RASH ON WRIST ELBOWS,ANKLE,(MACULOPAPULAR)	329.009.00302	03APR96	8, ., -7	Not Stated	0	CON	MOD	STP	PSR	No	No
Rash	NON PAPULAR RASH (UPPER TORSO AND BACK)	329.009.00200	19MAR96	57, ., 0	Not Stated	0	CON	MIL	NO	PBU	No	No
	RASH	329.004.00213	20DEC96	141, 87,-100	8 Days	0	CON	MIL	NO	PBU	No	No
	RASH ON BACK	329.003.00086	13FEB95	78, 21,-201	72 Days	0	CON	MOD	NO	PSR	Yes	No
	RASH ON BOTH FOREARMS	329.005.00111	30JAN95	20, -37, -90	6 Days	0	CON	MOD	NO	PBU	No	No
	RASH {MINOR OF UNKNOWN CAUSES}	329.003.00094	28OCT95	5, ., -68	24:00 Hrs	0	1	MIL	NO	PBU	No	No
Sweating	SWEATY HANDS	329.002.00097	17JAN95	15, -44,-246	127 Days	0		MIL	NO	PBU	No	No
Urticaria	HIVES	329.005.00010	02MAR95	80, 23,-175	6 Days	0	CON	MOD	NO	UNR	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Special Senses

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Abnormal Vision	BLURRING VISION	329.002.00097	18JAN95	16, -43,-245	126 Days	0	99	MOD	NO	PSR	No	No
	BLURRY VISION	329.004.00018	20JUN95	49, ., -24	21 Days	0	CON	MOD	NO	PSR	No	No
Eye Disorder	EYE INFECTION	329.008.00162	07DEC95	37, -29,-223	11 Days	0	1	MIL	NO	UNR	No	No
Otitis Media	EAR INFECTION	329.002.00320	09SEP96	117, 56, -29	11 Days	0	1	MOD	NO	UNR	Yes	No
	EAR INFECTION LEFT	329.012.00225	29MAR97	124, 60,-134	11 Days	0	CON	MOD	NO	UNR	Yes	No
	OTITIS MEDIA(EAR INFECTION)	329.012.00027	26NOV95	-10, ., -46	12 Days	0	CON	MOD	NO	UNR	Yes	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Urogenital System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Albuminuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS POSITIVE PROTEIN]	329.005.00334	27MAR97	56, ., 0	1 Days	0	CON	MOD	NO	UNR	No	No
	URINE 1+PROTEIN	329.001.00064	28MAR95	139, 85, -13	Not Stated	0	CON	MIL	NO	PBU	No	No
		329.001.00069	13APR95	57, ., -5	Not Stated	0	CON	MIL	NO	PBU	No	No
Breast Pain	BREAST SORENESS {FEMALE}	329.008.00158	12SEP95	-1, -63,-106	16 Days	0		MIL	NO	UNR	No	No
Dysmenorrhea	CRAMPS (MENSTRUAL)	329.010.00282	19SEP96	56, ., -23	12:00 Hrs	0	CON	MIL	NO	PBU	Yes	No
	MENSTRUAL CRAMPS	329.005.00254	09MAR96	24, -32,-234	12:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			28MAY96	104, 49,-154	06:30 Hrs	0	CON	SEV	NO	UNR	Yes	No
		329.005.00298	06JUL96	46, -11,-202	2 Days	0	CON	MOD	NO	UNR	Yes	No
			04NOV96	167, 111, -81	24:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			07DEC96	200, 144, -48	3 Days	0	CON	MOD	NO	UNR	Yes	No
			07JAN97	231, 175, -17	3 Days	0	CON	MOD	NO	UNR	Yes	No
		329.012.00224	09OCT96	24, -43,-143	Not Stated	0		MOD	NO	UNR	Yes	No
Kidney Function Abnormal	DECREASED UREA NITROGEN	329.005.00120	22AUG95	-8, ., -65	66 Days	0	CON	MIL	NO	UNR	No	No
Menstrual Disorder	2 MENSTRUAL CYCLES IN JULY-2 WEEKS APART	329.005.00010	03JUL95	203, 146, -52	6 Days	0	CON	MOD	NO	PBU	No	No
			18JUL95	218, 161, -37	7 Days	0	CON	MOD	NO	PBU	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

Treatment Group=PLACEBO Body System=Urogenital System

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Pyuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS MODERATE BACTERIA]	329.005.00334	27MAR97	56, ., 0	1 Days	0	CON	MOD	NO	UNR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.001.00063	Abdominal Pain	STOMACH ACHE	09NOV94	2, ., -46	8 Days	20	5	MIL	NO	PSR	No	No
			30NOV94	23, ., -25	Not Stated	20	CON	MIL	NO	PSR	No	No
	Decreased Appetite	ANOREXIA	10NOV94	3, ., -45	Not Stated	20	CON	MIL	NO	PSR	No	No
	Diarrhea	DIARRHEA	09NOV94	2, ., -46	14 Days	20	3	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	10NOV94	3, ., -45	5 Mins	20	1	MIL	NO	PSR	No	No
	Ear Pain	RIGHT EARACHE	05DEC94	28, ., -20	9 Days	20	CON	MOD	NO	UNR	Yes	No
	Manic Reaction	MANIA SYMPTOMS	11DEC94	34, ., -14	Not Stated	20	CON	MOD	STP	PSR	No	No
	Nausea	NAUSEA	30NOV94	23, ., -25	Not Stated	20	CON	MIL	NO	PSR	No	No
	Paresthesia	TINGLING LEG AND FEET	10NOV94	3, ., -45	7 Days	20	2	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	05DEC94	28, ., -20	9 Days	20	CON	MOD	NO	UNR	Yes	No
	Tendinous Disorder	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENED) [TENDONITIS]	05NOV94	-3, ., -50	12 Days	0	CON	MIL	NO	UNR	No	No
	Trauma	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENED) [SPRAIN]	05NOV94	-3, ., -50	12 Days	0	CON	MIL	NO	UNR	No	No
	Tremor	TREMBLING JAW	10NOV94	3, ., -45	7 Days	20	3	MIL	NO	PSR	No	No
		TREMORS	11DEC94	34, ., -14	Not Stated	20	3	MIL	NO	PSR	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.001.00065	Depression	WORSENING OF DEPRESSION HOSPITALIZED	30NOV94	14, ., 0	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Dizziness	DIZZINESS	18NOV94	2, ., -12	Not Stated	20	4	MIL	NO	REL	No	No
		LIGHTHEADED	18NOV94	2, ., -12	Not Stated	20	4	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	21NOV94	5, ., -9	Not Stated	20	CON	MIL	NO	REL	No	No
	Hostility	NEEDED 6 STITCHES TO HAND AFTER BREAKING PICTURES (DUE TO ANGER) RESULTED IN HOSPITALIZATION TO PREVENT AGGRESSION AGAINST SELF	30NOV94	14, ., 0	1 Days	20	CON	MOD	STP	PBU	No	Yes
	Nausea	NAUSEA	18NOV94	2, ., -12	Not Stated	20	4	MOD	NO	REL	No	No
	Vomiting	VOMITING	21NOV94	5, ., -9	1 Mins	20	1	MIL	NO	REL	No	No
329.001.00068	Dry Mouth	DRY MOUTH	10FEB95	3, ., -69	Not Stated	20	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	01MAR95	22, ., -50	29 Days	20	CON	MIL	NO	PSR	No	No
	Insomnia	MIDDLE INSOMNIA	15FEB95	8, ., -64	Not Stated	20	CON	MOD	NO	PSR	No	No
	Pharyngitis	SORE THROAT	27MAR95	48, ., -24	2 Days	40	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	VIRAL UPPER RESPIRATORY INFECTION	27FEB95	20, ., -52	7 Days	20	CON	MOD	NO	UNR	Yes	No
	Urine Abnormality	CLOUDY URINE ON URINALYSIS	05APR95	57, ., -15	Not Stated	40	CON	MIL	NO	UNR	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.001.00072	Decreased Appetite	APPETITE DECREASED	28MAR95	9, ., -23	Not Stated	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES	21MAR95	2, ., -30	3 Days	20	2	MIL	NO	PSR	No	No
329.001.00121	Acne	ACNE WORSE	12APR95	9, -48,-145	21 Days	20	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZY	23MAY95	50, -7,-104	20 Mins	30	1	MIL	NO	PBU	No	No
	Nausea	NAUSEA	06APR95	3, -54,-151	27 Days	20	CON	MIL	NO	PSR	No	No
	Weight Loss	WEIGHT LOSS	11APR95	8, -49,-146	22 Days	20	CON	MIL	NO	PSR	No	No
329.001.00205	Decreased Appetite	SLIGHT DECREASE APPETITE	09FEB96	3, ., -5	Not Stated	20	CON	MIL	NO	PSR	No	No
	Manic Reaction	MANIA AND HYPOMANIA SYMPTOMS	10FEB96	4, ., -4	Not Stated	20	CON	SEV	STP	PSR	No	No
329.001.00206	Dyspepsia	STOMACH UPSET	10MAR96	19, ., -39	2 Days	20	CON	MIL	NO	PBU	No	No
	Headache	HEADACHE	10MAR96	19, ., -39	2 Days	20	CON	MIL	NO	PBU	No	No
329.002.00055	Hostility	ALLEGATIONS OF SEXUAL AGGRESSION	25JUL94	32, -24,-124	1 Days	30		MIL	NO	UNR	No	No
	Photosensitivity	SUNBURN,APPROPRIATE TO DEGREE OF EXPOSURE(BEACH)	13JUL94	20, -36,-136	3 Days	20	1	MIL	NO	UNR	No	No
329.002.00058	Emotional Lability	INTENTIONAL OVERDOSE {TYLENOL OVERDOSE TOOK 80 PILLS}	19JAN95	122, 64, 3	1 Days	40	CON	MOD	STP	PBU	No	Yes

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.002.00058	Infection	REPORT OF SORE THROAT.POSITIVE CULTURE,THROAT.BETA HEMOLYTIC STREP,GROUP A.	16NOV94	58, -1, -61	3 Days	40	CON	MIL	NO	UNR	Yes	No
329.002.00099	Amnesia	"FORGETFUL"	30JUN95	121, 66,-134	63 Days	40	3	MIL	NO	PBU	No	No
	Dizziness	CONSTANT DIZZINESS (DAILY)	28JUN95	119, 64,-136	93 Days	40	CON	MOD	NO	PSR	No	No
		DIZZINESS ARISING FROM LAYING SITTING OR SOMETIMES WHEN SITTING	28MAR95	27, -29,-228	28 Days	20	78	MOD	NO	PSR	No	No
		DIZZINESS WHEN ARISING SUDDENLY	14MAR95	13, -43,-242	11 Days	20	33	MOD	NO	PSR	No	No
		DIZZY	04MAR95	3, -53,-252	30 Mins	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	03APR95	33, -23,-222	02:00 Hrs	20	CON	MIL	NO	PSR	Yes	No
	Insomnia	INITIAL INSOMNIA (INCREASE 2 HOURS)	24MAY95	84, 29,-171	02:00 Hrs	40	39	SEV	NO	PBU	No	No
		INITIAL INSOMNIA MOST NIGHTS INCREASE 2 HOURS	13JUN95	104, 49,-151	33 Days	40	10	MOD	NO	PSR	No	No
		RESTLESS AT NIGHT	05MAR95	4, -52,-251	10 Days	20	2	MIL	NO	PSR	No	No
	Nausea	NAUSEA	18APR95	48, -8,-207	7 Days	40	21	MIL	NO	PSR	No	No
		NAUSEA (FOR 10 MINUTES DAILY BEFORE BREAKFAST)	30JUN95	121, 66,-134	63 Days	40	25	MIL	NO	PSR	No	No
		NAUSEATED	04MAR95	3, -53,-252	11 Days	20	CON	MIL	NO	PSR	No	No
	Palpitation	HEART PALPITATIONS	30JUN95	121, 66,-134	63 Days	40	3	MOD	NO	PSR	No	No
	Respiratory Disorder	HEAD COLD	16MAR95	15, -41,-240	6 Days	20	CON	MIL	NO	UNR	Yes	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.002.00099	Rhinitis	STUFFY NOSE	29MAR95	28, -28,-227	16:00 Hrs	20	CON	MIL	NO	UNR	Yes	No
329.002.00102	Abdominal Pain	STOMACH ACHES	05SEP95	146, 92,-106	36 Days	40	1	MOD	NO	REL	No	No
	Dizziness	DIZZINESS	05SEP95	146, 92,-106	36 Days	40	1	MOD	NO	REL	No	No
	Dyspepsia	HEARTBURN ON AN EMPTY STOMACH WHEN TAKING MEDS.	09MAY95	27, -28,-225	7 Days	30	7	MIL	NO	REL	No	No
	Trauma	MOTOR VEHICLE ACCIDENT	02AUG95	112, 58,-140	1 Days	40	1	MIL	NO	UNR	No	No
329.002.00105	Diarrhea	DIARRHEA	03AUG95	8, ., -14	8 Days	20	4	MIL	NO	PSR	No	No
329.002.00106	Abdominal Pain	STOMACH ACHES	03AUG95	8, ., -40	10 Mins	20	10	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	03AUG95	8, ., -40	03:00 Hrs	20	CON	MIL	NO	REL	No	No
	Hostility	OPPOSITIONAL DEFIANT DISORDER	15SEP95	51, ., 3	16 Days	40	CON	SEV	NO	PBU	No	Yes
329.002.00242	Somnolence	MILD SEDATION	07MAR96	30, -29, -90	8 Days	30	1	MIL	NO	PSR	No	No
329.002.00245	Emotional Lability	TYLENOL OVERDOSE {INTENTIONAL}	10APR96	14, ., -4	1 Days	20	1	SEV	STP	UNR	No	Yes
329.002.00319	Abdominal Pain	STOMACH PAIN	09JUL96	71, 15,-174	16:00 Hrs	30	1	MIL	NO	UNR	No	No
	Asthenia	FATIGUE	01MAY96	2, -55,-243	202 Days	20	CON	MIL	NO	REL	No	No
	Chest Pain	CHEST PAIN	09JUL96	71, 15,-174	16:00 Hrs	30	1	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	01MAY96	2, -55,-243	202 Days	20	CON	MIL	NO	REL	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.002.00319	Headache	HEADACHE	18NOV96	203, 147, -42	04:00 Hrs	30	1	MOD	NO	PBU	Yes	No
	Infection	FLU SYMPTOMS - FEVER, HEADACHES, MUSCLE ACHES	06DEC96	221, 165, -24	6 Days	30	1	MOD	NO	UNR	No	No
	Pharyngitis	THROAT PAIN	09JUL96	71, 15,-174	16:00 Hrs	30	1	MIL	NO	UNR	No	No
329.003.00075	Amenorrhea	AMENORRHEA	01FEB95	8, -49,-232	161 Days	20	CON	MOD	NO	PSR	No	No
	Asthenia	TIRED	14JUN95	141, 85, -99	2 Days	20		MIL	NO	UNR	No	No
	Decreased Appetite	APPETITE SUPPRESSION	05APR95	71, 15,-169	98 Days	20	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	08MAR95	43, -14,-197	15 Days	20	CON	MOD	INC	PSR	No	No
			01JUL95	158, 102, -82	10 Days	20	CON	MIL	NO	PBU	No	No
			15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	25JAN95	1, -56,-239	4 Days	20	CON	MIL	NO	PSR	No	No
	Female Genital Disorders	ANORGASMIA {FEMALE}	25JAN95	1, -56,-239	57 Days	20	CON	SEV	DCR	REL	No	No
			23MAR95	58, 2,-182	56 Days	20	CON	MIL	NO	REL	No	No
	Gastrointestinal Disorder	NAUSEA AND REFLUX {ESOPHAGEAL}	15FEB95	22, -35,-218	24:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES	08FEB95	15, -42,-225	Not Stated	20	CON	MIL	NO	PBU	No	No
	Hyperkinesia	HYPERACTIVITY	13JUL95	170, 114, -70	70 Days	20	CON	MIL	NO	PBU	No	No
	Insomnia	TROUBLE SLEEPING	15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU	No	No
	Nausea	NAUSEA	08MAR95	43, -14,-197	128 Days	20	CON	MIL	INC	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.003.00075	Nausea	NAUSEA	15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU	No	No
	Nervousness	NERVOUS JITTERY TREMULOUS	25JAN95	1, -56,-239	8 Days	20	CON	MIL	NO	PSR	No	No
		TEETH CHATTERING(JITTERINESS)	16MAR95	51, -6,-189	13 Days	20	CON	MIL	NO	REL	No	No
	Somnolence	DROWSINESS	02MAR95	37, -20,-203	5 Days	20	CON	MIL	DCR	PSR	No	No
	Tachycardia	HEART RACING	06MAY95	102, 46,-138	12 Days	20	CON	MIL	NO	PSR	No	No
329.003.00077	Dry Mouth	DRY MOUTH	16APR95	42, -18, -52	10 Days	30		MIL	NO	PSR	No	No
	Dyspepsia	UPSET STOMACH AND HEARTBURN	12MAR95	7, -53, -87	08:30 Hrs	20	CON	MIL	NO	PBU	No	No
	Insomnia	INSOMNIA	24MAY95	80, 21, -14	Not Stated	30	CON	SEV	DCR	PSR	No	No
	Nausea	NAUSEA	21APR95	47, -13, -47	3 Days	30	3	MIL	NO	PSR	No	No
			02MAY95	58, -2, -36	35 Days	30	2	MIL	NO	PSR	No	No
	Tachycardia	HEART RACING	20APR95	46, -14, -48	3 Days	30	3	MIL	NO	PSR	No	No
329.003.00081	Dizziness	DIZZINESS	28DEC95	18, ., -41	14 Days	20	CON	MIL	NO	PBU	No	No
	Increased Appetite	INCREASED APPETITE	19DEC95	9, ., -50	16 Days	20	CON	MIL	NO	PSR	No	No
	Somnolence	SOMNOLENCE	19DEC95	9, ., -50	23 Days	20	CON	MIL	NO	PSR	No	No
329.003.00089	Asthenia	TIRED	10MAR95	4, ., -56	Not Stated	20	CON	MIL	NO	PSR	No	No
	Constipation	CONSTIPATION	21MAR95	15, ., -45	7 Days	20		MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.003.00089	Cough Increased	COUGH	02APR95	27, ., -33	Not Stated	20	CON	MIL	NO	UNR	No	No
	Dizziness	DIZZINESS WHEN STANDING	14MAR95	8, ., -52	24:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	21MAR95	15, ., -45	Not Stated	20	CON	MIL	NO	PSR	No	No
	Euphoria	ELATION AND EXPANSIVE MOOD	04APR95	29, ., -31	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Headache	HEADACHE	14MAR95	8, ., -52	8 Days	20	CON	MIL	NO	PSR	Yes	No
			17APR95	42, ., -18	24:00 Hrs	20		MOD	NO	UNR	Yes	No
	Insomnia	SLEEP PROBLEMS-EXAMPLE WAKES UP TOO EARLY	14MAR95	8, ., -52	Not Stated	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	10MAR95	4, ., -56	Not Stated	20	CON	MIL	NO	PSR	No	No
329.003.00091	Dizziness	DIZZINESS"FELT LIKE FAINTING"	01APR95	9, -46,-236	01:30 Hrs	20		MOD	NO	PSR	Yes	No
	Headache	HEADACHE	25MAR95	2, -53,-243	15 Mins	20		MIL	NO	PBU	No	No
	Nausea	NAUSEA	26MAR95	3, -52,-242	10 Mins	20		MIL	NO	PBU	No	No
	Pharyngitis	SORE THROAT	21SEP95	182, 128, -63	11 Days	40	1	MOD	NO	UNR	Yes	No
	Respiratory Disorder	COLD {SYMPTOMS}	28APR95	36, -19,-209	5 Days	40	1	MIL	NO	UNR	Yes	No
			20OCT95	211, 157, -34	11 Days	40	CON	MIL	NO	UNR	Yes	No
329.003.00248	Anemia	ANEMIA	23APR96	54, ., -9	Not Stated	30	CON	MIL	NO	PBU	No	No
	Arrhythmia	IRREGULAR PULSE	22FEB96	-8, ., -70	Not Stated	0	CON	MIL	NO	UNR	No	No

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329.003.00248	Dizziness	DIZZINESS	26MAR96	26, ., -37	17 Days	30	CON	MIL	NO	PSR	No	No
	Infection	FLU	02APR96	33, ., -30	10 Days	40	CON	MIL	NO	UNR	No	No
	Withdrawal Syndrome	MIGRAINE HEADACHE {WITHDRAWAL SYMPTOM}	29APR96	60, ., -3	6 Days	30	CON	SEV	NO	REL	Yes	Yes
329.003.00250	Allergic Reaction	ALLERGIES	29APR96	47, -11, -28	24:00 Hrs	40		MIL	NO	UNR	Yes	No
	Dizziness	DIZZINESS	15MAR96	2, -56, -73	5 Mins	20	2	MIL	NO	PBU	No	No
	Emotional Lability	OVERDOSE {INTENTIONAL}	19APR96	37, -21, -38	21 Days	40	CON	MOD	NO	UNR	No	Yes
			27MAY96	75, 18, 0	01:00 Hrs	30	1	SEV	STP	UNR	No	Yes
	Nausea	NAUSEOUS	15MAR96	2, -56, -73	12 Days	20	CON	MIL	NO	PBU	No	No
	Somnolence	SLEEPINESS	19APR96	37, -21, -38	Not Stated	40	CON	MOD	DCR	PSR	No	No
		SLEEPY	15MAR96	2, -56, -73	12 Days	20	CON	MIL	NO	PBU	No	No
329.003.00313	Dry Mouth	DRY MOUTH	18MAY96	2, ., -10	Not Stated	20	CON	MIL	NO	PSR	No	No
	Emotional Lability	SUPERFICIAL CUTS RISK TO SELF	28MAY96	12, ., 0	6 Days	20	CON	SEV	STP	PBU	No	Yes
	Hallucinations	AUDITORY HALLUCINATIONS	28MAY96	12, ., 0	6 Days	20	CON	SEV	STP	PBU	No	Yes
329.004.00015	Abdominal Pain	STOMACH ACHES INTERMITTENT AM AND LUNCH	08DEC94	1, -57,-202	12 Days	20	6	MIL	NO	REL	No	No
	Allergic Reaction	CONGESTION-NASAL DUE TO ALLERGIES	09JUN95	184, 127, -19	Not Stated	20	CON	MOD	NO	UNR	No	No

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Intent-to-Treat Population

Treatment Group=PAROXETINE

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329.004.00015	Allergic Reaction	ITCHY EYES-DUE TO ALLERGIES	09JUN95	184, 127, -19	Not Stated	20	CON	MOD	NO	UNR	No	No
	Asthenia	FATIGUE	08DEC94	1, -57,-202	15 Days	20	CON	MIL	NO	REL	No	No
			22DEC94	15, -43,-188	11 Days	20	CON	MOD	NO	REL	No	No
		FATIGUE NEW	02FEB95	57, -1,-146	43 Days	20	CON	MOD	NO	PBU	No	No
	Conjunctivitis	CONJUNCTIVITIS BILATERAL	08DEC94	1, -57,-202	11 Days	20	CON	MOD	NO	UNR	Yes	No
			03JAN95	27, -31,-176	12 Days	20	CON	MOD	NO	UNR	Yes	No
	Cough Increased	COUGH	12DEC94	5, -53,-198	5 Days	20	CON	MIL	NO	UNR	Yes	No
			02FEB95	57, -1,-146	34 Days	20	CON	MOD	NO	UNR	Yes	No
	Dizziness	DIZZINESS	18FEB95	73, 16,-130	31 Days	20	CON	MIL	NO	PBU	No	No
			05JUN95	180, 123, -23	2 Days	20	CON	MOD	NO	UNR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	17APR95	131, 74, -72	30 Mins	20	1	MOD	NO	UNR	Yes	No
		PREMENSTRUAL CRAMPS	29JAN95	53, -5,-150	02:00 Hrs	20	1	MOD	NO	UNR	Yes	No
	Emotional Lability	SELF-MUTILATION	07JAN95	31, -27,-172	30 Mins	20	1	MIL	NO	UNR	No	No
		SUICIDAL IDEATION	18FEB95	73, 16,-130	03:00 Hrs	20	1	MIL	NO	UNR	No	No
	Headache	HEADACHE	20DEC94	13, -45,-190	03:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			10JAN95	34, -24,-169	01:00 Hrs	20	1	SEV	NO	PBU	Yes	No
			17JAN95	41, -17,-162	02:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			14FEB95	69, 12,-134	01:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			24FEB95	79, 22,-124	01:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			05JUN95	180, 123, -23	2 Days	20	CON	MOD	NO	UNR	No	No
		HEADACHES 1 DAILY	11DEC94	4, -54,-199	7 Days	20	3	MIL	NO	PSR	Yes	No
	Pharyngitis	SORE THROAT	02FEB95	57, -1,-146	34 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	11DEC94	4, -54,-199	10 Days	20	CON	MIL	NO	UNR	Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.004.00015	Rhinitis	NASAL CONGESTION	02FEB95	57, -1,-146	34 Days	20	CON	MOD	NO	UNR	Yes	No
	Tremor	HANDS TREMBLING INTERMITTENT	10DEC94	3, -55,-200	14 Days	20	4	MOD	NO	REL	No	No
329.004.00017	Abdominal Pain	STOMACH PAIN	11NOV95	235, 179, -3	Not Stated	20	CON	MIL	NO	UNR	No	No
	Anxiety	ANXIETY	23MAR95	2, -55,-236	4 Days	20	CON	SEV	DCR	REL	No	No
	Chills	SHIVERING AND SHAKING	28MAR95	7, -50,-231	12 Days	20	CON	MIL	NO	PSR	No	No
	Constipation	CONSTIPATION	13APR95	23, -34,-215	12 Days	20	CON	MOD	NO	REL	No	No
			25APR95	35, -22,-203	28 Days	20	CON	MIL	NO	REL	No	No
	Cough Increased	COUGHING	23MAY95	63, 7,-175	15 Days	30	CON	MOD	NO	UNR	Yes	No
	Dizziness	DIZZINESS	06NOV95	230, 174, -8	5 Days	20	CON	MIL	NO	UNR	No	No
	Fever	FEVER	29AUG95	161, 105, -77	18:00 Hrs	30		MOD	NO	UNR	Yes	No
	Insomnia	INSOMNIA	27MAR95	6, -51,-232	5 Days	0	CON	MIL	NO	PSR	No	No
		INSOMNIA(NO SLEEP)	24MAR95	3, -54,-235	3 Days	20	CON	SEV	DCR	REL	No	No
	Manic Reaction	HOSPITALIZATION RULE-OUT HYPOMANIA	31AUG95	163, 107, -75	3 Days	30	CON	MIL	NO	UNR	No	Yes
	Nausea	NAUSEA	23MAR95	2, -55,-236	4 Days	20	CON	SEV	DCR	REL	No	No
			27MAR95	6, -51,-232	5 Days	0	CON	MIL	NO	REL	No	No
			06NOV95	230, 174, -8	7 Days	20	CON	MOD	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	09NOV95	233, 177, -5	5 Days	20	CON	MOD	NO	UNR	No	No
	Respiratory Disorder	RHINITIS-COLD	14SEP95	177, 121, -61	3 Days	30	CON	MIL	NO	UNR	Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.004.00017	Rhinitis	RHINITIS	09NOV95	233, 177, -5	5 Days	20	CON	MOD	NO	UNR	No	No
	Tremor	TREMORS	21APR95	31, -26,-207	11 Days	20	CON	MOD	NO	REL	No	No
			02MAY95	42, -15,-196	87 Days	30	CON	SEV	NO	REL	Yes	No
			28JUL95	129, 73,-109	40 Days	30	CON	MOD	NO	REL	No	No
			06SEP95	169, 113, -69	57 Days	30	CON	MIL	NO	REL	No	No
	Vomiting	VOMITING	08NOV95	232, 176, -6	5 Days	20	3	MOD	NO	UNR	No	No
329.004.00019	Dizziness	DIZZY GETTING OUT OF BED OR AFTER LYING DOWN A LONG TIME	03JUN95	4, ., -11	Not Stated	20		MIL	NO	REL	No	No
	Headache	HEADACHE	06JUN95	7, ., -8	09:00 Hrs	20	1	MOD	NO	PSR	Yes	No
329.004.00212	Somnolence	SEDATION	09JUN96	7, ., -16	12:00 Hrs	20	1	SEV	NO	PSR	No	No
			10JUN96	8, ., -15	2 Days	20	CON	MIL	NO	PSR	No	No
			12JUN96	10, ., -13	14 Days	20	CON	SEV	NO	PSR	No	No
329.004.00214	Dizziness	DIZZINESS	15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	No	No
			23DEC96	81, 21, -7	06:00 Hrs	20	3	MOD	NO	PSR	No	No
	Dyspepsia	UPSET STOMACH	09NOV96	37, -24, -51	2 Days	30	CON	MIL	DCR	REL	Yes	No
	Headache	HEADACHE	08NOV96	36, -25, -52	2 Days	30	CON	MIL	DCR	REL	Yes	No
			15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	Yes	No
	Hyperkinesia	HYPERACTIVE	08OCT96	5, -56, -83	01:00 Hrs	20	5	MIL	NO	PSR	No	No
	Insomnia	AWAKENING (MIDDLE OF NIGHT)	12OCT96	9, -52, -79	15 Mins	20	2	MIL	NO	PSR	No	No
	Nausea	NAUSEA	15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	Yes	No

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Intent-to-Treat Population

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329.004.00214	Nausea	NAUSEA	23DEC96	81, 21, -7	06:00 Hrs	20	3	MOD	NO	PSR	No	No
	Rash	RASH ON ARMS (RED, DRY, ITCHY)	01DEC96	59, -2, -29	10:00 Hrs	20	CON	MIL	NO	PBU	No	No
	Respiratory Disorder	COLD {SYMPTOMS}	17OCT96	14, -47, -74	4 Days	20	CON	MIL	NO	UNR	No	No
329.005.00002	Chest Pain	CHEST PAIN	19JUN94	26, -31,-121	06:30 Hrs	20	CON	MOD	NO	PSR	No	No
	Drug Dependence	POSITIVE CANNABIS	20MAY94	-5, -61,-151	1 Days	0	1	MIL	NO	UNR	No	No
	Headache	HEADACHE	20MAY94	-5, -61,-151	03:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
			17JUL94	54, -3, -93	4 Days	40	3	MOD	NO	PSR	Yes	No
	Palpitation	CHEST PALPITATIONS	19JUN94	26, -31,-121	06:30 Hrs	20	CON	MOD	NO	PSR	No	No
	Urticaria	HIVES - BOTH ARMS BOTH LEGS AND STOMACH AREA (QUESTIONABLE)	13JUN94	20, -37,-127	2 Days	20	CON	MIL	NO	PSR	No	No
329.005.00004	Headache	HEADACHE	24OCT94	15, -45, -88	02:30 Hrs	20	CON	MIL	NO	PBU	No	No
			29DEC94	81, 22, -22	2 Days	40	CON	MOD	NO	PBU	No	No
	Pharyngitis	SORE THROAT	29DEC94	81, 22, -22	2 Days	40	CON	MOD	NO	UNR	Yes	No
329.005.00008	Abdominal Pain	STOMACH ACHE	10DEC94	25, -31,-117	3 Days	20	CON	MOD	NO	UNR	No	No
	Asthenia	EXTREME SLEEPINESS/FATIGUE	29DEC94	44, -12, -98	11 Days	40	CON	SEV	DCR	REL	No	No
	Diarrhea	DIARRHEA	10DEC94	25, -31,-117	3 Days	20	CON	MOD	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	20NOV94	5, -51,-137	140 Days	20	CON	MIL	NO	PSR	No	No

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329.005.00008	Headache	HEADACHE	10DEC94	25, -31,-117	3 Days	20	CON	MOD	NO	UNR	No	No
	Infection	STOMACH FLU WITH NAUSEA,VOMITING AND DIARRHEA	27NOV94	12, -44,-130	3 Days	20	CON	SEV	NO	UNR	No	No
		STOMACH FLU-NAUSEA,VOMITING AND DIARRHEA	16DEC94	31, -25,-111	4 Days	30	CON	SEV	NO	UNR	No	No
	Personality Disorder	BEHAVIOR PROBLEMS-->STOLE MOM'S CAR AND WRECKED IT.	31JAN95	77, 22, -65	02:00 Hrs	30	1	SEV	NO	PSR	No	No
		SKIPPING SCHOOL TALKING BACK TO MOM {BEHAVIOR PROBLEMS}	22DEC94	37, -19,-105	47 Days	40	CON	SEV	NO	PSR	No	No
	Postural Hypotension	POSTURAL HYPOTENSION	12NOV94	-4, -59,-145	2 Mins	0	2	MIL	NO	PSR	No	No
	Somnolence	DROWSINESS-SLEEPINESS	16NOV94	1, -55,-141	17 Days	20	7	MIL	NO	PSR	No	No
			02DEC94	17, -39,-125	160 Days	20	CON	MOD	NO	REL	No	No
329.005.00011	Asthenia	FATIGUE WITH DIZZINESS AND DROWSINESS [FATIGUE WITH DROWSINESS]	28JAN95	47, -10,-109	Not Stated	40	CON	MIL	NO	PSR	No	No
		TIREDNESS INCREASED FATIGUE	19DEC94	7, -50,-149	10 Days	20	4	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	02JAN95	21, -36,-135	34 Days	20		MIL	NO	REL	No	No
		FATIGUE WITH DIZZINESS AND DROWSINESS [DIZZINESS]	28JAN95	47, -10,-109	Not Stated	40	CON	MIL	NO	PSR	No	No

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329.005.00011	Emotional Lability	[OVERDOSE{WITH BAYER EXTRA STRENGTH}[INTENTIONAL]	17MAY95	156, 100, 0	1 Days	30	1	SEV	STP	UNR	Yes	Yes
	Headache	HEADACHES	20DEC94	8, -49,-148	15 Days	20	14	MOD	NO	PSR	Yes	No
329.005.00109	Drug Dependence	POSITIVE URINE DRUG SCREEN CANNABINOIDS	25MAY95	147, 94, 9	1 Days	20	1	SEV	NO	UNR	No	No
	Headache	HEADACHE	20MAR95	81, 28, -57	3 Days	20	4	MOD	NO	UNR	Yes	No
	Infection	COLD AND FLU STUFFY NOSE/NAUSEA/VOMITING DIARRHEA	09FEB95	42, -12, -96	4 Days	20	CON	MOD	NO	UNR	No	No
	Peptic Ulcer Hemorrhage	BLEEDING ULCER {PEPTIC}	07MAY95	129, 76, -9	4 Days	20	CON	SEV	NO	UNR	Yes	Yes
	Tremor	HAND TREMORS	20JAN95	22, -32,-116	12 Days	20	CON	MIL	NO	REL	No	No
	Vomiting	NAUSEA AND VOMITING	10MAY95	132, 79, -6	2 Days	20	CON	SEV	NO	PSR	No	No
329.005.00112	Fever	FEVER	24JAN95	-2, -57, -94	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	24JAN95	-2, -57, -94	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Infection	NAUSEA VOMITING DIARRHEA (FLU)	13MAR95	47, -9, -46	2 Days	20	CON	SEV	NO	UNR	No	No
	Tooth Disorder	TOOTHACHE	26FEB95	32, -24, -61	10:30 Hrs	20	CON	MOD	NO	UNR	No	No
329.005.00116	Bronchitis	BRONCHITIS WITH COUGH	04MAR95	26, -33,-129	25 Days	20	CON	SEV	NO	UNR	Yes	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00116	Contact Dermatitis	POISON IVY	17JUN95	131, 73, -24	26 Days	30	CON	SEV	STP	UNR	Yes	No
	Cough Increased	COUGH	22APR95	75, 17, -80	16 Days	20	5	MOD	NO	UNR	Yes	No
	Dry Mouth	DRY MOUTH	10FEB95	4, -55,-151	152 Days	20	CON	MOD	NO	REL	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	28MAY95	111, 53, -44	3 Days	20	CON	SEV	NO	UNR	Yes	No
	Dyspepsia	UPSET STOMACH	08FEB95	2, -57,-153	6 Days	20	10	MOD	NO	PBU	No	No
		UPSET STOMACH {WHEN TAKES MEDICATIONS AT BEDTIME}	04APR95	57, -2, -98	99 Days	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	12APR95	65, 7, -90	1 Days	20	3	MOD	NO	PBU	Yes	No
	Increased Appetite	INCREASED APPETITE	15FEB95	9, -50,-146	162 Days	20	CON	MOD	NO	PSR	No	No
	Infection	NAUSEA,VOMITING,DIARRHEA (STOMACH FLU)	06MAR95	28, -31,-127	24:00 Hrs	20	CON	SEV	NO	UNR	No	No
	Myalgia	CRAMPS IN LEFT LEG	08MAR95	30, -29,-125	2 Days	20	CON	MOD	NO	UNR	No	No
	Otitis Media	EAR INFECTION/ACHE	04MAR95	26, -33,-129	25 Days	20	CON	SEV	NO	UNR	Yes	No
	Pharyngitis	TONSILLITIS	24JUN95	138, 80, -17	14 Days	30	CON	SEV	NO	UNR	Yes	No
	Tremor	HAND TREMORS	04MAR95	26, -33,-129	29 Days	20	CON	MIL	NO	REL	No	No
329.005.00119	Abdominal Pain	"STOMACH ACHE"	23OCT95	105, 46, -36	5 Days	40	5	MOD	NO	PBU	No	No
		STOMACH ACHE	20JUL95	10, -50,-131	4 Days	20	2	MIL	NO	PBU	No	No
	Asthenia	FATIGUE	11JUL95	1, -59,-140	4 Days	20	CON	MOD	NO	PSR	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00119	Headache	HEADACHE	17JUL95	7, -53,-134	02:00 Hrs	20		MOD	NO	PSR	Yes	No
			20AUG95	41, -19,-100	01:00 Hrs	40	2	MOD	NO	PBU	No	No
	Hostility	PHYSICAL FIGHT {AGGRESSION}	28JUL95	18, -42,-123	10 Mins	20	1	MIL	NO	PBU	No	No
	Respiratory Disorder	COLD SYMPTOMS	27SEP95	79, 20, -62	4 Days	40	CON	MOD	NO	PBU	Yes	No
	Vomiting	NAUSEA AND VOMITING	23OCT95	105, 46, -36	5 Days	40	5	MOD	NO	PBU	No	No
329.005.00151	Albuminuria	PROTEIN IN URINE	31JAN96	148, 91, -91	92 Days	30	CON	MOD	NO	PBU	No	No
	Back Pain	BACK PAIN	06SEP95	1, -57,-238	1 Days	20	1	MOD	NO	UNR	Yes	No
			19OCT95	44, -14,-195	02:00 Hrs	20	1	MIL	NO	UNR	Yes	No
	Infection	SORE THROAT AND EAR INFECTION DIAGNOSIS:STREP THROAT	15OCT95	40, -18,-199	12 Days	20	CON	SEV	NO	UNR	Yes	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION	22OCT95	47, -11,-192	17 Days	20	CON	MOD	NO	UNR	Yes	No
	Trauma	FOREIGN OBJECT IN EYE	06FEB96	154, 97, -85	3 Days	30	CON	MOD	NO	UNR	Yes	No
	Urinary Casts	COURSE GRANULAR CASTS HYALINE CAST IN URINE	31JAN96	148, 91, -91	92 Days	30	CON	MOD	NO	PBU	No	No
	Weight Gain	WEIGHT GAIN	28NOV95	84, 27,-155	156 Days	20	CON	MOD	NO	PSR	No	No
329.005.00152	Diarrhea	DIARRHEA	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No	No
	Headache	HEADACHE	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00152	Nausea	NAUSEA	27OCT95	2, ., -3	4 Days	20	CON	SEV	STP	REL	No	No
	Vomiting	NAUSEA AND VOMITING	27OCT95	2, ., -3	4 Days	20	8	SEV	STP	REL	No	No
		VOMITING	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No	No
329.005.00257	Asthma	EXERCISE INDUCED ASTHMA	01SEP96	175, 119, -64	Not Stated	30	CON	MOD	NO	UNR	Yes	No
	Haematuria	RBC IN URINE (PT MENSTRUATING WHEN SAMPLE TAKEN)	21OCT96	225, 169, -14	Not Stated	30	CON	MOD	NO	UNR	No	No
	Headache	HEADACHE	14AUG96	157, 101, -82	8 Days	30	2	MIL	NO	PBU	Yes	No
	Nervousness	"JITTERINESS"	21OCT96	225, 169, -14	Not Stated	30	CON	MOD	NO	PSR	No	No
	Otitis Externa	SWIMMER'S EAR	31JUL96	143, 87, -96	3 Days	30	CON	MOD	NO	PBU	Yes	No
	Respiratory Disorder	SORE THROAT (COLD SYMPTOM)	18MAR96	8, -49,-231	9 Days	20	CON	MOD	NO	PBU	Yes	No
		STUFFY NOSE (COLD SYMPTOMS)	18MAR96	8, -49,-231	9 Days	20	CON	MOD	NO	PBU	Yes	No
	Sinusitis	SINUS INFECTION	24MAR96	14, -43,-225	7 Days	20		MOD	NO	PBU	Yes	No
			14APR96	35, -22,-204	37 Days	20	CON	MOD	NO	PBU	Yes	No
	Urinary Tract Infection	YEAST INFECTION (SQUAMOUS EPITHELIAL CELLS IN URINE)	15OCT96	219, 163, -20	Not Stated	30	CON	MOD	NO	PBU	No	No
	Weight Gain	WEIGHT GAIN	03JUN96	85, 29,-154	Not Stated	30	CON	MOD	NO	PSR	No	No
329.005.00258	Abdominal Pain	STOMACH ACHE	21MAR96	10, ., -47	02:00 Hrs	20	1	MOD	NO	PBU	No	No
			05APR96	25, ., -32	4 Days	20	4	MOD	NO	PBU	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00258	Cough Increased	COUGH	08MAR96	-4, ., -60	8 Days	0	1	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	21MAR96	10, ., -47	4 Days	20	2	MOD	NO	PBU	No	No
			05APR96	25, ., -32	4 Days	20	3	MOD	NO	PBU	No	No
	Tooth Disorder	ORTHODONTIC DISCOMFORT	01APR96	21, ., -36	03:30 Hrs	20	1	MOD	NO	UNR	Yes	No
			08APR96	28, ., -29	02:40 Hrs	20	1	MOD	NO	UNR	Yes	No
	Urine Abnormality	ABNORMAL URINE ROUTINE & MICROSCOPIC(URINALYSIS	07MAY96	57, ., 0	Not Stated	30	CON	MOD	NO	PBU	No	No
329.005.00299	Abdominal Pain	STOMACH ACHE	31JUL96	54, -7,-110	3 Days	20	2	MOD	NO	PSR	Yes	No
	Abnormal Vision	BLURRED VISION	24OCT96	139, 79, -25	6 Days	30	CON	MIL	NO	PBU	No	No
			05NOV96	151, 91, -13	8 Days	20	CON	MOD	NO	PSR	No	No
	Dizziness	DIZZINESS	05NOV96	151, 91, -13	8 Days	20	CON	MOD	NO	PSR	No	No
		DIZZINESS UPON RISING	14JUN96	7, -54,-157	27 Days	20		MOD	NO	PSR	No	No
	Epistaxis	NOSEBLEED	12NOV96	158, 98, -6	10 Mins	20	1	MIL	NO	PSR	No	No
	Headache	HEADACHE	31JUL96	54, -7,-110	5 Days	20	2	MOD	NO	PSR	Yes	No
			03SEP96	88, 28, -76	03:00 Hrs	20	4	MOD	NO	PBU	No	No
			23OCT96	138, 78, -26	02:00 Hrs	30	1	MOD	NO	PBU	Yes	No
			19NOV96	165, 105, 1	04:00 Hrs	20	1	MOD	NO	PBU	No	No
		HEADACHE UPON RISING	14JUN96	7, -54,-157	27 Days	20		MOD	NO	PSR	No	No
	Respiratory Disorder	COLD {SYMPTOMS}	10SEP96	95, 35, -69	Not Stated	20	CON	MOD	NO	UNR	Yes	No
	Syncope	FAINTED	17JUN96	10, -51,-154	1 Mins	20	1	MOD	NO	PSR	No	No
329.005.00300	Dry Mouth	DRY MOUTH	24SEP96	6, ., -51	27 Days	20	CON	MOD	NO	REL	No	No
			21OCT96	33, ., -24	10 Days	20	CON	MIL	NO	REL	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00300	Headache	HEADACHE	12NOV96	55, ., -2	02:00 Hrs	20	CON	MOD	NO	UNR	No	No
	Hostility	OPPOSITIONAL BEHAVIOR (PHYSICALLY AND VERBALLY FIGHTING WITH MOTHER)	18OCT96	30, ., -27	7 Days	20	6	SEV	NO	PBU	No	No
			25OCT96	37, ., -20	Not Stated	20		MOD	NO	PBU	No	No
	Somnolence	SLEEPINESS (IN AM)	01OCT96	13, ., -44	11 Days	20	CON	MOD	NO	REL	No	No
			12OCT96	24, ., -33	Not Stated	20	CON	SEV	NO	REL	No	No
329.005.00333	Abnormal Dreams	VIVID DREAMS	10FEB97	19, ., -14	11 Days	20	10	MOD	NO	PSR	No	No
	Diarrhea	DIARRHEA	21FEB97	30, ., -3	08:00 Hrs	20	CON	SEV	NO	UNR	Yes	No
	Dyspnea	SHORTNESS OF BREATH	11FEB97	20, ., -13	3 Days	20	5	MIL	NO	PBU	No	No
	Emotional Lability	SUICIDAL IDEATION	28FEB97	37, ., 4	103 Days	20	CON	SEV	NO	UNR	No	Yes
	Headache	HEADACHE	24JAN97	2, ., -31	03:20 Hrs	20	CON	MIL	NO	UNR	Yes	No
			26JAN97	4, ., -29	02:30 Hrs	20	CON	MIL	NO	UNR	No	No
			13FEB97	22, ., -11	8 Days	20	7	MOD	NO	PSR	Yes	No
			24FEB97	33, ., 0	03:00 Hrs	20	CON	MOD	NO	PBU	Yes	No
	Rash	BLOTCHES (RED) ON LEGS	10FEB97	19, ., -14	3 Days	20	CON	MOD	NO	PSR	No	No
	Rhinitis	"STUFFY" NOSE	23JAN97	1, ., -32	Not Stated	20	CON	MOD	NO	UNR	No	No
	Somnolence	SLEEPINESS	01FEB97	10, ., -23	7 Days	20	CON	SEV	NO	PSR	Yes	No
			21FEB97	30, ., -3	Not Stated	20	CON	SEV	NO	PSR	No	No
329.005.00336	Back Pain	BACKACHE	28MAR97	25, ., -33	2 Days	20	CON	MIL	NO	UNR	No	No
			20APR97	48, ., -10	4 Days	20	CON	MIL	NO	UNR	Yes	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00336	Cough Increased	COUGH	04APR97	32, ., -26	6 Days	20	CON	MOD	NO	UNR	Yes	No
			10APR97	38, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Dizziness	DIZZINESS	10MAR97	7, ., -51	13 Days	20	2	MIL	NO	REL	No	No
		GIDDINESS	14MAR97	11, ., -47	4 Days	20	4	MIL	NO	PSR	No	No
			27MAR97	24, ., -34	3 Days	20	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	09MAR97	6, ., -52	39 Days	20	CON	MIL	NO	REL	No	No
	Myoclonus	LEG TWITCHES	19APR97	47, ., -11	4 Days	20	4	MIL	NO	PSR	No	No
		LEG TWITCHES (NIGHTLY)	29MAR97	26, ., -32	5 Days	20	4	SEV	NO	PSR	No	No
			02APR97	30, ., -28	8 Days	20	7	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	04APR97	32, ., -26	6 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	STUFFY NOSE	10APR97	38, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Tremor	HAND TREMORS	08MAR97	5, ., -53	4 Days	20	CON	MOD	NO	REL	No	No
			13MAR97	10, ., -48	7 Days	20	CON	MIL	NO	REL	No	No
			04APR97	32, ., -26	13 Days	20	CON	MIL	NO	PSR	No	No
329.006.00038	Chest Pain	CHEST PAIN-APPROXIMATELY 3 OCCASIONS-INTENSE JAB THEN REMITS	27MAR95	41, ., -16	3 Days	20	3	SEV	NO	PSR	No	No
	Constipation	CONSTIPATION	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
	Dizziness	DIZZINESS	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
	Emotional Lability	ATTEMPTED SUICIDE {INTENTIONAL}	12APR95	57, ., 0	1 Days	20	1	SEV	STP	UNR	No	Yes

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.006.00038	Headache	HEADACHE	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
	Hostility	ANGRY(PATIENT NOTICED)	15MAR95	29, ., -28	8 Days	20	CON	MIL	NO	PSR	No	No
	Myalgia	MUSCLE ACHE	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
	Myasthenia	MUSCLE WEAKNESS	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	No
	Sinusitis	COLD-SINUS SYMPTOMS	22FEB95	8, ., -49	10 Days	20	CON	MIL	NO	UNR	No	No
329.006.00039	Asthenia	VERY TIRED	22MAR95	43, -19, -49	7 Days	20	CON	SEV	NO	PSR	No	No
	Depression	MORE DEPRESSED	22MAR95	43, -19, -49	7 Days	20	CON	SEV	NO	PSR	No	No
	Headache	HEADACHES-MORE SEVERE THAN USUAL	24APR95	76, 15, -16	5 Days	30	3	SEV	NO	PBU	Yes	No
	Myoclonus	GRIMACING FACE WITH BLINKING EYES {TIC}	22MAR95	43, -19, -49	7 Days	20	CON	MIL	NO	PSR	No	No
	Nervousness	IRRITABLE MOOD	22MAR95	43, -19, -49	7 Days	20	CON	MOD	NO	PSR	No	No
	Trauma	SUPERFICIAL SCRATCHES	25FEB95	18, -44, -74	12 Days	20	CON	MIL	NO	PBU	No	No
329.006.00260	Esophagitis	BURNING ACHE IN UPPER ESOPHAGUS REGION	05AUG96	19, -40,-135	5 Mins	20	3	MOD	NO	PSR	No	No
		BURNING ACHE IN UPPER ESOPHAGUS REGION-BRIEF	07AUG96	21, -38,-133	45 Mins	20	1	MOD	NO	PSR	No	No
	Headache	HEADACHE	23JUL96	6, -53,-148	45 Mins	20	1	MIL	NO	UNR	Yes	No
			24JUL96	7, -52,-147	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No
			27JUL96	10, -49,-144	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			28JUL96	11, -48,-143	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No

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Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.006.00260	Headache	HEADACHE	29JUL96	12, -47,-142	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			30JUL96	13, -46,-141	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			11AUG96	25, -34,-129	45 Mins	20	1	MIL	NO	PBU	Yes	No
			20AUG96	34, -25,-120	30 Mins	30	1	MIL	NO	PBU	Yes	No
			26AUG96	40, -19,-114	40 Mins	30	1	MOD	NO	PBU	Yes	No
			02SEP96	47, -12,-107	30 Mins	30	1	MIL	NO	PBU	Yes	No
			06SEP96	51, -8,-103	45 Mins	30	1	MOD	NO	PBU	Yes	No
			08SEP96	53, -6,-101	45 Mins	30	1	SEV	NO	PBU	Yes	No
			11SEP96	56, -3, -98	30 Mins	30	1	MOD	NO	PBU	Yes	No
			16SEP96	61, 3, -93	02:00 Hrs	30	1	SEV	NO	PBU	Yes	No
			08OCT96	83, 25, -71	01:00 Hrs	30	1	MIL	NO	PBU	Yes	No
			05NOV96	111, 53, -43	01:00 Hrs	30	1	MIL	NO	PBU	No	No
	Respiratory Disorder	COLD {SYMPTOMS}	08OCT96	83, 25, -71	08:00 Hrs	30	1	MIL	NO	PBU	Yes	No
	Tooth Disorder	TOOTHACHE	06AUG96	20, -39,-134	30 Mins	20	1	SEV	NO	UNR	Yes	No
		TOOTHACHE PAIN	25JUL96	8, -51,-146	09:00 Hrs	20	1	MOD	NO	UNR	Yes	No
329.006.00261	Headache	HEADACHE	22JAN97	58, -1, -97	01:00 Hrs	30	1	MOD	NO	PBU	Yes	No
	Infection	SCABIES ON BOTH ARMS	18FEB97	85, 27, -70	44 Days	30	CON	MOD	NO	UNR	No	No
329.007.00140	Fungal Dermatitis	RINGWORM	13OCT95	29, -27, -40	21 Days	20	CON	MIL	NO	UNR	No	No
329.007.00142	Infection	FLU	01DEC95	45, ., -3	8 Days	40	1	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	30NOV95	44, ., -4	1 Days	40	1	MIL	NO	UNR	Yes	No
329.007.00145	Headache	HEADACHE	30APR96	111, 55,-115	16 Days	40	CON	SEV	DCR	PSR	Yes	No
	Hyperkinesia	AKATHISIA	02MAY96	113, 57,-113	29 Days	30	CON	MOD	DCR	REL	No	No
	Hypertension	HYPERTENSION	14MAY96	125, 69,-101	17 Days	20	CON	MOD	DCR	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.007.00145	Respiratory Disorder	FEVER, COLD SYMPTOMS, SORE THROAT	21AUG96	224, 168, -2	3 Days	20	CON	MIL	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	01FEB96	22, -35,-204	2 Days	20	1	MIL	NO	UNR	Yes	No
	Thrombocytopenia	THROMBOCYTOPENIA	30MAY96	141, 85, -85	29 Days	20	CON	MIL	NO	PSR	No	No
329.007.00268	Agitation	FIDGETY/PSYCHOMOTOR AGITATION	16SEP96	169, 110, -93	17 Days	40	CON	MIL	DCR	PSR	No	No
	Back Pain	NECK PAIN	26MAY96	56, -4,-206	5 Days	30	CON	MOD	NO	UNR	Yes	No
	Constipation	CONSTIPATION	19NOV96	233, 174, -29	02:00 Hrs	30	1	MOD	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	03APR96	3, -57,-259	8 Days	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	26MAY96	56, -4,-206	5 Days	30	CON	MOD	NO	UNR	Yes	No
		HEADACHES (DAILY)	01OCT96	184, 125, -78	38 Days	30	35	MIL	NO	PSR	Yes	No
	Insomnia	TERMINAL INSOMNIA	09SEP96	162, 103,-100	24 Days	40	12	MOD	DCR	PSR	No	No
	Myalgia	MUSCLE PAIN	07JUL96	98, 39,-164	124 Days	30	CON	MIL	NO	UNR	Yes	No
	Nausea	NAUSEA	27OCT96	210, 151, -52	10 Days	30	CON	MOD	NO	PBU	Yes	No
		NAUSEA DUE TO RIDES AT AMUSEMENT PARK	29APR96	29, -31,-233	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No
	Otitis Media	EAR INFECTION	10APR96	10, -50,-252	5 Days	20	CON	MOD	NO	UNR	Yes	No
		LEFT EAR INFECTION	21JUN96	82, 23,-180	9 Days	30	CON	MOD	NO	UNR	Yes	No

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Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.007.00268	Syncope	BLACKNESS IN FRONT OF EYES, LIGHTHEADED, SWEATING {PRE-SYNCOPAL EPISODE/HEAT EXPOSURE}	01AUG96	123, 64,-139	20 Mins	40	CON	MIL	NO	UNR	No	No
	Trauma	HEADACHE DUE TO ACCIDENT	26MAY96	56, -4,-206	5 Days	30	CON	MOD	NO	UNR	Yes	No
		NECK PAIN DUE TO ACCIDENT	26MAY96	56, -4,-206	13 Days	30	CON	MOD	NO	UNR	Yes	No
		PATIENT ACCIDENTALLY THROWN FROM 3 WHEELER STRIKING HEAD AND A NUMBER OF ABRASIONS	26MAY96	56, -4,-206	5 Mins	30	1	SEV	NO	UNR	Yes	No
	Vestibular Disorder	LEFT INNER EAR INFECTION	01JUL96	92, 33,-170	10 Days	30	CON	MOD	NO	UNR	Yes	No
	Weight Gain	WEIGHT GAIN	30SEP96	183, 124, -79	95 Days	30	CON	MOD	NO	PSR	Yes	No
329.007.00294	Abdominal Pain	CRAMPS (ABDOMINAL)	07APR97	39, ., -3	02:00 Hrs	30	CON	MOD	NO	UNR	Yes	No
	Back Pain	BACKACHE	21MAR97	22, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHES (DAILY, 1-2X /DAY)	04MAR97	5, ., -37	Not Stated	20		MOD	NO	PSR	Yes	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION	02APR97	34, ., -8	6 Days	20	CON	MIL	NO	UNR	Yes	No
	Somnolence	DROWSINESS DURING DAY	28FEB97	1, ., -41	19 Days	20	CON	MIL	NO	PBU	No	No
329.007.00309	Abdominal Pain	STOMACH ACHE	27OCT96	105, 53,-150	3 Days	20	CON	MIL	NO	UNR	No	No
	Bronchitis	BRONCHITIS	13SEP96	61, 9,-194	7 Days	20	CON	MOD	NO	UNR	Yes	No

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Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.007.00309	Dizziness	DIZZINESS	17JUL96	3, -50,-252	2 Days	20	2	MIL	NO	PSR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	16AUG96	33, -20,-222	4 Days	20	CON	MOD	NO	UNR	Yes	No
	Ear Pain	EARACHE	06JAN97	176, 124, -79	8 Days	20	CON	MIL	NO	UNR	Yes	No
	Fever	FEVER	04DEC96	143, 91,-112	3 Days	20	CON	MIL	NO	UNR	Yes	No
	Gingivitis	ABSCESSED TOOTH	26SEP96	74, 22,-181	1 Days	20	CON	SEV	NO	UNR	Yes	No
	Headache	HEADACHE (CHANGE IN SEVERITY)	05DEC96	144, 92,-111	04:00 Hrs	20	CON	SEV	NO	PBU	No	No
		HEADACHES (DAILY)	14JAN97	184, 132, -71	30 Days	20	24	MOD	NO	PBU	Yes	No
		HEADACHES (INCREASED FREQUENCY)	24SEP96	72, 20,-183	19 Days	20	20	MOD	NO	PBU	Yes	No
	Infection	FLU (COUGH, HEAD CONGESTION, LOW-GRADE FEVER)	12DEC96	151, 99,-104	11 Days	20	CON	MOD	NO	UNR	No	No
	Nausea	NAUSEA	27OCT96	105, 53,-150	3 Days	20	CON	MIL	NO	UNR	No	No
			10MAR97	239, 187, -16	Not Stated	30	CON	MIL	NO	UNR	No	No
	Respiratory Disorder	UPPER RESPIRATORY ILLNESS	30AUG96	47, -6,-208	9 Days	20	CON	MOD	NO	UNR	Yes	No
		URI (UPPER RESPIRATORY INFECTION)	26JUL96	12, -41,-243	21 Days	20	CON	MIL	NO	UNR	No	No
	Rhinitis	CONGESTION {NOSE}	04DEC96	143, 91,-112	5 Days	20	CON	MOD	NO	UNR	Yes	No
	Tooth Disorder	TOOTHACHE (CUTTING WISDOM TEETH)	26AUG96	43, -10,-212	17 Days	20	CON	MOD	NO	UNR	Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
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Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.007.00309	Tremor	TREMOR (HANDS, HEAD, TEETH)	15JUL96	1, -52,-254	47 Days	20	CON	MIL	NO	PSR	No	No
329.007.00310	Arthralgia	LEFT KNEE PAIN	14NOV96	50, -11,-221	Not Stated	20	CON	MOD	NO	UNR	Yes	No
	Gastrointestinal Disorder	FOOD POISONING	16NOV96	52, -9,-219	2 Days	20	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	17DEC96	83, 23,-188	3 Days	20	CON	SEV	NO	PBU	No	No
			14MAR97	170, 110,-101	10 Days	20	CON	MOD	NO	PBU	Yes	No
		MILD HEADACHE	17OCT96	22, -39,-249	03:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Hypertonia	STIFF NECK	14MAR97	170, 110,-101	10 Days	20	CON	MOD	NO	UNR	Yes	No
	Infection	"FLU" HEADACHE, SORE THROAT AND WEAKNESS, FEVER, EARACHE	05OCT96	10, -51,-261	12 Days	20	CON	MOD	NO	PBU	No	No
		POSSIBLE STREP THROAT	17MAR97	173, 113, -98	12 Days	20	CON	MOD	NO	UNR	Yes	No
	Myalgia	PAIN IN NECK MUSCLES	07OCT96	12, -49,-259	9 Days	20	CON	MOD	NO	PBU	Yes	No
	Pharyngitis	SORE THROAT	19DEC96	85, 25,-186	11 Days	20	CON	MOD	NO	UNR	Yes	No
	Photosensitivity	SUNBURN	01MAY97	218, 158, -53	8 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	19DEC96	85, 25,-186	12 Days	20	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	05OCT96	10, -51,-261	25 Days	20	CON	MOD	NO	PBU	Yes	No
329.008.00160	Breast Enlargement	INCREASE IN BREAST SIZE {FEMALE}	27NOV95	27, -40,-254	Not Stated	20	CON	MIL	NO	PSR	No	No
	Dyspnea	SHORTNESS OF BREATH	20NOV95	20, -47,-261	8 Days	20	CON	MIL	NO	UNR	Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.008.00160	Nervousness	JITTERINESS	20NOV95	20, -47,-261	8 Days	20	1	MIL	NO	UNR	No	No
329.008.00188	Anxiety	ANXIETY ATTACKS	24FEB96	52, ., -3	30 Mins	40	1	MIL	NO	PBU	No	No
	Migraine	MIGRAINES	20FEB96	48, ., -7	04:00 Hrs	40	2	MOD	NO	UNR	No	No
	Nervousness	JITTERINESS	07JAN96	4, ., -51	Not Stated	20	12	MIL	NO	PSR	No	No
329.008.00271	Asthenia	DECREASED ENERGY/TIRED	07MAY96	58, -7,-197	Not Stated	40	CON	MIL	NO	PSR	No	No
	Concentration Impaired	DECREASED CONCENTRATION	11MAY96	62, -3,-193	4 Days	40	CON	MIL	NO	PSR	No	No
	Conjunctivitis	DRY ITCHY EYES	07APR96	28, -37,-227	2 Days	20	CON	MIL	NO	PSR	No	No
	Decreased Appetite	REDUCED APPETITE	18MAR96	8, -57,-247	24 Days	20	CON	MIL	NO	REL	No	No
	Dizziness	COLD CLAMMY	05APR96	26, -39,-229	15 Mins	20	1	MIL	DCR	PSR	No	No
		LIGHTHEADEDNESS [LIGHTHEADEDNESS]										
		LIGHTHEADED	03APR96	24, -41,-231	15 Mins	20	2	MIL	DCR	PSR	No	No
		LIGHTHEADED {WHEN STANDING}	11MAY96	62, -3,-193	Not Stated	40	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	06APR96	27, -38,-228	11 Days	20	CON	MIL	NO	PBU	No	No
	Headache	HEADACHE (DAILY)	07MAY96	58, -7,-197	6 Days	40		MIL	NO	PSR	Yes	No
	Hypertonia	STIFF NECK	07APR96	28, -37,-227	30 Mins	20	3	MIL	NO	PBU	No	No
	Nervousness	INCREASED IRRITABILITY	12MAY96	63, -2,-192	Not Stated	40	CON	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT SWALLOWING	06APR96	27, -38,-228	11 Days	20	CON	MIL	NO	PBU	No	No

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Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.008.00271	Skin Disorder	COLD, CLAMMY	05APR96	26, -39,-229	15 Mins	20	1	MIL	DCR	PSR	No	No
		LIGHTHEADEDNESS [COLD, CLAMMY]										
	Somnolence	SOMNOLENCE DAYTIME	15MAR96	5, -60,-250	52 Days	20	CON	MIL	NO	PSR	No	No
	Tremor	SHAKY	14MAY96	65, 1,-190	Not Stated	40	CON	MIL	NO	PSR	No	No
		SUBJECTIVE FEELINGS OF SHAKINESS	03APR96	24, -41,-231	14 Days	20	3	MIL	DCR	PSR	No	No
	Vasodilatation	FEELING HOT	06MAR96	-5, -69,-259	61 Days	0		MIL	NO	PSR	No	No
329.008.00275	Dizziness	DIZZINESS	25JUN96	49, -7,-174	9 Days	40	3	MIL	NO	REL	No	No
			19JUL96	73, 18,-150	5 Days	30	3	MIL	NO	REL	No	No
			10AUG96	95, 40,-128	3 Mins	30	1	MIL	NO	REL	No	No
			08SEP96	124, 69, -99	3 Days	30	2	MIL	NO	REL	No	No
		LIGHTHEADEDNESS	05JUN96	29, -27,-194	3 Days	30	2	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	08MAY96	1, -55,-222	Not Stated	20	CON	MIL	NO	PSR	No	No
			21JUL96	75, 20,-148	06:00 Hrs	30	1	MIL	NO	REL	No	No
			12AUG96	97, 42,-126	9 Days	30	3	MIL	NO	REL	No	No
			03SEP96	119, 64,-104	2 Days	30	3	MIL	NO	REL	No	No
			04NOV96	181, 126, -42	26:00 Hrs	30	2	MIL	NO	REL	No	No
329.009.00130	Abdominal Pain	STOMACH ACHE	13SEP95	149, 93, -33	Not Stated	20		MIL	NO	PBU	Yes	No
	Agitation	["HYPER"{AGITATION}]	19MAY95	32, -25,-150	26 Days	20	3	MOD	NO	PSR	No	No
	Nausea	NAUSEA	23MAY95	36, -21,-146	3 Days	20	2	MIL	NO	PSR	No	No
	Sinusitis	SINUS INFECTION	04SEP95	140, 84, -42	10 Days	20	CON	MOD	NO	PBU	Yes	No
		SINUSITIS	25APR95	8, -49,-174	10 Days	20	CON	MOD	NO	PBU	Yes	No

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00131	Acne	ACNE-FACIAL	30MAY95	29, -28, -89	Not Stated	20	CON	MOD	NO	PSR	Yes	No
	Constipation	CONSTIPATION	20MAY95	19, -38, -99	3 Days	20	1	MOD	NO	PSR	Yes	No
	Thrombocythemia	INCREASED PLATELET COUNT	27JUN95	57, 1, -61	29 Days	20	CON	MIL	NO	PBU	No	No
329.009.00133	Diarrhea	LOOSE STOOLS	29JUN95	17, ., -28	Not Stated	20		MOD	NO	PSR	Yes	No
	Nausea	NAUSEA	29JUN95	17, ., -28	Not Stated	20	CON	MOD	NO	PSR	No	No
	Sweating	SWEATING INCREASED	07JUL95	25, ., -20	Not Stated	20	CON	MOD	NO	PSR	No	No
	Tooth Disorder	WISDOM TOOTH EXTRACTION {TOOTH DISORDER}	14JUL95	32, ., -13	03:00 Hrs	30	CON	MIL	NO	UNR	Yes	No
329.009.00170	Agitation	AGITATION	09JUL96	246, 189, 1	12:00 Hrs	20	CON	MOD	NO	PSR	No	Yes
	Asthenia	FATIGUE	27JUN96	234, 177, -11	11 Days	20	CON	MOD	NO	PSR	No	Yes
	Constipation	CONSTIPATION	07JUL96	244, 187, -1	Not Stated	20	CON	MIL	NO	UNR	No	No
	Decreased Appetite	LOSS OF APPETITE	09NOV95	3, -55,-242	43 Days	20	CON	MIL	NO	PSR	No	No
			21DEC95	45, -13,-200	14 Days	40	CON	MOD	DCR	PSR	No	No
	Dysmenorrhea	DYSMENORRHEA	07JUL96	244, 187, -1	Not Stated	20	CON	MIL	NO	UNR	Yes	No
	Increased Appetite	INCREASED APPETITE	01APR96	147, 90, -98	85 Days	30	CON	MIL	NO	PSR	No	No
			30JUN96	237, 180, -8	9 Days	20	CON	MOD	NO	PSR	No	No
	Insomnia	MIDDLE INSOMNIA	23NOV95	17, -41,-228	6 Days	20	CON	MIL	NO	PSR	No	No
			28NOV95	22, -36,-223	37 Days	20	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	27JUN96	234, 177, -11	12 Days	20	CON	SEV	NO	REL	Yes	Yes

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329.009.00170	Somnolence	DROWSY	27JUN96	234, 177, -11	11 Days	20	CON	MOD	NO	PSR	No	Yes
		SLEEPINESS WHEN TAKING EVENING MEDS	21DEC95	45, -13,-200	14 Days	40	CON	MOD	NO	PSR	No	No
	Tremor	SHAKY TREMORS	27JUN96	234, 177, -11	2 Days	20	CON	MOD	NO	PSR	No	Yes
	Vomiting	VOMITING	01JUL96	238, 181, -7	6 Days	20	CON	SEV	NO	REL	Yes	No
	Weight Loss	WEIGHT LOSS	21DEC95	45, -13,-200	14 Days	40	CON	MIL	NO	PBU	No	No
329.009.00173	Asthenia	FATIGUE	01JAN96	43, -21, -57	Not Stated	30	CON	MOD	NO	PSR	No	No
	Insomnia	INSOMNIA	15JAN96	57, -7, -43	Not Stated	20	CON	MOD	NO	PSR	No	No
	Nervousness	RESTLESSNESS	29DEC95	40, -24, -60	18 Days	30	CON	MOD	DCR	PSR	No	No
	Somnolence	INCREASED DAYTIME SLEEPINESS SOMNOLENCE	13DEC95	24, -40, -76	Not Stated	20	CON	MOD	NO	PSR	No	No
329.009.00193	Nervousness	RESTLESSNESS	01DEC95	4, ., -67	12 Days	20	CON	MIL	NO	PSR	No	No
	Respiratory Disorder	COLD SYNDROME (URI) {UPPER RESPIRATORY INFECTION}	10DEC95	13, ., -58	18 Days	20	CON	MOD	NO	UNR	Yes	No
329.009.00196	Asthma	ASTHMA	29JAN96	43, ., -27	Not Stated	30	CON	SEV	NO	UNR	Yes	No
	Constipation	CONSTIPATION	20DEC95	3, ., -67	Not Stated	20	7	MIL	NO	PBU	No	No
	Decreased Appetite	DECREASED APPETITE	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	03JAN96	17, ., -53	6 Days	20	CON	MIL	NO	PSR	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00196	Dyspepsia	HEARTBURN	27JAN96	41, ., -29	Not Stated	30	CON	MIL	NO	PBU	Yes	No
	Insomnia	INSOMNIA (INITIAL)	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PSR	No	No
	Sinusitis	SINUS INFECTION	29JAN96	43, ., -27	Not Stated	30	CON	MOD	NO	PBU	Yes	No
329.009.00201	Agitation	AGITATION	03APR96	58, ., -1	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Hostility	AGGRESSIVE ASSAULTIVE BEHAVIOR	03APR96	58, ., -1	Not Stated	20	CON	SEV	STP	PSR	Yes	Yes
	Infection	TONSILLITIS (STREP PHARYNGITIS)	01APR96	56, ., -3	Not Stated	30	CON	MIL	NO	UNR	Yes	No
	Insomnia	INITIAL INSOMNIA	28FEB96	23, ., -36	Not Stated	20	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	07MAR96	31, ., -28	1 Days	20	CON	MIL	NO	PBU	No	No
	Paranoid Reaction	PARANOIA	03APR96	58, ., -1	Not Stated	20	CON	MOD	STP	PSR	No	Yes
	Rhinitis	NASAL CONGESTION	07APR96	62, ., 3	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Somnolence	SOMNOLENCE	26MAR96	50, ., -9	Not Stated	30	CON	MIL	NO	PSR	No	No
	Vomiting	VOMITING	07MAR96	31, ., -28	1 Days	20		MIL	NO	UNR	No	No
	Weight Gain	WEIGHT GAIN {11LBS}[WEIGHT GAIN]	02APR96	57, ., -2	Not Stated	20	CON	MOD	NO	PSR	No	No
329.009.00204	Nausea	NAUSEA	26MAR96	8, -49,-203	22 Days	20	CON	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00235	Arrhythmia	SINUS ARRHYTHMIA (PER EKG)	17MAR97	90, 36, -40	Not Stated	20	CON	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	30DEC96	13, -42,-117	43 Days	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	17MAR97	90, 36, -40	29 Days	20	CON	MIL	NO	PSR	No	No
	Insomnia	INSOMNIA (INITIAL)	03FEB97	48, -7, -82	8 Days	20	CON	MIL	NO	UNR	No	No
	Nausea	NAUSEA	27JAN97	41, -14, -89	50 Days	20	CON	MIL	NO	PSR	No	No
	Tachycardia	ELEVATED PULSE	06JAN97	20, -35,-110	36 Days	20	CON	MIL	NO	REL	No	No
329.009.00240	Concentration Impaired	ATTENTION DEFICIT HYPERACTIVITY DISORDER	26MAR97	72, ., 21	Not Stated	0	CON	MOD	NO	UNR	Yes	No
	Depression	WORSENING OF DEPRESSION	02MAR97	48, ., -3	Not Stated	30	CON	SEV	STP	UNR	Yes	Yes
	Insomnia	WORSENING OF SLEEP DISTURBANCE	05MAR97	51, ., 0	Not Stated	30	CON	SEV	NO	PSR	Yes	Yes
	Rash	BILATERAL ERYTHEMATOUS EYELIDS	11FEB97	29, ., -22	8 Days	20	CON	MIL	NO	UNR	No	No
	Sinusitis	SINUS CONGESTION	11FEB97	29, ., -22	14 Days	20	CON	MIL	NO	UNR	No	No
329.009.00303	Allergic Reaction	SEASONAL ALLERGIES	29APR96	28, -29,-237	1 Days	20	CON	MIL	NO	UNR	No	No
329.009.00304	Headache	HEADACHE(WORSENING FROM BASELINE)	21MAY96	43, -14,-167	8 Days	30	CON	MOD	NO	PSR	No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	21MAY96	43, -14,-167	30 Mins	30	CON	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00304	Somnolence	DAYTIME SLEEPINESS	14MAY96	36, -21,-174	15 Days	30	CON	MOD	NO	PSR	No	No
	Weight Gain	WEIGHT GAIN {10 LBS}[WEIGHT GAIN]	30JUL96	113, 57, -97	Not Stated	30	CON	MIL	NO	PSR	No	No
329.009.00324	Abnormal Dreams	INCREASED DREAMING	25NOV96	29, ., -44	Not Stated	20	CON	MIL	NO	PSR	No	No
		NIGHTMARES	11NOV96	15, ., -58	15 Days	20	CON	MIL	NO	PSR	No	No
	Decreased Appetite	DECREASED APPETITE	16DEC96	50, ., -23	31 Days	20	CON	MIL	NO	PSR	No	No
	Insomnia	INSOMNIA	11NOV96	15, ., -58	8 Days	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	29OCT96	2, ., -71	21 Days	20	CON	MIL	NO	PSR	No	No
	Rash	RASH	27DEC96	61, ., -12	20 Days	20	CON	MOD	STP	REL	No	No
	Respiratory Disorder	COLD {SYMPTOMS}	09DEC96	43, ., -30	8 Days	20	CON	MIL	NO	UNR	No	No
329.009.00329	Depression	WORSENING OF DEPRESSION	12NOV96	35, ., -35	22 Days	20	CON	MOD	NO	PBU	No	No
	Dizziness	DIZZINESS IN AM	14OCT96	6, ., -64	10 Days	20	CON	MIL	NO	REL	No	No
	Somnolence	SLEEPINESS IN AM	14OCT96	6, ., -64	16 Days	20	CON	MIL	NO	REL	No	No
329.010.00182	Headache	HEADACHE	28DEC95	10, ., -22	1 Days	20	CON	MIL	NO	PSR	Yes	No
329.010.00278	Abdominal Pain	ABDOMINAL PAIN(PRESENT PREVIOUSLY)	22MAR96	43, -14,-197	5 Days	40	CON	SEV	NO	PBU	Yes	No
	Dry Mouth	DRY MOUTH	29MAR96	50, -7,-190	6 Days	40	CON	MIL	NO	REL	No	No
	Infection	MONONUCLEOSIS	01SEP96	206, 150, -34	Not Stated	40	CON	SEV	NO	PBU	Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.010.00278	Larynx Disorder	LARYNGITIS	01MAR96	22, -35,-218	4 Days	20	1	MIL	NO	UNR	No	No
	Nervousness	RESTLESSNESS	03MAR96	24, -33,-216	5 Days	20	CON	MIL	NO	PSR	No	No
329.010.00280	Acne	ACNE	16JUN96	31, -25, -43	Not Stated	20	CON	MIL	NO	PSR	No	No
	Dizziness	LIGHT-HEADED (X2 MINUTES)	10JUL96	55, -1, -19	2 Mins	40	1	MIL	NO	PSR	No	No
	Headache	HEADACHE	25JUN96	40, -16, -34	60 Mins	30	1	MIL	NO	PSR	Yes	No
			27JUN96	42, -14, -32	60 Mins	40	1	MIL	NO	PSR	Yes	No
	Rhinitis	CONGESTION (NASAL)	15MAY96	-2, -57, -75	2 Days	0	1	MIL	NO	UNR	Yes	No
	Urine Abnormality	ABNORMAL URINALYSIS	21AUG96	97, 42, 23	Not Stated	0	CON	MIL	NO	UNR	No	No
329.011.00283	Headache	HEADACHE	25FEB96	18, -40, -40	01:00 Hrs	20	1	MIL	NO	PBU	No	No
			11MAR96	33, -25, -25	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
	Tremor	"SHAKINESS"	05MAR96	27, -31, -31	6 Days	20	6	MIL	NO	PSR	No	No
329.011.00288	Cough Increased	COUGH	26JUL96	2, ., -41	Not Stated	20	CON	MIL	NO	UNR	Yes	No
329.012.00025	Abdominal Pain	DISCOMFORT ACROSS ALL OF ABDOMEN	06NOV95	14, ., -59	02:00 Hrs	20	1	MOD	NO	PBU	No	No
	Asthenia	FATIGUE	16NOV95	24, ., -49	Not Stated	20	CON	MOD	NO	REL	No	No
	Insomnia	INITIAL AND MIDDLE INSOMNIA	24OCT95	1, ., -72	Not Stated	20	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	06NOV95	14, ., -59	02:00 Hrs	20	1	MOD	NO	PBU	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.012.00025	Somnolence	DROWSINESS	16NOV95	24, ., -49	20 Days	20	CON	MOD	NO	REL	No	No
	Tremor	SHAKINESS OF WHOLE BODY	24OCT95	1, ., -72	02:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Urinary Tract Infection	[URINARY INFECTION QUESTIONABLE]	19DEC95	57, ., -16	9 Days	40	CON	MIL	NO	UNR	No	No
329.012.00220	Abnormal Vision	BLURRED VISION	25JUN96	9, -52,-150	2 Days	20	CON	MIL	NO	REL	No	No
	Bronchitis	BRONCHITIS	26SEP96	102, 42, -57	37 Days	30	CON	MOD	NO	PBU	Yes	No
	Dizziness	DIZZINESS	25JUN96	9, -52,-150	3 Days	20	CON	MOD	NO	REL	No	No
	Nausea	NAUSEA	13SEP96	89, 29, -70	04:00 Hrs	30	1	MIL	NO	PBU	No	No
329.012.00222	Cystitis	BLADDER INFECTION	18JUL96	21, -43, -65	4 Days	20	CON	MIL	NO	UNR	Yes	No
329.012.00226	Av Block	PR PROLONGATION CARDIAC CONDUCTION DELAY	20DEC96	18, ., 0	4 Days	20	CON	MOD	STP	PSR	No	No
	Nausea	NAUSEA	12DEC96	10, ., -8	12 Days	20	CON	MIL	NO	PBU	No	No
	Respiratory Disorder	COLD SYMPTOMS (SORE THROAT, COUGH)	30NOV96	-3, ., -20	24 Days	0	CON	MIL	NO	UNR	No	No
329.012.00228	Dry Mouth	DRY MOUTH	20MAR97	2, ., -2	4 Days	20	CON	MIL	NO	PBU	No	No
	Insomnia	INITIAL INSOMNIA	20MAR97	2, ., -2	4 Days	20	CON	MIL	NO	PBU	No	No
329.012.00231	Conjunctivitis	ITCHY EYES	23APR97	48, -14,-117	4 Days	20	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS	25MAY97	80, 19, -85	10 Days	30	4	MIL	NO	PBU	No	No

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Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.012.00231	Dry Mouth	DRY MOUTH	20MAR97	14, -48,-151	41 Days	20	CON	MIL	NO	PBU	No	No
	Headache	HEADACHE	18APR97	43, -19,-122	2 Days	20	CON	MOD	NO	PBU	No	No
			24APR97	49, -13,-116	02:00 Hrs	20	CON	MOD	NO	PBU	Yes	No
			28APR97	53, -9,-112	Not Stated	30		MIL	NO	PBU	Yes	No
		MODERATE HEADACHE	28APR97	53, -9,-112	Not Stated	30		MOD	NO	PSR	Yes	No
	Nausea	NAUSEA	25MAY97	80, 19, -85	10 Days	30	4	MIL	NO	PBU	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.001.00061	Concentration Impaired	DECREASE CONCENTRATION	30JUL94	2, ., -46	27 Days	50	CON	MOD	NO	REL	No	No
			01SEP94	35, ., -13	Not Stated	200	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS UPON GETTING UP SUDDENLY	06AUG94	9, ., -39	20 Days	100	CON	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	11AUG94	14, ., -34	Not Stated	150	CON	MIL	NO	REL	No	No
	Dysphagia	DIFFICULTY SWALLOWING 1 HOUR DURATION AFTER AWAKENING	28AUG94	31, ., -17	Not Stated	200	3	MIL	NO	PSR	No	No
	Insomnia	INSOMNIA MIDDLE	18AUG94	21, ., -27	Not Stated	200	7	MIL	NO	REL	No	No
	Pharyngitis	SORE THROAT 1 HOUR DURATION AFTER AWAKENING	28AUG94	31, ., -17	Not Stated	200	3	MIL	NO	PSR	No	No
	Qt Interval Prolonged	WIDENED CORRECTED QT {INTERVAL} QRS	01SEP94	35, ., -13	Not Stated	200	CON	MIL	STP	REL	No	No
	Tremor	HAND TREMORS	25AUG94	28, ., -20	Not Stated	200	4	MIL	NO	REL	No	No
329.001.00066	Abnormal Vision	BLURRED VISION WHEN READING LONG TIME	02DEC94	11, ., -11	Not Stated	100	3	MIL	NO	PSR	No	No
	Decreased Appetite	DECREASE APPETITE	23NOV94	2, ., -20	Not Stated	50	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZY	02DEC94	11, ., -11	5 Mins	100	1	MIL	NO	PSR	No	No
	Headache	HEADACHE	23NOV94	2, ., -20	5 Days	50	2	MIL	NO	PSR	No	No
	Nausea	NAUSEA	23NOV94	2, ., -20	13 Days	50	CON	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.001.00066	Tachycardia	INCREASED HEART RATE	05DEC94	14, ., -8	Not Stated	100	CON	MOD	STP	REL	No	No
329.001.00067	Dizziness	FAINTNESS	30NOV94	9, ., -13	Not Stated	100	CON	MOD	STP	PSR	No	No
	Postural Hypotension	POSTURAL HYPOTENSION	30NOV94	9, ., -13	Not Stated	100	CON	MOD	STP	PSR	No	No
	Somnolence	HYPERSOMNIA	30NOV94	9, ., -13	Not Stated	100	5	MIL	NO	PSR	No	No
329.001.00070	Agitation	INCREASE AGITATION	28FEB95	7, ., -24	Not Stated	100	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	08MAR95	15, ., -16	Not Stated	150	CON	MIL	NO	REL	No	No
	Insomnia	MIDDLE INSOMNIA	22FEB95	1, ., -30	16 Days	50	CON	MIL	NO	PBU	No	No
		TERMINAL INSOMNIA	11MAR95	18, ., -13	Not Stated	150	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	23FEB95	2, ., -29	Not Stated	50	CON	MIL	NO	PSR	No	No
	Syncope	FAINTNESS UPON STANDING	10MAR95	17, ., -14	Not Stated	150	3	MIL	NO	PSR	No	No
	Tachycardia	PULSE {INCREASED} 2 CONSECUTIVE WEEKS	08MAR95	15, ., -16	Not Stated	150	CON	SEV	STP	REL	No	No
	Tremor	HAND TREMORS	23FEB95	2, ., -29	Not Stated	50	CON	MIL	NO	PSR	No	No
	Vasodilatation	HOT FLASHES	01MAR95	8, ., -23	Not Stated	100	2	MIL	NO	PBU	No	No
329.001.00122	Amnesia	MORE FORGETFUL	11JUL95	22, -36,-160	15 Days	200	CON	MIL	NO	PSR	No	No
	Constipation	CONSTIPATION	05JUL95	16, -42,-166	4 Days	150	CON	MIL	NO	PSR	No	No
			14JUL95	25, -33,-157	19 Days	200	CON	MIL	NO	PSR	No	No

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Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.001.00122	Extrasystoles	PVC'S ON EKG [PREMATURE VENTRICULAR CONTRACTIONS]	27JUN95	8, -50,-174	9 Days	100	CON	MIL	NO	PBU	No	No
	Hypesthesia	NUMBNESS IN HANDS AND ARMS WHEN AWAKES	18JUL95	29, -29,-153	30 Days	200	CON	MIL	NO	PBU	No	No
	Increased Appetite	INCREASED APPETITE	11OCT95	114, 57, -68	Not Stated	200	CON	MOD	NO	REL	No	No
	Myoclonus	MUSCLE TWITCH RIGHT EYE	14JUL95	25, -33,-157	19 Days	200	CON	MIL	NO	PSR	No	No
		RIGHT KNEE TWITCH	14JUL95	25, -33,-157	62 Days	200	CON	MIL	NO	REL	No	No
	Rhinitis	CONGESTION BACK OF THROAT	07OCT95	110, 53, -72	8 Days	200	CON	MIL	NO	UNR	No	No
	Tachycardia	HEART RACING (BEATS HARD)	12SEP95	85, 28, -97	30 Days	200	2	MIL	NO	REL	No	No
	Tremor	HAND TREMORS	08AUG95	50, -8,-132	120 Days	200	CON	MOD	NO	REL	No	No
		RIGHT KNEE TREMOR	14JUL95	25, -33,-157	62 Days	200	CON	MIL	NO	REL	No	No
	Weight Gain	WEIGHT GAIN	11OCT95	114, 57, -68	Not Stated	200	CON	MOD	NO	REL	No	No
329.002.00050	Cough Increased	COUGHING	23MAR95	1, ., -34	12 Days	50	CON	MIL	NO	PBU	Yes	No
	Fever	FEVER	23MAR95	1, ., -34	6 Days	50	CON	MOD	NO	PBU	Yes	No
	Headache	HEADACHE	23MAR95	1, ., -34	5 Days	50	CON	MIL	NO	PBU	Yes	No
	Pharyngitis	SORE THROAT	23MAR95	1, ., -34	6 Days	50	CON	MOD	NO	PBU	Yes	No
	Postural Hypotension	DIZZINESS WITH ORTHOSTATIC HYPOTENSION	30MAR95	8, ., -27	6 Days	100	CON	MIL	STP	PSR	No	No

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329.002.00050	Tachycardia	HEART RATE INCREASE	23MAR95	1, ., -34	22 Days	50	CON	MOD	STP	PSR	No	No
	Urination Impaired	URINARY HESITANCY	30MAR95	8, ., -27	6 Days	100	CON	MIL	STP	PSR	No	No
329.002.00056	Tachycardia	INCREASED HEART RATE	02AUG94	15, ., -21	22 Days	150	CON	MIL	STP	PSR	No	No
329.002.00057	Hyperkinesia	SENSATION OF RESTLESSNESS IN LEGS NO OBSERVABLE TREMORS	27SEP94	20, -38,-109	45 Mins	150	CON	MIL	NO	PBU	No	No
	Unintended Pregnancy	PREGNANCY NAUSEA VOMITING	10DEC94	94, 37, -35	Not Stated	300	CON	MOD	STP	UNR	No	No
	Vomiting	NAUSEA, VOMITING	06OCT94	29, -29,-100	20 Mins	250	CON	MIL	NO	UNR	No	No
329.002.00098	Constipation	CONSTIPATION	02MAR95	59, ., -14	Not Stated	250	CON	MIL	DCR	PSR	No	No
	Dry Mouth	DRY MOUTH	10JAN95	8, ., -65	Not Stated	100	CON	MOD	DCR	PSR	No	No
	Headache	HEADACHES	21FEB95	50, ., -23	9 Days	250	CON	MOD	DCR	PSR	No	No
	Tremor	SHAKING	14FEB95	43, ., -30	Not Stated	250	CON	MOD	DCR	PSR	No	No
329.002.00100	Dizziness	DIZZINESS"OFF AND ON"	14APR95	39, -20, -46	15 Mins	250	15	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	14APR95	39, -20, -46	10 Mins	250	12	MIL	NO	PSR	No	No
329.002.00103	Abdominal Pain	STOMACH ACHE	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
		STOMACH ACHE FOLLOWING INGESTION OF MEDS	21APR95	2, -55,-126	21 Days	50	14	MIL	NO	PSR	No	No
		STOMACH ACHE FOLLOWING INGESTION OF STUDY MEDS	20JUN95	62, 6, -66	52 Days	250	2	MIL	NO	PSR	No	No

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329.002.00103	Abnormal Vision	BLURRED VISION WHEN STANDS QUICKLY	08JUN95	50, -7, -78	36 Days	250	10	MIL	NO	PSR	No	No
	Chills	CHILLS / GOOSE BUMPS WHILE EXERCISING (1X)	08MAY95	19, -38,-109	2 Mins	150	CON	MIL	NO	PSR	No	No
		FEELING HOT/COLD	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
	Dizziness	DIZZINESS	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
		DIZZINESS (WHEN GOING FROM SIT TO STAND)	10AUG95	113, 57, -15	16 Days	250		MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
	Rash	RED SPOTS / BLOTCHES ON SKIN ARMS, THROAT, CHEST	11MAY95	22, -35,-106	35 Days	200		MIL	NO	PSR	No	No
329.002.00104	Dizziness	DIZZINESS	24MAY95	21, -36,-238	133 Days	150	CON	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	11MAY95	8, -49,-251	76 Days	100	CON	MOD	NO	REL	No	No
	Infection	STREP THROAT	21DEC95	232, 176, -27	11 Days	300	1	MOD	NO	UNR	Yes	No
	Urination Impaired	DIFFICULTY INITIATING URINATION	04MAY95	1, -56,-258	8 Days	50	2	MIL	NO	REL	No	No
	Vomiting	NAUSEA AND VOMITING DURING DOWN TITRATION	10JAN96	252, 196, -7	6 Days	100	1	MOD	NO	PSR	No	No
		VOMITING WHEN FORGOT DOSE	25JUL95	83, 27,-176	1 Days	300	1	MOD	NO	REL	No	No
329.002.00243	Abdominal Pain	STOMACH ACHES	21MAR96	8, ., -15	Not Stated	100	CON	MIL	NO	REL	No	No

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329.002.00243	Asthenia	TIREDNESS AND DROWSINESS	14MAR96	1, ., -22	Not Stated	50	CON	MOD	NO	PSR	No	No
	Constipation	CONSTIPATION	04APR96	22, ., -1	Not Stated	150	CON	SEV	NO	PSR	No	No
	Nausea	NAUSEA	21MAR96	8, ., -15	Not Stated	100	CON	MIL	NO	REL	No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	28MAR96	15, ., -8	Not Stated	150	CON	MIL	NO	PSR	No	No
	Rash	ITCHING AND RASH TO RIGHT FOREARM AND BOTH CALVES	17MAR96	4, ., -19	6 Days	50	CON	MOD	NO	UNR	Yes	No
	Trauma	DIZZINESS - (HIT HEAD DURING FALL)	17MAR96	4, ., -19	Not Stated	50	CON	MOD	STP	PSR	No	No
	Tremor	(WORSENING) ENTIRE BODY SHAKES AND SHAKY HAND	22MAR96	9, ., -14	Not Stated	100	CON	MOD	NO	PSR	No	No
329.002.00244	Asthenia	FEELS MORE TIRED AFTER TAKING MEDS	22MAR96	2, -56, -82	14 Days	50	CON	MIL	NO	PSR	No	No
	Depersonalization	"SPACEY" 1X	23MAR96	3, -55, -81	02:00 Hrs	50	7	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS UPON STANDING {1-2X/DAILY}	29MAR96	9, -49, -75	24 Days	100	48	MOD	NO	PSR	No	No
	Dry Mouth	DRY THROAT, MOUTH	29MAR96	9, -49, -75	61 Days	100	CON	MOD	NO	PSR	No	No
	Thirst	INCREASED THIRST	29MAR96	9, -49, -75	61 Days	100	CON	MOD	NO	PBU	No	No

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329.002.00321	Hostility	PSYCHIATRIC HOSPITALIZATION FOLLOWING ASSAULTIVE BEHAVIOR	02JUN96	11, ., -1	Not Stated	50	1	SEV	STP	UNR	No	Yes
329.002.00322	Abdominal Pain	STOMACH ACHE	21JAN97	13, ., -33	02:00 Hrs	100	1	MOD	NO	PBU	No	No
		STOMACH ACHE, RE-OCCURRING	06FEB97	29, ., -17	Not Stated	200		MIL	NO	PSR	No	No
	Arrhythmia	ORTHOSTATIC CHANGES [IRREGULAR PULSE]	13FEB97	36, ., -10	Not Stated	200	CON	MOD	STP	PSR	No	No
	Dizziness	DIZZINESS	11JAN97	3, ., -43	Not Stated	50	CON	MOD	STP	PBU	No	No
		ORTHOSTATIC CHANGES [DIZZINESS]	13FEB97	36, ., -10	Not Stated	200	CON	MOD	STP	PSR	No	No
329.003.00073	Gastrointestinal Disorder	NAUSEA,VOMITING HEADACHES,DIARRHEA(GASTROINTESTINAL ILLNESS)	23FEB95	36, ., -9	Not Stated	250	CON	MOD	NO	UNR	No	No
	Postural Hypotension	ORTHOSTATIC SYMPTOMS {ORTHOSTATIC HYPOTENSION}	03FEB95	16, ., -29	Not Stated	150	CON	MOD	NO	PSR	No	No
	Vomiting	VOMITING	04MAR95	45, ., 0	Not Stated	250	CON	SEV	STP	PSR	Yes	No
329.003.00076	Dizziness	DIZZINESS	06AUG95	188, 133, -52	66 Days	200	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	01FEB95	2, -54,-238	48 Days	50	CON	MIL	NO	PSR	No	No
329.003.00079	Insomnia	INSOMNIA (FREQUENT AWAKENING)	11MAY95	9, ., -8	Not Stated	100	CON	MOD	NO	PSR	No	No

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329.003.00079	Pharyngitis	SORE THROAT	17MAY95	15, ., -2	Not Stated	100	CON	MIL	NO	PBU	Yes	No
329.003.00082	Dizziness	DIZZY	03JAN96	24, ., -14	Not Stated	150	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	17JAN96	38, ., 0	Not Stated	250	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	02JAN96	23, ., -15	04:00 Hrs	100	1	MOD	NO	PSR	No	No
			17JAN96	38, ., 0	Not Stated	250	CON	MIL	NO	PSR	No	No
329.003.00088	Abnormal Vision	BLURRED VISION	14MAR95	15, ., -26	Not Stated	100	CON	MIL	NO	PSR	No	No
	Constipation	CONSTIPATION	14MAR95	15, ., -26	Not Stated	100	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	14MAR95	15, ., -26	764 Days	100	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	21MAR95	22, ., -19	Not Stated	200	CON	MIL	NO	PSR	No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	12MAR95	13, ., -28	1 Days	100	1	MIL	NO	PSR	No	No
	Taste Perversion	BAD TASTE	10MAR95	11, ., -30	21 Days	100	CON	MIL	NO	PSR	No	No
	Urinary Retention	URINARY RETENTION	14MAR95	15, ., -26	Not Stated	100	CON	SEV	STP	REL	No	No
329.003.00090	Constipation	CONSTIPATION	26APR95	44, ., -25	6 Days	250	CON	SEV	DCR	PSR	Yes	No
			02MAY95	50, ., -19	Not Stated	200	CON	MOD	NO	PSR	Yes	No
	Dizziness	DIZZINESS	28MAR95	15, ., -54	29 Days	100	CON	MIL	NO	PSR	No	No
			09MAY95	57, ., -12	Not Stated	200	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	28MAR95	15, ., -54	15 Days	100	CON	MIL	NO	PSR	No	No
	Dyspepsia	HEARTBURN	02MAY95	50, ., -19	Not Stated	200	CON	MIL	NO	PSR	Yes	No
		INDIGESTION	26APR95	44, ., -25	6 Days	250	CON	MOD	DCR	PSR	No	No

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329.003.00090	Dyspepsia	INDIGESTION	02MAY95	50, ., -19	Not Stated	200	CON	MIL	NO	PSR	Yes	No
	Headache	HEADACHE	16MAR95	3, ., -66	13 Days	50	CON	SEV	DCR	PSR	Yes	No
		HEADACHES	11APR95	29, ., -40	15 Days	200	CON	MIL	NO	PSR	Yes	No
			26APR95	44, ., -25	9 Days	250	CON	MOD	DCR	PSR	Yes	No
			05MAY95	53, ., -16	1 Days	200	3	MIL	NO	PSR	Yes	No
	Taste Perversion	BAD TASTE	16MAR95	3, ., -66	5 Days	50	CON	MIL	DCR	PSR	No	No
329.003.00092	Abdominal Pain	STOMACH ACHE	22DEC95	234, 176, -27	02:00 Hrs	200	1	MIL	NO	PBU	No	No
		STOMACH CRAMPS	21MAY95	19, -40,-242	30 Mins	150	2	MIL	NO	PBU	No	No
			10JUN95	39, -20,-222	1 Days	200	1	MOD	NO	PBU	Yes	No
	Dry Mouth	DRY MOUTH	04MAY95	2, -57,-259	146 Days	50	CON	MIL	NO	PSR	No	No
	Gastrointestinal Disorder	STOMACH PROBLEMS	22OCT95	173, 115, -88	2 Days	0		MOD	DCR	PBU	Yes	No
	Pharyngitis	SORE THROAT	01MAY95	-2, -60,-262	16 Days	0	CON	MIL	NO	UNR	No	No
	Somnolence	DROWSINESS	17MAY95	15, -44,-246	16 Days	150	CON	MIL	NO	PSR	No	No
329.003.00093	Dizziness	DIZZINESS	08AUG95	49, -15, -31	20 Mins	300	1	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	20JUN95	-1, -64, -80	106 Days	0	CON	MIL	NO	PSR	No	No
329.003.00247	Asthenia	TIRED	30APR96	90, 36, -21	1 Days	200	1	MIL	NO	UNR	No	No
	Dizziness	DIZZINESS WHEN WAKING UP IN AM	10FEB96	10, -45,-101	32 Days	100		MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	10FEB96	10, -45,-101	23 Days	100	CON	MIL	NO	PSR	No	No
			07MAR96	36, -19, -75	15 Days	200	CON	MIL	NO	PSR	No	No

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329.003.00247	Nervousness	IRRITABLE EDGY BURNT SELF WITH CIGARETTE	16MAR96	45, -10, -66	11 Days	200	1	MIL	DCR	PSR	No	No
	Postural Hypotension	DIZZINESS WHEN STANDING UP ORTHOSTATIC HYPOTENSION	09FEB96	9, -46,-102	33 Days	100	CON	MIL	NO	PSR	No	No
	Respiratory Disorder	COLD {SYMPTOMS}	05MAR96	34, -21, -77	3 Days	200	CON	MOD	NO	UNR	Yes	No
329.003.00249	Dizziness	DIZZINESS	15APR96	40, ., -22	1 Mins	300	1	MIL	NO	PSR	No	No
		DIZZINESS (ORTHOSTATIC)	16APR96	41, ., -21	2 Mins	300		MIL	NO	PSR	No	No
		LIGHT HEADEDNESS	20MAR96	14, ., -48	14 Days	150	CON	MIL	NO	PSR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	13APR96	38, ., -24	3 Days	300		MIL	NO	UNR	Yes	No
	Headache	HEADACHE	07MAR96	1, ., -61	3 Days	50	2	MIL	NO	PSR	Yes	No
	Respiratory Disorder	COLD {SYMPTOMS}	23APR96	48, ., -14	8 Days	300		MIL	NO	UNR	Yes	No
329.003.00289	Anemia	ANEMIA	11OCT96	227, 171, -11	Not Stated	150	CON	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	11MAR96	13, -44,-225	31 Days	100		MIL	NO	PSR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	24APR96	57, 1,-181	Not Stated	200	6	MIL	NO	UNR	No	No
	Headache	HEADACHES	28FEB96	1, -56,-237	85 Days	50		MIL	NO	PBU	No	No
	Insomnia	INSOMNIA	13MAR96	15, -42,-223	129 Days	150		MIL	NO	PBU	No	No
329.003.00290	Dry Mouth	DRY MOUTH	12MAR96	2, ., -10	24:00 Hrs	50	1	MIL	NO	PBU	No	No
	Hypertension	HIGH BLOOD PRESSURE	20MAR96	10, ., -2	15 Days	100	CON	MIL	STP	PSR	No	No

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329.003.00290	Tachycardia	TACHYCARDIA	20MAR96	10, ., -2	Not Stated	100	CON	MIL	STP	PSR	No	No
329.003.00314	Dizziness	DIZZINESS	17DEC96	57, ., -20	Not Stated	200	CON	MIL	NO	PSR	No	No
		LIGHT HEADED	24OCT96	3, ., -74	13 Days	50	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	14NOV96	24, ., -53	Not Stated	200	1	MIL	NO	PSR	No	No
	Dyspepsia	HEARTBURN	04DEC96	44, ., -33	48:00 Hrs	200	1	MIL	NO	UNR	No	No
	Ear Pain	EARACHE	20DEC96	60, ., -17	24:00 Hrs	250	1	MIL	NO	UNR	Yes	No
	Infection	FLU	15NOV96	25, ., -52	3 Days	200	1	MIL	NO	UNR	Yes	No
	Insomnia	INSOMNIA	23OCT96	2, ., -75	3 Days	50	3	MOD	NO	PSR	No	No
329.003.00317	Allergic Reaction	ALLERGY	14JAN97	27, ., -43	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
	Back Pain	BACKACHE	07JAN97	20, ., -50	27 Days	150	3	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS ORTHOSTATIC	07JAN97	20, ., -50	29 Days	150	4	MIL	NO	PSR	No	No
	Headache	HEADACHES	19DEC96	1, ., -69	48 Days	50	7	MIL	NO	PSR	Yes	No
	Respiratory Disorder	COLD {COMMON}	14JAN97	27, ., -43	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
329.004.00013	Abnormal Vision	VISUAL BRIGHT SPOTS	20JUL94	2, -58,-246	5 Days	50	8	MIL	NO	REL	No	No
	Dizziness	DIZZINESS	20JUL94	2, -58,-246	5 Days	50	CON	MOD	NO	REL	No	No
	Dry Mouth	DRY MOUTH	30JUL94	12, -48,-236	Not Stated	100	CON	MOD	NO	REL	No	No
	Headache	HEADACHES	20JUL94	2, -58,-246	5 Days	50	CON	SEV	NO	REL	No	No

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329.004.00013	Somnolence	SLEEPINESS	20JUL94	2, -58,-246	3 Days	50	2	MIL	NO	REL	No	No
	Sweating	SWEATING	20JUL94	2, -58,-246	3 Days	50	CON	MIL	NO	REL	No	No
	Tinnitus	RINGING IN EARS-5-10 MINUTES IN A.M.	03AUG94	16, -44,-232	8 Days	150	7	MIL	NO	REL	No	No
	Tremor	TREMBLING OF HANDS	07AUG94	20, -40,-228	4 Days	150	2	MIL	NO	REL	No	No
329.004.00014	Constipation	CONSTIPATED	02DEC94	4, ., -11	Not Stated	50	CON	MOD	NO	REL	No	No
	Dysphagia	LUMP IN THE THROAT	29NOV94	1, ., -14	11 Days	50	7	MOD	NO	REL	No	No
	Nausea	NAUSEA	05DEC94	7, ., -8	3 Days	100	1	MOD	NO	PSR	No	No
			07DEC94	9, ., -6	Not Stated	100	18	SEV	NO	PSR	No	No
		RETCHING	05DEC94	7, ., -8	Not Stated	100	21	MOD	STP	PSR	No	No
	Polyuria	POLYURIA	05DEC94	7, ., -8	1 Days	100		MIL	NO	PSR	No	No
	Respiratory Disorder	COMMON COLD	24NOV94	-5, ., -19	6 Days	0	1	MIL	NO	UNR	Yes	No
329.004.00211	Dizziness	DIZZINESS	19FEB96	18, ., -31	18 Days	150	CON	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	05FEB96	4, ., -45	14 Days	50	CON	MIL	NO	PSR	No	No
			19FEB96	18, ., -31	15 Days	150	CON	SEV	NO	REL	No	No
			05MAR96	33, ., -16	14 Days	200	CON	MOD	NO	REL	No	No
			19MAR96	47, ., -2	Not Stated	200	CON	SEV	STP	REL	No	No
	Gastroenteritis	BACTERIAL GASTROENTERITIS	21MAR96	49, ., 0	3 Days	200	CON	SEV	STP	UNR	Yes	No
	Headache	HEADACHE	23FEB96	22, ., -27	Not Stated	200	CON	MOD	NO	PBU	Yes	No

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329.004.00211	Hypertonia	STIFF NECK	23FEB96	22, ., -27	18 Days	200	CON	MIL	NO	PBU	No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	12FEB96	11, ., -38	7 Days	100	CON	MIL	NO	PSR	No	No
			19FEB96	18, ., -31	15 Days	150	CON	MOD	NO	REL	No	No
			05MAR96	33, ., -16	Not Stated	200	CON	MIL	NO	REL	No	No
	Trauma	MOUTH CUTS	20MAR96	48, ., -1	Not Stated	200	CON	SEV	STP	REL	Yes	No
	Tremor	TREMORS	19FEB96	18, ., -31	22 Days	150	CON	MIL	NO	PSR	No	No
	Ulcerative Stomatitis	MOUTH SORES	20MAR96	48, ., -1	Not Stated	200	CON	SEV	STP	REL	Yes	No
329.004.00215	Abnormal Dreams	NIGHTMARES	25APR97	37, ., -3	7 Days	200	CON	MOD	STP	REL	No	Yes
	Arthralgia	JOINT PAINS	30APR97	42, ., 2	Not Stated	200	CON	MIL	STP	REL	Yes	No
	Asthenia	WEAKNESS	30APR97	42, ., 2	Not Stated	200	CON	MOD	STP	REL	No	No
	Dizziness	DIZZINESS	04APR97	16, ., -24	2 Days	150	CON	MIL	NO	REL	No	No
			25APR97	37, ., -3	Not Stated	200	CON	MOD	STP	REL	No	Yes
	Dry Mouth	DRY MOUTH	28MAR97	9, ., -31	Not Stated	100	CON	MOD	NO	REL	No	No
	Esophagitis	ESOPHAGEAL IRRITATION	09APR97	21, ., -19	3 Days	150	CON	MIL	NO	PSR	No	No
	Hallucinations	VISUAL HALLUCINATIONS	25APR97	37, ., -3	7 Days	200	CON	SEV	STP	REL	No	Yes
	Headache	HEADACHE	25MAR97	6, ., -34	2 Days	50	1	MIL	NO	UNR	No	No
			01APR97	13, ., -27	30 Days	100	CON	MIL	NO	PSR	No	No
		HEADACHES	01MAY97	43, ., 3	Not Stated	200	CON	SEV	STP	REL	Yes	No
	Nausea	NAUSEA	30APR97	42, ., 2	Not Stated	200	CON	SEV	STP	REL	Yes	No

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329.004.00215	Nervousness	IRRITABILITY	25APR97	37, ., -3	7 Days	200	CON	SEV	STP	REL	No	Yes
	Pharyngitis	SORE THROAT	25MAR97	6, ., -34	5 Days	50	CON	MIL	NO	UNR	Yes	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	01APR97	13, ., -27	21 Days	100	CON	MOD	NO	REL	No	No
			22APR97	34, ., -6	11 Days	200	CON	MIL	NO	REL	No	No
	Rhinitis	RHINITIS	26MAR97	7, ., -33	4 Days	50	CON	MIL	NO	UNR	Yes	No
	Vomiting	VOMITING	30APR97	42, ., 2	Not Stated	200	CON	SEV	STP	REL	Yes	No
329.005.00003	Dizziness	DIZZINESS	27SEP94	8, ., -7	10 Days	100	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	23SEP94	4, ., -11	03:00 Hrs	50	1	MOD	NO	PSR	No	No
	Sweating	SWEATINESS	22SEP94	3, ., -12	6 Days	50	CON	MOD	NO	PSR	No	No
	Tachycardia	"RACING HEART"	23SEP94	4, ., -11	12 Days	50	4	MOD	NO	PBU	No	No
		RACING HEARTBEAT	30SEP94	11, ., -4	5 Days	100	2	MOD	STP	REL	No	No
	Tremor	SHAKINESS	27SEP94	8, ., -7	10 Days	100	CON	MOD	NO	PSR	No	No
329.005.00006	Dizziness	DIZZINESS WHEN GETTING OUT OF BED IN AM	11NOV94	8, -53,-167	25 Days	50	CON	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	09NOV94	6, -55,-169	Not Stated	50	CON	MOD	NO	REL	No	No
	Dyspepsia	UPSET STOMACH	26NOV94	23, -38,-152	64 Days	150	CON	MOD	NO	UNR	Yes	No
	Increased Appetite	CRAVINGS:CEREALS,PASTAS, CARBOHYDRATES	24NOV94	21, -40,-154	41 Days	150	CON	MOD	NO	PSR	No	No

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329.005.00006	Infection	STREP THROAT/FEVER/SORE THROAT	26NOV94	23, -38,-152	5 Days	150	CON	SEV	NO	UNR	Yes	No
	Nausea	NAUSEA	26NOV94	23, -38,-152	64 Days	150	CON	MOD	NO	UNR	Yes	No
	Neurosis	OBSESSIVE THOUGHTS	27FEB95	116, 56, -59	Not Stated	300	CON	MOD	STP	PBU	No	No
	Pyuria	URINALYSIS - WBC'S {INCREASED}	28APR95	176, 116, 1	Not Stated	50		MIL	NO	UNR	No	No
329.005.00007	Abnormal Dreams	NIGHTMARES	02APR95	145, 82, -47	15 Days	250	10	SEV	NO	UNR	No	No
	Convulsion	SEIZURE	24MAY95	197, 134, 5	5 Mins	250	CON	SEV	STP	UNR	Yes	No
	Dehydration	DEHYDRATION	18MAY95	191, 128, -1	8 Days	250	CON	SEV	STP	PBU	Yes	No
	Dry Mouth	DRY MOUTH	20DEC94	42, -22,-150	151 Days	250	CON	MOD	NO	REL	No	No
	Headache	HEADACHE	07MAY95	180, 117, -12	03:30 Hrs	250	CON	MOD	NO	UNR	Yes	No
	Infection	GI VIRUS-NAUSEA,VOMITING AND DIARRHEA	10DEC94	32, -32,-160	4 Days	200	CON	SEV	NO	UNR	No	No
		NAUSEA,VOMITING,DIARRHEA ,FLU	30DEC94	52, -12,-140	2 Days	250	CON	SEV	NO	UNR	No	No
	Myalgia	LEG CRAMPS AND ACHES	28JAN95	81, 18,-111	Not Stated	250	CON	MOD	NO	PSR	Yes	No
	Postural Hypotension	DIZZINESS-POSTURAL HYPOTENSION(ONLY IN GYM CLASSES)	01DEC94	23, -41,-169	14 Days	150	1	MOD	NO	REL	No	No
	Rash	RASH-BILATERAL FOREARMS	10NOV94	2, -62,-190	5 Days	50	CON	MOD	STP	PBU	Yes	No

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329.005.00007	Tremor	HAND TREMORS	20DEC94	42, -22,-150	6 Days	250	CON	MIL	NO	REL	No	No
			26DEC94	48, -16,-144	3 Days	300	CON	MOD	DCR	REL	No	No
			29DEC94	51, -13,-141	142 Days	250	CON	MIL	NO	REL	No	No
	Urticaria	HIVES-BILATERAL FOREARMS	10NOV94	2, -62,-190	5 Days	50	CON	MOD	NO	PBU	Yes	No
329.005.00009	Dry Mouth	DRY MOUTH	16DEC94	5, ., -68	Not Stated	50	CON	MOD	NO	REL	No	No
			09JAN95	29, ., -44	Not Stated	200	CON	MOD	NO	REL	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	20JAN95	40, ., -33	5 Days	300	CON	SEV	NO	UNR	No	No
	Dyspepsia	HEARTBURN	09JAN95	29, ., -44	03:00 Hrs	200	1	MOD	NO	PBU	No	No
		UPSET STOMACH/INDIGESTION	17DEC94	6, ., -67	Not Stated	50	6	MIL	NO	PSR	No	No
	Haematuria	[URINE OCCULT BLOOD]	07DEC94	-5, ., -77	1 Days	0	1	MIL	NO	UNR	No	No
	Headache	HEADACHE	16DEC94	5, ., -68	4 Days	50	3	MOD	NO	PSR	Yes	No
			01JAN95	21, ., -52	04:00 Hrs	150	1	SEV	NO	PSR	Yes	No
		HEADACHES	22DEC94	11, ., -62	6 Days	100	3	SEV	NO	PSR	Yes	No
	Hyperglycemia	GLUCOSE ELEVATED	08FEB95	59, ., -14	1 Days	250	1	SEV	NO	UNR	No	No
	Leukocytosis	NEUTROPHILS, SEGS {INCREASED}	07DEC94	-5, ., -77	1 Days	0	1	MIL	NO	UNR	No	No
	Leukopenia	LYMPHOCYTES {DECREASED}	07DEC94	-5, ., -77	1 Days	0	1	MIL	NO	UNR	No	No
	Tremor	HAND TREMORS	12JAN95	32, ., -41	Not Stated	250	CON	MIL	NO	REL	No	No
			15JAN95	35, ., -38	10 Days	250	CON	MIL	NO	REL	No	No
			24JAN95	44, ., -29	8 Days	300	CON	SEV	DCR	REL	No	No
329.005.00110	Dizziness	DIZZINESS	15JAN95	5, ., -4	5 Mins	50	CON	MIL	NO	PSR	No	No

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329.005.00110	Unintended Pregnancy	POSITIVE PREGNANCY TEST RESULT	21JAN95	11, ., 2	1 Days	100	CON	SEV	STP	UNR	No	No
329.005.00113	Abnormal Vision	BLURRED VISION	06FEB95	8, ., -24	Not Stated	50	10	MIL	NO	REL	No	No
	Dizziness	DIZZINESS	06FEB95	8, ., -24	Not Stated	50	9	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	05FEB95	7, ., -25	Not Stated	50	CON	MOD	NO	REL	No	No
	Emotional Lability	SUICIDAL IDEATION	02MAR95	32, ., 0	1 Days	200	CON	MOD	STP	UNR	No	No
	Headache	HEADACHE	31JAN95	2, ., -30	03:45 Hrs	50	1	SEV	NO	UNR	Yes	No
	Palpitation	HEART WAS POUNDING	19FEB95	21, ., -11	30 Mins	150	1	MOD	NO	REL	No	No
	Tachycardia	QUESTIONABLE INCREASED HEART RATE QUESTIONABLE TACHYCARDIA	19FEB95	21, ., -11	30 Mins	150	1	MOD	NO	REL	No	No
	Tremor	HAND TREMORS	06FEB95	8, ., -24	Not Stated	50	CON	MIL	NO	REL	No	No
329.005.00117	Chills	CHILLS-INCREASED AND DECREASED BACK AND ARMS-NO FEVER	18MAR95	1, ., -69	31 Days	50	11	MOD	NO	PSR	No	No
	Diarrhea	DIARRHEA	19MAR95	2, ., -68	3 Days	50	1	MOD	NO	PSR	No	No
	Epistaxis	NOSEBLEEDS	14APR95	28, ., -42	15 Mins	200	2	MIL	NO	PBU	No	No
	Gastritis	GASTRITIS	27APR95	41, ., -29	Not Stated	200	CON	MOD	NO	PBU	Yes	No
	Headache	HEADACHE	25APR95	39, ., -31	Not Stated	200	CON	SEV	NO	PBU	No	No

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329.005.00117	Nervousness	INCREASED IRRITABILITY	15APR95	29, ., -41	Not Stated	200	CON	MOD	NO	PBU	No	No
	Pruritus	ITCHING-WITHOUT HIVES	19MAR95	2, ., -68	3 Days	50	1	MIL	NO	PSR	No	No
	Tachycardia	INCREASED HEART RATE	10APR95	24, ., -46	22 Days	200	CON	MOD	NO	PSR	No	No
	Tooth Disorder	PAIN DUE TO WISDOM TOOTH EXTRACTION	08MAY95	52, ., -18	8 Days	200	CON	MOD	NO	UNR	Yes	No
	Vasodilatation	FLUSHED FACE-NO HIVES	18MAR95	1, ., -69	4 Days	50	3	MIL	NO	PSR	No	No
	Vomiting	NAUSEATED AND VOMITING	07APR95	21, ., -49	Not Stated	150	CON	SEV	NO	PBU	No	No
329.005.00118	Dizziness	LIGHT-HEADEDNESS	23MAY95	7, ., -43	23 Days	50	5	MIL	NO	PSR	No	No
	Headache	HEADACHE	09JUN95	24, ., -26	02:00 Hrs	200	2	MOD	NO	PBU	No	No
	Migraine	MIGRAINE HEADACHE	20MAY95	4, ., -46	04:00 Hrs	50	CON	SEV	NO	UNR	No	No
	Pharyngitis	SORE THROAT	20MAY95	4, ., -46	4 Days	50	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	CHEST CONGESTION AND COUGH	19MAY95	3, ., -47	6 Days	50	CON	MOD	NO	UNR	Yes	No
329.005.00153	Back Pain	BACK PAIN	23JAN96	-2, -58,-237	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	Decreased Appetite	DECREASED APPETITE	25JAN96	1, -56,-235	42 Days	50	CON	MOD	NO	PSR	No	No
	Dizziness	LIGHTHEADED	25JAN96	1, -56,-235	29 Days	50	7	MIL	NO	PSR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	31JAN96	7, -50,-229	12:00 Hrs	50	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	10FEB96	17, -40,-219	05:00 Hrs	150	CON	MIL	NO	PBU	Yes	No

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329.005.00153	Headache	HEADACHE	21FEB96	28, -29,-208	03:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
			02MAR96	38, -19,-198	03:30 Hrs	250	CON	MIL	NO	UNR	Yes	No
			21MAR96	57, 1,-179	28 Days	250	3	MOD	NO	UNR	Yes	No
			17APR96	84, 28,-152	57 Days	300	9	MIL	NO	UNR	Yes	No
			12JUN96	140, 84, -96	55 Days	300	3	MIL	NO	UNR	Yes	No
	Palpitation	PALPITATIONS	02FEB96	9, -48,-227	9 Days	100		MIL	NO	PSR	No	No
	Sweating	SWEATING	16FEB96	23, -34,-213	13 Days	200	5	MIL	NO	PSR	No	No
	Tachycardia	INCREASED PULSE ON EXERTION	26FEB96	33, -24,-203	4 Days	250	4	MIL	NO	PSR	No	No
		TACHYCARDIA INCREASED PULSE	03FEB96	10, -47,-226	8 Days	100		MIL	NO	PSR	No	No
329.005.00255	Abdominal Pain	STOMACH ACHE	05MAR96	2, ., -69	04:00 Hrs	50	1	MOD	NO	PBU	No	No
	Abnormal Vision	BLURRED VISION	15APR96	43, ., -28	8 Days	250	15	SEV	DCR	REL	No	No
	Eosinophilia	EOSINOPHILS ELEVATED	29APR96	57, ., -14	Not Stated	200	CON	MOD	NO	PBU	No	No
	Headache	HEADACHE	04MAR96	1, ., -70	22 Days	50	16	MOD	NO	PSR	Yes	No
		HEADACHES	24MAR96	21, ., -50	9 Days	150	4	MOD	NO	PBU	No	No
		SOMATIC COMPLAINT HEADACHE	29APR96	57, ., -14	Not Stated	200		MOD	NO	PSR	No	No
	Nausea	SOMATIC COMPLAINT NAUSEA	29APR96	57, ., -14	Not Stated	200		MOD	NO	PSR	No	No
	Pharyngitis	SORE THROAT	14APR96	42, ., -29	4 Days	300	CON	MIL	NO	PBU	No	No
	Tremor	"SHAKINESS"	05MAR96	2, ., -69	4 Days	50	CON	MOD	NO	PSR	No	No
		HAND TREMORS	05APR96	33, ., -38	19 Days	250	CON	MOD	DCR	REL	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00255	Vaginal Moniliasis	YEAST INFECTION (VAGINAL)	19APR96	47, ., -24	5 Days	250	CON	MOD	NO	PBU	Yes	No
	Vasodilatation	FLUSHED FACE	11MAR96	8, ., -63	04:00 Hrs	100	1	MOD	NO	PSR	No	No
329.005.00256	Back Pain	BACKACHE	17MAR96	13, -44,-122	4 Days	100	CON	MOD	NO	UNR	Yes	No
	Dizziness	DIZZINESS UPON STANDING	04APR96	31, -26,-104	13 Days	250	4	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	30MAR96	26, -31,-109	33 Days	200	CON	MOD	NO	PSR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	20MAR96	16, -41,-119	2 Days	100	CON	MOD	NO	UNR	Yes	No
	Dyspepsia	GI UPSET	11JUL96	129, 73, -6	Not Stated	50	CON	MOD	NO	UNR	Yes	No
	Fever	FEVER	05MAR96	1, -56,-134	2 Days	50	1	MOD	NO	PBU	No	No
	Headache	HEADACHE	05MAR96	1, -56,-134	3 Days	50	1	MOD	NO	PBU	Yes	No
			17MAR96	13, -44,-122	4 Days	100	CON	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	05MAR96	1, -56,-134	3 Days	50	1	MOD	NO	PBU	No	No
	Pharyngitis	SORE THROAT	28MAR96	24, -33,-111	5 Days	200	CON	MOD	NO	UNR	Yes	No
	Vasodilatation	HOT FLASHES	23MAR96	19, -38,-116	3 Days	150	2	MOD	NO	PSR	No	No
329.005.00295	Chest Pain	CHEST PAIN	15APR96	19, ., -50	2 Days	150	2	MOD	NO	PSR	No	No
	Dizziness	DIZZINESS	04MAY96	38, ., -31	2 Days	200	4	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	07APR96	11, ., -58	55 Days	100	CON	MOD	NO	REL	No	No

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329.005.00295	Emotional Lability	SUICIDAL THREAT WITH SCISSORS	19APR96	23, ., -46	1 Days	200	1	MOD	NO	PBU	No	No
	Headache	HEADACHE	18APR96	22, ., -47	03:30 Hrs	200	CON	MIL	NO	PBU	No	No
			05MAY96	39, ., -30	04:30 Hrs	200	CON	MOD	NO	PSR	No	No
		HEADACHES	21MAR96	-7, ., -75	1 Days	0	1	MOD	NO	UNR	Yes	No
	Hostility	HOMICIDAL TENDENCIES TOWARDS PARENTS	18MAY96	52, ., -17	04:30 Hrs	250	CON	SEV	STP	PSR	No	No
	Nausea	NAUSEA	05MAY96	39, ., -30	02:00 Hrs	200	CON	MIL	NO	PSR	No	No
	Vomiting	VOMITING	15MAY96	49, ., -20	30 Mins	250	CON	MOD	NO	PBU	No	No
329.005.00297	Dyspepsia	HEARTBURN	24APR96	6, ., -20	04:00 Hrs	50	CON	MOD	NO	UNR	No	No
	Headache	HEADACHE	10MAY96	22, ., -4	02:00 Hrs	150	2	MOD	NO	PSR	Yes	No
	Respiratory Disorder	HEADCOLD AND NASAL CONGESTION	14APR96	-5, ., -30	3 Days	0	CON	MOD	NO	UNR	Yes	No
329.005.00332	Dizziness	DIZZINESS IN GYM CLASS X1	20DEC96	9, ., -63	5 Mins	100	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	03JAN97	23, ., -49	4 Days	200	CON	MIL	NO	REL	No	No
	Headache	HEADACHE - AFTER GYM CLASS OR EXERCISE	16DEC96	5, ., -67	30 Mins	50	CON	MIL	NO	PSR	No	No
329.005.00335	Diarrhea	UPSET STOMACH WITH DIARRHEA	10MAR97	11, ., -57	2 Days	100	CON	SEV	NO	UNR	No	No
	Dizziness	DIZZINESS	01MAR97	2, ., -66	4 Days	50	CON	MIL	NO	REL	No	No

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329.005.00335	Dizziness	DIZZINESS	05MAR97	6, ., -62	01:00 Hrs	50	CON	SEV	NO	REL	No	No
	Dry Mouth	DRY MOUTH	08MAR97	9, ., -59	Not Stated	100	CON	MOD	NO	REL	No	No
	Electrocardiogram Abnormal	EKG CHANGE	03APR97	35, ., -33	1 Days	200	CON	MOD	DCR	REL	No	No
	Headache	HEADACHE	27FEB97	-1, ., -68	03:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			10MAR97	11, ., -57	03:30 Hrs	100	CON	MIL	NO	UNR	No	No
			17MAR97	18, ., -50	4 Days	150	6	MOD	NO	UNR	No	No
			21MAR97	22, ., -46	6 Days	200	5	MOD	NO	UNR	No	No
			30MAR97	31, ., -37	4 Days	250	3	MOD	NO	UNR	No	No
			11APR97	43, ., -25	04:00 Hrs	200	CON	SEV	NO	PBU	Yes	No
			22APR97	54, ., -14	03:30 Hrs	200	CON	MOD	NO	PBU	Yes	No
	Tremor	HAND TREMORS	01MAR97	2, ., -66	4 Days	50	CON	MIL	NO	REL	No	No
			05MAR97	6, ., -62	12:00 Hrs	50	CON	SEV	NO	REL	No	No
			06MAR97	7, ., -61	14 Days	50	CON	MOD	NO	REL	No	No
			01APR97	33, ., -35	5 Days	250	CON	MOD	NO	REL	No	No
			06APR97	38, ., -30	4 Days	200	CON	MIL	NO	REL	No	No
329.006.00040	Asthenia	FATIGUE	22FEB95	7, ., -7	8 Days	50	CON	SEV	STP	REL	No	No
	Constipation	CONSTIPATION	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
	Dizziness	DIZZINESS	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
	Dyspepsia	INDIGESTION	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	PSR	No	No
	Mydriasis	EYE DILATION	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
	Nervousness	IRRITABLE MOOD	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No

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Intent-to-Treat Population

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.006.00040	Tachycardia	ELEVATED HEART RATE	01MAR95	14, ., 0	14 Days	50	CON	MOD	STP	REL	No	No
	Urinary Retention	URINARY RETENTION	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
329.006.00041	Headache	HEADACHE	23AUG95	141, 77,-104	1 Days	300	1	SEV	NO	PBU	Yes	No
	Insomnia	INSOMNIA	16AUG95	134, 70,-111	8 Days	300	6	MOD	NO	UNR	No	No
	Nervousness	IRRITABLE MOOD	16APR95	12, -53,-233	3 Days	100	1	MOD	NO	UNR	No	No
	Nocturia	NOCTURIA	24MAY95	50, -15,-195	8 Days	250	CON	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	16APR95	12, -53,-233	3 Days	100	1	MOD	NO	PBU	Yes	No
	Respiratory Disorder	COLD SYMPTOMS	22AUG95	140, 76,-105	3 Days	300	CON	MOD	NO	UNR	Yes	No
	Syncope	LIGHTHEADED FAINT SYNCOPE	22APR95	18, -47,-227	1 Mins	150	1	MIL	NO	PSR	No	No
	Vomiting	EMESIS	22AUG95	140, 76,-105	1 Days	300	2	MIL	NO	UNR	No	No
329.007.00139	Chest Pain	CHEST PAIN	17MAY95	10, ., -8	8 Days	50	4	MOD	STP	PSR	No	No
	Dyspnea	SHORTNESS OF BREATH	17MAY95	10, ., -8	8 Days	50	CON	MIL	STP	PSR	No	No
329.007.00143	Acne	ACNE	15NOV95	7, ., -16	Not Stated	50	CON	MOD	STP	PSR	No	No
329.007.00146	Anxiety	ANXIETY	14JUL96	172, 119, -69	04:00 Hrs	200	CON	MIL	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	04JUL96	162, 109, -79	02:00 Hrs	200	CON	MOD	NO	UNR	Yes	No
	Dyspepsia	UPSET STOMACH	22MAR96	58, 5,-183	04:00 Hrs	200	CON	MOD	NO	PBU	Yes	No

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Appendix D.2

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Intent-to-Treat Population

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.007.00146	Myalgia	LEFT KNEE MUSCLE SPASMS	18SEP96	238, 185, -3	06:00 Hrs	50	CON	MIL	NO	UNR	Yes	No
	Respiratory Disorder	COLD SYMPTOMS	20JUL96	178, 125, -63	3 Days	200	CON	MIL	NO	UNR	Yes	No
329.007.00269	Electrocardiogram Abnormal	LOW OR NEGATIVE T WAVES	18APR96	8, ., -7	15 Days	100	CON	MIL	STP	REL	No	No
	Nausea	NAUSEA	16APR96	6, ., -9	1 Days	50	CON	MIL	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	18APR96	8, ., -7	15 Days	100	CON	MIL	STP	REL	No	No
	Trauma	FOOT PAIN{INJURY}	21APR96	11, ., -4	2 Days	100	CON	MIL	NO	UNR	Yes	No
329.007.00270	Chest Pain	CHEST PAIN, CHEST TIGHTNESS	19JUN96	42, ., -1	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes
			20JUN96	43, ., 0	05:00 Hrs	200	CON	MIL	STP	PSR	No	No
	Contact Dermatitis	POISON IVY	17MAY96	9, ., -34	3 Days	100	CON	MOD	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	19JUN96	42, ., -1	30 Mins	200	CON	MIL	NO	UNR	No	No
			24JUN96	47, ., 4	2 Days	200	CON	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	23MAY96	15, ., -28	15 Days	150	CON	MIL	NO	PSR	No	No
	Dyspnea	SHORTNESS OF BREATH	19JUN96	42, ., -1	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes
	Fungal Dermatitis	RINGWORM	30MAY96	22, ., -21	17 Days	200	CON	MIL	NO	UNR	Yes	No
	Headache	HEADACHE	24JUN96	47, ., 4	2 Days	200	CON	MOD	NO	UNR	No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	01JUN96	24, ., -19	4 Days	200	5	MIL	NO	PSR	No	No
329.007.00307	Dry Mouth	DRY MOUTH	18MAY96	3, ., -33	39 Days	50	CON	MIL	NO	REL	No	No

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329.007.00307	Headache	HEADACHES	04JUL96	50, ., 14	Not Stated	0	20	MOD	NO	UNR	No	No
	Maculopapular Rash	MORBILLIFORM "MEASLES LIKE" ERUPTION, GENERALIZED SIMILAR TO TRICYCLIC RASH, ON TRUNK, BACK, EXTREMITIES, CHEST, BUTTOCKS, TORSO/FRONT AND BACK, AND LOWER NECK	16JUN96	32, ., -4	10 Days	200	CON	MOD	STP	REL	Yes	Yes
	Sinusitis	SINUSITIS	02JUN96	18, ., -18	6 Days	150	CON	MIL	NO	UNR	Yes	No
			23JUL96	69, ., 33	Not Stated	0	CON	MOD	NO	UNR	Yes	No
	Tremor	TREMORS	30MAY96	15, ., -21	25 Days	150	CON	MIL	NO	REL	No	No
329.007.00308	Nausea	NAUSEA	30JUN96	-2, ., -11	01:00 Hrs	0	CON	MIL	NO	PSR	Yes	No
	Vomiting	VOMITING	30JUN96	-2, ., -11	01:00 Hrs	0	CON	MIL	NO	PSR	No	No
329.008.00159	Dizziness	DIZZINESS	24OCT95	42, -21, -92	9 Days	250		MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	04OCT95	22, -41,-112	29 Days	200	CON	MIL	NO	PSR	No	No
	Insomnia	TROUBLE GETTING TO SLEEP AND EARLY AWAKENING	29OCT95	47, -16, -87	8 Days	250	CON	MIL	NO	PSR	No	No
329.008.00161	Dry Mouth	DRY MOUTH	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No
	Hostility	INTENSE ANGER	24DEC95	39, -17, -17	30 Mins	200	2	MOD	NO	PSR	No	No
	Insomnia	POOR SLEEP	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No

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329.008.00161	Nervousness	RESTLESSNESS	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No
329.008.00187	Acne	INCREASED ACNE (FACE,CHEST,BACK)	30NOV95	2, ., -71	Not Stated	50	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	30NOV95	2, ., -71	Not Stated	50	CON	MIL	NO	PSR	No	No
	Dyspnea	SHORTNESS OF BREATH (WITH EXERCISE)	07JAN96	40, ., -33	Not Stated	200	CON	MIL	NO	PSR	No	No
	Nausea	INFREQUENTLY NAUSEA	10DEC95	12, ., -61	Not Stated	100	CON	MIL	NO	PSR	No	No
	Photophobia	LIGHT SENSITIVITY	18DEC95	20, ., -53	Not Stated	150	CON	MIL	NO	REL	No	No
	Somnolence	SEDATION	22DEC95	24, ., -49	Not Stated	200	CON	MOD	NO	REL	No	No
	Sweating	EPISODIC CALOR AND PERSPIRATION	10DEC95	12, ., -61	Not Stated	100	CON	MIL	NO	PSR	No	No
	Taste Perversion	BITTER TASTE IN MOUTH	30NOV95	2, ., -71	Not Stated	50	CON	MIL	NO	PSR	No	No
329.008.00192	Dizziness	LIGHTHEADEDNESS	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU	No	No
	Dry Mouth	DRY MOUTH	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU	No	No
	Dyspepsia	HEARTBURN	30MAR96	26, ., -12	Not Stated	200	CON	MIL	DCR	PSR	No	No
	Somnolence	DROWSINESS	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU	No	No
329.008.00272	Asthenia	FATIGUE	04APR96	2, -55,-167	Not Stated	50	CON	MIL	NO	PSR	No	No
	Somnolence	DROWSINESS	24JUL96	113, 57, -56	Not Stated	200	CON	MIL	NO	REL	No	No

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329.008.00273	Accidental Overdose	TRICYCLIC TOXICITY	09SEP96	116, 53, 0	8 Days	300		SEV	STP	REL	No	Yes
329.009.00127	Chest Pain	CHEST PAIN WHEN TAKING MEDS	17APR95	8, ., -39	45 Days	100	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS	24APR95	15, ., -32	38 Days	150		MOD	NO	REL	No	No
	Headache	OCCASIONAL HEADACHE	12APR95	3, ., -44	Not Stated	50		MIL	NO	PSR	No	No
	Insomnia	INITIAL INSOMNIA	17APR95	8, ., -39	45 Days	100	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	24APR95	15, ., -32	38 Days	150		MOD	STP	REL	No	No
	Somnolence	DAYTIME DROWSINESS	12APR95	3, ., -44	Not Stated	50	CON	MIL	NO	PSR	No	No
329.009.00132	Headache	HEADACHE	18JUN95	27, -31,-140	3 Days	200	CON	MIL	NO	UNR	No	No
	Nausea	NAUSEA	18JUN95	27, -31,-140	3 Days	200		MIL	NO	UNR	No	No
			24AUG95	94, 37, -73	62 Days	200		MIL	NO	PSR	No	No
	Vomiting	VOMITING	19JUN95	28, -30,-139	06:00 Hrs	200		MIL	NO	UNR	No	No
329.009.00134	Asthenia	FATIGUE	10JUL95	5, ., -61	65 Days	50	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	11AUG95	37, ., -29	33 Days	200	CON	MOD	STP	REL	No	No
	Dry Mouth	DRY MOUTH	27JUL95	22, ., -44	48 Days	200	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE(OCCASIONAL)	12AUG95	38, ., -28	Not Stated	200		MIL	NO	PSR	Yes	No
	Postural Hypotension	POSTURAL HYPOTENSION	11AUG95	37, ., -29	33 Days	200	3	MOD	NO	PSR	No	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00134	Qt Interval Prolonged	INCREASED QT/{CORRECTED}QTC RATIO	29AUG95	55, ., -11	15 Days	150	CON	MOD	STP	REL	No	No
	Somnolence	HYPERSOMNOLENCE	10JUL95	5, ., -61	65 Days	50	CON	MOD	NO	PSR	No	No
	Sweating	INCREASED SWEATING	27JUL95	22, ., -44	48 Days	200	CON	MIL	NO	PSR	No	No
	Syncope	BLACKOUTS	11AUG95	37, ., -29	33 Days	200	3	MOD	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	11AUG95	37, ., -29	33 Days	200		MOD	NO	PSR	No	No
329.009.00137	Asthenia	FATIGUE	14NOV95	36, ., -32	22 Days	200	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	17NOV95	39, ., -29	4 Days	200		MIL	NO	PSR	No	No
	Somnolence	SOMNOLENCE	25OCT95	16, ., -52	42 Days	150	CON	MOD	NO	PSR	No	No
	Urinary Frequency	INCREASED URINATION	17OCT95	8, ., -60	8 Days	100	CON	MIL	NO	PBU	No	No
329.009.00171	Maculopapular Rash	RASH{FINE MACULAR ON FACE,INSIDE ELBOWS,BACK}	10NOV95	4, ., -4	Not Stated	50	CON	SEV	STP	PBU	No	No
	Pharyngitis	SORE THROAT	14NOV95	8, ., 0	Not Stated	50	CON	MIL	NO	PBU	No	No
	Sinusitis	SINUS CONGESTION	14NOV95	8, ., 0	Not Stated	50	CON	MIL	NO	PBU	No	No
329.009.00172	Abnormal Dreams	NIGHTMARES	18DEC95	36, -22,-215	52 Days	200		MOD	NO	PSR	No	No
	Diarrhea	DIARRHEA	18JUL96	249, 192, -2	2 Days	50	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS	03DEC95	21, -37,-230	233 Days	150	CON	MOD	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	05DEC95	23, -35,-228	231 Days	200	CON	MOD	NO	PSR	No	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00172	Insomnia	INITIAL INSOMNIA	10JUN96	211, 154, -40	29 Days	200	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	18JUL96	249, 192, -2	2 Days	50	CON	MIL	NO	PBU	No	No
	Somnolence	SOMNOLENCE	29NOV95	17, -41,-234	6 Days	150	CON	MOD	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	14NOV95	2, -56,-249	14 Days	50	2	MIL	NO	PBU	No	No
	Thinking Abnormal	RACING THOUGHTS	22DEC95	40, -18,-211	13 Days	200		MIL	NO	PBU	No	No
	Tinnitus	RINGING IN EARS	03DEC95	21, -37,-230	30 Days	150		MIL	NO	PSR	No	No
	Urinary Retention	URINARY RETENTION	09JAN96	58, 1,-193	8 Days	200	CON	MOD	NO	PBU	No	No
	Urination Impaired	HARD TO INITIATE URINATION	09JAN96	58, 1,-193	8 Days	200	CON	MOD	NO	PBU	No	No
329.009.00194	Abdominal Pain	STOMACH ACHE	19DEC95	15, -42,-169	181 Days	150	CON	MOD	NO	REL	Yes	No
	Abnormal Dreams	INCREASED DREAMING	07DEC95	3, -54,-181	34 Days	50		MOD	NO	PSR	No	No
		NIGHTMARES	07DEC95	3, -54,-181	13 Days	50	1	MOD	NO	PSR	No	No
	Insomnia	INITIAL INSOMNIA	27FEB96	85, 29, -99	64 Days	200	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	16JAN96	43, -14,-141	153 Days	200	CON	MOD	STP	PSR	No	No
	Respiratory Disorder	COLD SYNDROME UPPER RESPIRATORY TRACT INFECTION(URI)	02JAN96	29, -28,-155	15 Days	200	CON	MIL	NO	UNR	Yes	No
	Sweating	NIGHT SWEATS	02APR96	120, 64, -64	76 Days	200	CON	MIL	NO	PSR	No	No
329.009.00195	Chest Pain	CHEST PAIN	04JAN96	21, ., -15	19 Days	200	2	MOD	NO	PSR	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00195	Dizziness	DIZZINESS	04JAN96	21, ., -15	19 Days	200	CON	MOD	NO	PSR	No	No
	Extrasystoles	CARIDAC ARRHYTHMIA [PREMATURE VENTRICULAR CONTRACTIONS]	08JAN96	25, ., -11	15 Days	150	CON	MOD	STP	REL	No	No
	Headache	HEAD PAIN	02JAN96	19, ., -17	21 Days	200	20	MOD	NO	PSR	No	No
	Sweating	SWEATING	25DEC95	11, ., -25	29 Days	100	CON	MOD	NO	PSR	No	No
	Vasodilatation	FACIAL FLUSHING	25DEC95	11, ., -25	29 Days	100	CON	MOD	NO	PSR	No	No
	Weight Loss	WEIGHT LOSS	27DEC95	13, ., -23	13 Days	150	CON	MIL	NO	PSR	No	No
329.009.00199	Dizziness	DIZZINESS	17JAN96	2, ., -69	Not Stated	50	CON	MOD	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	24JAN96	9, ., -62	15 Days	100	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES	13MAR96	58, ., -13	Not Stated	200	5	MIL	NO	PBU	No	No
	Nausea	NAUSEA	17JAN96	2, ., -69	42 Days	50	CON	MOD	NO	PSR	No	No
			28FEB96	44, ., -27	15 Days	250	CON	MIL	NO	PSR	No	No
329.009.00203	Av Block	1ST DEGREE AV BLOCK	26MAR96	23, ., -10	Not Stated	150	CON	MOD	STP	REL	No	No
	Nausea	NAUSEA WHEN TAKING PM MEDS	05MAR96	2, ., -31	Not Stated	50	CON	MIL	NO	PSR	No	No
	Palpitation	PALPITATIONS	24MAR96	21, ., -12	Not Stated	150	CON	MOD	NO	PSR	No	No
	Qt Interval Prolonged	PROLONGED QT-QUANTITATIVE TIP CULTURES	26MAR96	23, ., -10	Not Stated	150	CON	MOD	STP	REL	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00203	Thirst	INCREASED THIRST	24MAR96	21, ., -12	Not Stated	150	CON	MIL	NO	PSR	No	No
	Vasodilatation	HOT FLASHES(FACIAL FLUSHING)	24MAR96	21, ., -12	Not Stated	150	CON	MOD	NO	PSR	No	No
329.009.00236	Dizziness	DIZZINESS	20JAN97	22, ., -19	Not Stated	200	CON	MOD	STP	REL	No	No
	Insomnia	MIDDLE INSOMNIA	15JAN97	17, ., -24	6 Days	150	CON	MIL	NO	PSR	No	No
	Somnolence	DAYTIME SEDATION	20JAN97	22, ., -19	Not Stated	200	CON	MOD	STP	REL	No	No
329.009.00239	Bradycardia	SINUS BRADYCARDIA PER EKG	12MAY97	175, 118, 28	Not Stated	0	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	09DEC96	21, -37,-126	8 Days	200	CON	MIL	NO	PSR	No	No
			06JAN97	49, -9, -98	10 Days	200	CON	MIL	NO	PSR	No	No
	Dry Skin	DRY FINGERTIPS	17MAR97	119, 62, -28	Not Stated	200	CON	MIL	NO	PSR	Yes	No
	Dysphagia	DIFFICULTY SWALLOWING PILL	16DEC96	28, -30,-119	8 Days	200	CON	MIL	NO	REL	No	No
	Headache	HEADACHE	18FEB97	92, 35, -55	Not Stated	200	CON	MIL	NO	PSR	No	No
	Insomnia	MIDDLE INSOMNIA	30DEC96	42, -16,-105	8 Days	200	CON	MIL	NO	PSR	Yes	No
	Nausea	NAUSEA	26DEC96	38, -20,-109	5 Days	200	CON	MOD	NO	PBU	No	No
	Respiratory Disorder	HEAD COLD	06JAN97	49, -9, -98	10 Days	200	CON	MIL	NO	UNR	No	No
	Sinusitis	SINUS CONGESTION	18FEB97	92, 35, -55	28 Days	200	CON	MIL	NO	UNR	Yes	No
	Somnolence	DAYTIME SOMNOLENCE	09DEC96	21, -37,-126	22 Days	200	CON	MIL	NO	PSR	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00239	Tachycardia	ELEVATED PULSE	25NOV96	7, -51,-140	141 Days	100	CON	MIL	NO	REL	No	No
	Vomiting	VOMITING	26DEC96	38, -20,-109	5 Days	200	CON	MOD	NO	PBU	Yes	No
329.009.00262	Av Block	INCREASED PR INTERVAL (PER EKG)	07MAR97	19, ., -50	11 Days	200	CON	MIL	NO	PSR	No	No
	Cough Increased	COUGH	15MAR97	27, ., -42	2 Days	200	CON	MIL	NO	PBU	Yes	No
	Dry Mouth	DRY MOUTH	24FEB97	8, ., -61	64 Days	100	CON	MIL	NO	REL	No	No
	Ear Pain	EARACHE	03MAR97	15, ., -54	5 Days	150	CON	MIL	NO	PBU	No	No
	Eye Disorder	EYE INFECTION (LEFT AND RIGHT EYE)	10FEB97	-7, ., -75	57 Days	0	CON	MOD	NO	UNR	Yes	No
	Heart Malformation	POSSIBLE RIGHT ATRIAL ENLARGEMENT (PER EKG)	17MAR97	29, ., -40	15 Days	200	CON	MIL	NO	PSR	No	No
	Postural Hypotension	MILD OTHOSTATIC STATE (1X) (DUE TO BLOOD DRAW) {ORTHOSTATIC HYPOTENSION}	14APR97	57, ., -12	5 Mins	200	CON	MIL	NO	PSR	No	No
	Somnolence	DAYTIME SOMNOLENCE	24FEB97	8, ., -61	8 Days	100	CON	MIL	NO	PSR	No	No
329.009.00264	Agitation	AGITATION	11NOV96	11, ., -54	8 Days	150	CON	MOD	NO	PSR	No	No
	Electrocardiogram Abnormal	NONSPECIFIC T-WAVE ABNORMALITY (PER EKG) BASELINE ARTIFACT	23DEC96	53, ., -12	Not Stated	200	CON	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00264	Insomnia	DECREASED SLEEP (INITIAL, MIDDLE)	11DEC96	41, ., -24	6 Days	200	CON	MIL	NO	PSR	No	No
	Somnolence	DAYTIME SOMNOLENCE	08NOV96	8, ., -57	25 Days	100	CON	MOD	NO	PSR	No	No
			16DEC96	46, ., -19	Not Stated	200	CON	MOD	NO	PSR	No	No
	Tachycardia	INCREASED HEART RATE	11NOV96	11, ., -54	Not Stated	150	CON	MIL	NO	PSR	No	No
		SINUS TACHYCARDIA	23DEC96	53, ., -12	Not Stated	200	CON	MIL	NO	PSR	No	No
329.009.00301	Dizziness	DIZZINESS	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No	No
	Infection	INCREASED SWEATING(VIRAL SYNDROME)	09APR96	22, -35, -75	20 Mins	150	CON	MIL	NO	PBU	No	No
		NAUSEA(VIRAL SYNDROME)	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No	No
		VOMITING(VIRAL SYNDOME)	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No	No
	Tachycardia	INCREASE IN PULSE(SECONDARY TO ALUPENT)	23APR96	36, -21, -61	15 Mins	200	CON	MOD	NO	PBU	No	No
329.009.00305	Abnormal Vision	BLURRED VISION	03JUL96	58, 1,-203	35 Days	200	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	14MAY96	8, -50,-253	15 Days	100	CON	MOD	NO	PSR	No	No
			28MAY96	22, -36,-239	71 Days	200	CON	MIL	NO	PSR	No	No
			09SEP96	126, 69,-135	142 Days	200	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	14MAY96	8, -50,-253	22 Days	100	CON	MOD	NO	PSR	No	No
			03JUL96	58, 1,-203	35 Days	200	CON	MIL	NO	PSR	No	No
			09SEP96	126, 69,-135	142 Days	200	CON	MIL	NO	PSR	No	No
	Electrocardiogram Abnormal	POSITIVE/NEGATIVE RIGHT AXIS DEVIATION (EKG)	10JAN97	249, 192, -12	19 Days	200	CON	MIL	NO	PBU	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00305	Nausea	NAUSEA	14MAY96	8, -50,-253	15 Days	100	CON	MOD	NO	PSR	No	No
			28MAY96	22, -36,-239	23 Days	200	CON	MIL	NO	PSR	No	No
			02JUL96	57, -1,-204	1 Days	200	CON	MOD	NO	UNR	Yes	No
329.009.00325	Abnormal Dreams	INCREASED DREAMING	30SEP96	35, -21, -89	11 Days	200	CON	MIL	NO	PSR	No	No
	Chills	CHILLS	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
	Cough Increased	COUGH	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
	Dizziness	DIZZINESS	01SEP96	6, -50,-118	16 Days	50	CON	MOD	NO	PSR	No	No
			17SEP96	22, -34,-102	Not Stated	200	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	23SEP96	28, -28, -96	8 Days	200	CON	MIL	NO	PSR	No	No
	Dyspnea	SHORTNESS OF BREATH	01SEP96	6, -50,-118	16 Days	50	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	PBU	Yes	No
	Keratoconjunctivitis	IRRITATION IN EYES (DRY EYES)	09SEP96	14, -42,-110	8 Days	150	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	06SEP96	11, -45,-113	11 Days	100	CON	MIL	NO	PSR	No	No
			23SEP96	28, -28, -96	8 Days	200	CON	MIL	NO	PSR	No	No
	Rhinitis	NASAL CONGESTION	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
	Syncope	DIZZINESS WITH SYNCOPE	01SEP96	6, -50,-118	1 Days	50	CON	MIL	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	23OCT96	58, 3, -66	27 Days	200		MOD	NO	PSR	No	No
329.009.00326	Dizziness	DIZZINESS	14OCT96	40, -14, -75	4 Days	200	CON	MIL	NO	PSR	No	No

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PAROXETINE - PROTOCOL 329

Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00326	Hyperkinesia	AKATHISIA	30SEP96	26, -28, -89	18 Days	200	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	14OCT96	40, -14, -75	4 Days	200	CON	MIL	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	30SEP96	26, -28, -89	Not Stated	200	CON	MIL	NO	PSR	No	No
329.010.00279	Abdominal Pain	STOMACH PAIN	02OCT96	195, 139, -51	6 Days	300	5	MOD	DCR	PBU	No	No
		STOMACH PAINS	30SEP96	193, 137, -53	02:00 Hrs	300	CON	MIL	NO	PSR	Yes	No
	Acne	ACNE	15JUN96	86, 30,-160	Not Stated	300	CON	MOD	NO	PBU	Yes	No
	Contact Dermatitis	POISON IVY	09JUL96	110, 54,-136	11 Days	300	CON	MIL	NO	UNR	Yes	No
			23AUG96	155, 99, -91	51 Days	300	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	01APR96	11, -46,-235	03:00 Hrs	100	1	MOD	NO	PBU	Yes	No
	Infection	FLU	01MAY96	41, -16,-205	3 Days	300	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	01OCT96	194, 138, -52	03:00 Hrs	300	CON	MIL	NO	PSR	No	No
			02OCT96	195, 139, -51	6 Days	300	5	MOD	DCR	PBU	No	No
	Respiratory Disorder	COLD - RUNNY NOSE, CONGESTION	08MAY96	48, -9,-198	4 Days	300	CON	MIL	NO	PBU	No	No
	Thinking Abnormal	"STRANGE THOUGHTS"	23APR96	33, -24,-213	2 Days	250	1	MIL	NO	PBU	No	No
	Tooth Disorder	MOLAR ERUPTING	07AUG96	139, 83,-107	02:00 Hrs	300	CON	MOD	NO	UNR	Yes	No
	Ulcerative Stomatitis	MOUTH SORES	03OCT96	196, 140, -50	Not Stated	300	CON	MOD	NO	PBU	No	No
329.010.00281	Abdominal Pain	STOMACH ACHE	18DEC96	146, 85, -32	2 Days	300	CON	MIL	NO	PBU	No	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.010.00281	Asthenia	FATIGUE	05DEC96	133, 72, -45	20 Days	300	CON	MOD	NO	PSR	No	No
			24DEC96	152, 91, -26	30 Days	300	CON	SEV	STP	PSR	No	No
	Bundle Branch Block	PROLONGED QRS DURATION	18SEP96	55, -7,-123	15 Days	300	CON	MIL	NO	REL	No	No
	Headache	HEADACHE	03SEP96	40, -22,-138	16:00 Hrs	250	1	MOD	NO	PSR	Yes	No
			18DEC96	146, 85, -32	2 Days	300	CON	MIL	NO	PBU	Yes	No
329.011.00163	Dizziness	DIZZINESS	28NOV95	4, ., -24	18:00 Hrs	50	1	MIL	NO	PBU	No	No
	Headache	HEADACHE	23NOV95	-2, ., -29	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
			28NOV95	4, ., -24	18:00 Hrs	50	1	MOD	NO	PBU	Yes	No
	Nausea	NAUSEA	28NOV95	4, ., -24	18:00 Hrs	50	1	MIL	NO	PBU	No	No
			17DEC95	23, ., -5	5 Days	150	CON	MIL	NO	PBU	No	No
			22DEC95	28, ., 0	Not Stated	200	CON	MOD	STP	PSR	No	No
			23DEC95	29, ., 1	Not Stated	200	CON	MOD	STP	PSR	No	No
	Pharyngitis	SORE THROAT	30NOV95	6, ., -22	20:00 Hrs	50	CON	MIL	NO	UNR	Yes	No
	Rash	RASH	21NOV95	-4, ., -31	Not Stated	0	CON	MIL	NO	UNR	Yes	No
	Vomiting	VOMITING	22DEC95	28, ., 0	4 Days	200	4	MOD	STP	PSR	No	No
329.011.00208	Abdominal Pain	STOMACH ACHE	16SEP96	11, -49, -68	03:00 Hrs	100	1	MIL	NO	UNR	No	No
			20SEP96	15, -45, -64	3 Days	150	6	MIL	NO	PBU	No	No
	Abnormal Laboratory Value	TOXIC IMIPRAMINE LEVEL	07NOV96	63, 4, -16	Not Stated	300		MIL	STP	REL	No	No
	Constipation	CONSTIPATION	12OCT96	37, -23, -42	13 Days	300	CON	MIL	NO	PSR	No	No
329.011.00209	Rhinitis	RUNNY NOSE	30SEP96	20, -43, -80	4 Days	150	CON	MIL	NO	UNR	Yes	No

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Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.011.00284	Constipation	CONSTIPATION	22APR96	32, -25,-106	11 Days	200	CON	MIL	NO	PSR	No	No
	Diarrhea	DIARRHEA	08JUN96	79, 23, -59	03:00 Hrs	250	3	MIL	NO	PBU	No	No
	Dysuria	DYSURIA	09JUN96	80, 24, -58	2 Days	250	3	MOD	NO	PBU	No	No
	Headache	HEADACHE	21APR96	31, -26,-107	01:00 Hrs	200	1	MOD	NO	PBU	Yes	No
			07JUN96	78, 22, -60	01:00 Hrs	250	CON	MIL	NO	PBU	Yes	No
	Leukopenia	LOW NEUTROPHILS	16MAY96	56, -1, -82	Not Stated	250	CON	MOD	NO	PBU	No	No
		LOW WHITE CELL COUNT	16MAY96	56, -1, -82	Not Stated	250	CON	MOD	NO	PBU	No	No
	Nausea	NAUSEA	21MAR96	-1, -57,-138	13 Days	0	4	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	30MAR96	9, -48,-129	4 Days	100	CON	MIL	NO	UNR	Yes	No
329.012.00221	Constipation	CONSTIPATION	14OCT96	112, 49, -20	19 Days	200	CON	MOD	NO	UNR	Yes	No
	Dizziness	DIZZINESS	02AUG96	39, -25, -93	8 Days	200	5	MOD	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	30AUG96	67, 4, -65	52 Days	200	CON	MOD	NO	PSR	No	No
	Emotional Lability	OVERDOSE {INTENTIONAL}	03NOV96	132, 69, 0	19:30 Hrs	200	CON	SEV	STP	UNR	No	Yes
	Euphoria	MILD ELATION AND DISINHIBITION	24JUL96	30, -34,-102	13 Days	250	CON	MIL	DCR	PSR	No	No
	Headache	HEADACHES (SEVERE)	10SEP96	78, 15, -54	06:00 Hrs	200	1	SEV	NO	PBU	Yes	No
	Insomnia	INSOMNIA	15AUG96	52, -12, -80	39 Days	200		MOD	NO	UNR	Yes	No
329.012.00223	Depression	MAJOR DEPRESSION	29SEP96	31, ., -13	Not Stated	200	CON	MOD	NO	UNR	No	Yes

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.012.00223	Emotional Lability	SELF MUTILATION	29SEP96	31, ., -13	Not Stated	200	CON	MOD	NO	UNR	No	Yes
		SUICIDAL IDEATION	24SEP96	26, ., -18	10 Days	200	1	MOD	NO	UNR	No	No
	Hypertension	HYPERTENSION	30SEP96	32, ., -12	Not Stated	200	CON	MOD	NO	UNR	No	Yes
329.012.00227	Drug Dependence	CANNABIS USE	18JAN97	32, -38,-228	1 Days	200	1	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	17JAN97	31, -39,-229	Not Stated	200	CON	MIL	NO	PBU	No	No
		SEVERE DRY MOUTH	25APR97	129, 60,-131	128 Days	300	CON	SEV	NO	PSR	No	No
	Headache	MODERATE HEADACHE	05JAN97	19, -51,-241	52 Days	100	5	MOD	NO	PSR	No	No
		SEVERE HEADACHES	24DEC96	7, -63,-253	07:00 Hrs	50	2	SEV	NO	PSR	No	No
	Hypertension	HYPERTENSION	25APR97	129, 60,-131	117 Days	300		MOD	NO	PBU	No	No
	Insomnia	TERMINAL INSOMNIA	07FEB97	52, -18,-208	Not Stated	200		MIL	INC	PBU	No	No
	Myalgia	MUSCLE SPASMS IN RIBS	09MAY97	143, 74,-117	11:00 Hrs	300	CON	MOD	NO	PBU	No	No
	Pharyngitis	PHARYNGITIS	06JAN97	20, -50,-240	36 Days	150	CON	MOD	NO	PBU	Yes	No
		SORE THROAT	10FEB97	55, -15,-205	11 Days	200	CON	MIL	NO	PBU	No	No
	Respiratory Disorder	COMMON COLD	05MAY97	139, 70,-121	18 Days	300	CON	MIL	NO	UNR	Yes	No
	Syncope	SYNCOPE	23MAR97	96, 27,-164	161 Days	300		MIL	NO	PBU	No	No
329.012.00230	Cystitis	FEELING BLADDER FULL AFTER URINATING	01MAY97	63, -7, -25	28 Days	200	CON	MIL	NO	PBU	Yes	No
	Dizziness	DIZZINESS	12MAR97	13, -57, -75	3 Days	100	2	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	11MAR97	12, -58, -76	77 Days	100	CON	MOD	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.012.00230	Dyspepsia	HEARTBURN	14MAR97	15, -55, -73	74 Days	150		MIL	NO	PBU	Yes	No
	Headache	HEADACHE	31MAR97	32, -38, -56	1 Days	200	CON	MIL	NO	PBU	Yes	No
	Nausea	NAUSEA	18APR97	50, -20, -38	7 Days	200		MOD	NO	UNR	No	No
			07MAY97	69, -1, -19	14:00 Hrs	250	CON	MIL	NO	UNR	Yes	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	18APR97	50, -20, -38	19 Days	200		MIL	NO	PBU	No	No
	Tooth Disorder	PAIN RE: 4 IMPACTED WISDOM TEETH EXTRACTED UNDER GENERAL ANESTHETIC	18APR97	50, -20, -38	1 Days	200	CON	MOD	NO	UNR	Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.001.00062	Back Pain	BACK AND NECK ACHES	31OCT94	12, ., -15	19 Days	0		MOD	NO	PSR	No	No
	Dizziness	DIZZINESS WHEN RIDING IN ELEVATOR OR ESCALATOR	10NOV94	22, ., -5	9 Days	0		MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	04NOV94	16, ., -11	Not Stated	0	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	23OCT94	4, ., -23	Not Stated	0	CON	MOD	NO	PSR	No	No
329.001.00064	Abdominal Pain	STOMACH ACHE	23NOV94	14, -41,-138	03:00 Hrs	0	1	MIL	NO	PSR	No	No
			01DEC94	22, -33,-130	8 Days	0	2	MIL	NO	PSR	No	No
	Albuminuria	URINE 1+PROTEIN	28MAR95	139, 85, -13	Not Stated	0	CON	MIL	NO	PBU	No	No
	Cough Increased	CONGESTED COUGH	24DEC94	45, -10,-107	18 Days	0	CON	MIL	NO	UNR	No	No
	Diarrhea	DIARRHEA	23NOV94	14, -41,-138	03:00 Hrs	0	2	MIL	NO	PSR	No	No
			31JAN95	83, 29, -69	2 Days	0	CON	MIL	NO	UNR	No	No
	Dizziness	DIZZY UPON POSITION CHANGE	12NOV94	3, -52,-149	6 Days	0	5	MIL	NO	PSR	No	No
	Headache	HEADACHE	26JAN95	78, 24, -74	6 Days	0	2	MIL	NO	PBU	No	No
	Nausea	NAUSEA	31JAN95	83, 29, -69	2 Days	0	CON	MIL	NO	UNR	No	No
	Rhinitis	NASAL CONGESTION	24DEC94	45, -10,-107	18 Days	0	CON	MIL	NO	UNR	No	No
	Trauma	FRACTURED LEFT INDEX FINGER	25JAN95	77, 23, -75	35 Days	0	CON	MOD	NO	UNR	No	No
		SPRAINED ANKLE	04JAN95	56, 2, -96	18 Days	0	CON	MOD	NO	UNR	No	No
329.001.00069	Albuminuria	URINE 1+PROTEIN	13APR95	57, ., -5	Not Stated	0	CON	MIL	NO	PBU	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.001.00069	Decreased Appetite	ANOREXIA	18MAR95	31, ., -31	21 Days	0	CON	MIL	NO	PSR	No	No
	Dyspepsia	STOMACH UPSET	22MAR95	35, ., -27	17 Days	0	2	MIL	NO	PSR	No	No
	Nausea	NAUSEA	21FEB95	6, ., -56	02:30 Hrs	0	1	MIL	NO	PSR	No	No
		NAUSEA AM	22MAR95	35, ., -27	17 Days	0	2	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	09MAR95	22, ., -40	8 Days	0	CON	MIL	NO	UNR	No	No
	Respiratory Disorder	UPPER RESPIRATORY CONGESTION	09MAR95	22, ., -40	12 Days	0	CON	MIL	NO	UNR	No	No
	Syncope	FAINT UPON STANDING	17MAR95	30, ., -32	22 Days	0	CON	MIL	NO	PSR	No	No
329.001.00071	Lymphadenopathy	SWOLLEN LYMPH NODES IN NECK	13MAR95	19, ., -52	4 Days	0	CON	MIL	NO	UNR	No	No
	Myalgia	ARM AND LEG MUSCLE ACHES	21MAR95	27, ., -44	5 Days	0	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	04APR95	41, ., -30	23 Days	0	CON	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	13MAR95	19, ., -52	15 Days	0	CON	MOD	NO	UNR	No	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION	13MAR95	19, ., -52	15 Days	0	CON	MOD	NO	UNR	No	No
329.001.00123	Bronchitis	BRONCHITIS WITH BRONCHOSPASMS	13JAN96	10, ., -39	13 Days	0	CON	MOD	NO	UNR	Yes	No
	Cough Increased	DRY COUGH	07JAN96	4, ., -45	19 Days	0	CON	MOD	NO	UNR	No	No
	Depression	WORSENING OF DEPRESSION	18FEB96	46, ., -3	Not Stated	0	CON	SEV	STP	REL	No	Yes

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329.001.00123	Emotional Lability	SUICIDAL THOUGHTS	18FEB96	46, ., -3	Not Stated	0	CON	SEV	STP	REL	No	Yes
	Headache	HEADACHE	21FEB96	49, ., 0	Not Stated	0	CON	MOD	NO	PSR	Yes	No
		HEADACHES	21JAN96	18, ., -31	8 Days	0	CON	MIL	NO	UNR	No	No
	Nausea	NAUSEA	22JAN96	19, ., -30	7 Days	0	CON	MIL	NO	UNR	No	No
			21FEB96	49, ., 0	Not Stated	0	CON	MIL	NO	PSR	No	No
		NAUSEA (POST TAKING MEDS)	05JAN96	2, ., -47	04:30 Hrs	0	2	MIL	NO	PSR	No	No
			29JAN96	26, ., -23	5 Days	0	CON	MIL	NO	PSR	No	No
	Pain	BODY ACHES	22JAN96	19, ., -30	7 Days	0	CON	MIL	NO	UNR	No	No
	Tremor	HAND TREMORS	04FEB96	32, ., -17	Not Stated	0	3	MIL	NO	PSR	No	No
329.001.00207	Abdominal Pain	STOMACH CRAMPS	03MAR96	5, ., -53	23:00 Hrs	0	CON	MIL	NO	UNR	No	No
		STOMACH CRAMPS (SINCE STARTING BIAXIN)	24APR96	57, ., -1	3 Days	0	CON	MIL	NO	UNR	No	No
	Cough Increased	COUGH	05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No	No
	Decreased Appetite	DECREASED APPETITE	21MAR96	23, ., -35	15 Days	0	CON	MIL	NO	PBU	No	No
	Diarrhea	DIARRHEA	03MAR96	5, ., -53	15:00 Hrs	0	3	MOD	NO	UNR	No	No
			06APR96	39, ., -19	13:00 Hrs	0	4	MIL	NO	PBU	No	No
			24APR96	57, ., -1	3 Days	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	18APR96	51, ., -7	8 Days	0	CON	MOD	NO	PBU	Yes	No
	Pain	BODY ACHES	18APR96	51, ., -7	7 Days	0	CON	MIL	NO	UNR	No	No
	Pharyngitis	SORE THROAT	10APR96	43, ., -15	2 Days	0	CON	MIL	NO	UNR	No	No

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329.001.00207	Rhinitis	STUFFY NOSE	05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No	No
	Sinusitis	HEAD CONGESTION	22MAR96	24, ., -34	4 Days	0	CON	MIL	NO	UNR	No	No
			05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No	No
		SINUS INFECTION	18APR96	51, ., -7	15 Days	0	CON	MOD	NO	UNR	Yes	No
329.002.00049	Headache	HEADACHE	25MAR95	17, ., -57	3 Days	0	3	MIL	NO	PSR	Yes	No
329.002.00097	Abdominal Pain	STOMACH ACHE	23MAR95	80, 22,-181	20 Mins	0	3	MIL	NO	PSR	No	No
	Abnormal Vision	BLURRING VISION	18JAN95	16, -43,-245	126 Days	0	99	MOD	NO	PSR	No	No
	Dizziness	DIZZINESS (WHEN STANDS QUICKLY)	23MAR95	80, 22,-181	1 Mins	0	3	MIL	NO	PSR	No	No
	Infection	FLU SYMPTOMS	16JAN95	14, -45,-247	3 Days	0	CON	MIL	NO	UNR	Yes	No
	Sweating	SWEATY HANDS	17JAN95	15, -44,-246	127 Days	0		MIL	NO	PBU	No	No
	Vasodilatation	HOT FLASHES	25JAN95	23, -36,-238	5 Mins	0	4	MIL	NO	PSR	No	No
329.002.00101	Drug Dependence	POSITIVE MARIJUANA URINE SCREEN (PROTOCOL DEVIATION)	22JUN95	87, 29, -19	1 Days	0	CON	MOD	NO	UNR	No	No
329.002.00107	Dizziness	DIZZINESS (WHEN STANDING)	25AUG96	214, 158, -44	Not Stated	0	CON	MIL	NO	PSR	No	No
	Infection	STREP THROAT	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes	No
	Pharyngitis	TONSILLITIS	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes	No
	Wbc Abnormality	ELEVATED ATYPICAL LYMPHS	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes	No

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Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.002.00241	Cough Increased	COUGH	09APR96	64, 8, -44	22 Days	0	CON	MOD	NO	UNR	Yes	No
	Emotional Lability	PT. HOSPITALIZED FOR SUICIDAL IDEATION	23MAY96	108, 52, 0	Not Stated	0	CON	SEV	STP	PBU	Yes	Yes
	Hostility	PT. HOSPITALIZED FOR HOMICIDAL IDEATION	23MAY96	108, 52, 0	Not Stated	0	CON	SEV	STP	PBU	No	Yes
	Vomiting	NAUSEA AND VOMITING	03MAR96	27, -30, -81	3 Days	0	2	MIL	NO	PBU	No	No
329.002.00246	Abdominal Pain	STOMACH ACHES (IF TAKES MEDS WITHOUT FOOD)	20MAY96	33, ., -39	Not Stated	0		MIL	NO	PSR	No	No
	Asthenia	FATIGUE	25APR96	8, ., -64	Not Stated	0	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	23MAY96	36, ., -36	7 Days	0	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	25APR96	8, ., -64	Not Stated	0	CON	MIL	NO	REL	No	No
	Headache	HEADACHES (WORSENING)	10MAY96	23, ., -49	Not Stated	0		MIL	NO	PSR	Yes	No
	Herpes Zoster	VARICELLA	12JUN96	56, ., -16	5 Days	0		MOD	NO	UNR	No	No
	Trauma	CAR ACCIDENT (NO INJURIES)	15MAY96	28, ., -44	1 Days	0	CON	MIL	NO	UNR	No	No
		FALL FROM ROPE RESULTING IN DIZZINESS,HEADACHES, AND FATIGUE	26MAY96	39, ., -33	5 Days	0		MOD	NO	UNR	No	No
	Vomiting	VOMITING	02MAY96	15, ., -57	2 Days	0	2	MIL	NO	PBU	No	No
329.002.00320	Back Pain	BACK PAIN	17SEP96	125, 64, -21	Not Stated	0	CON	MOD	NO	UNR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
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Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.002.00320	Dizziness	FAINTING	03SEP96	111, 50, -35	Not Stated	0	CON	MOD	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	14JUN96	30, -32,-116	11 Days	0	CON	MIL	NO	PSR	No	No
	Otitis Media	EAR INFECTION	09SEP96	117, 56, -29	11 Days	0	1	MOD	NO	UNR	Yes	No
	Trauma	SHOULDER TRAUMA	16JUN96	32, -30,-114	1 Days	0	CON	MOD	NO	UNR	Yes	No
329.002.00323	Asthenia	FATIGUE	04MAR97	113, 55,-114	Not Stated	0	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS (ESPECIALLY DURING AEROBICS AND HEAVY LIFTING)	19NOV96	8, -51,-219	37 Days	0	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	01FEB97	82, 24,-145	4 Days	0	1	MIL	NO	PSR	No	No
		HEADACHES	30DEC96	49, -10,-178	11 Days	0	CON	MIL	NO	PSR	Yes	No
	Pharyngitis	PHARYNGITIS	11APR97	151, 93, -76	8 Days	0	1	MIL	NO	UNR	Yes	No
	Somnolence	FALLING ASLEEP IN THE AFTERNOON	15NOV96	4, -55,-223	42 Days	0	CON	MOD	NO	PSR	No	No
	Thirst	INCREASED THIRST	26NOV96	15, -44,-212	10 Days	0	CON	MIL	NO	REL	No	No
329.003.00074	Constipation	CONSTIPATION	18FEB95	25, -32,-249	12 Days	0	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES	09FEB95	16, -41,-258	01:30 Hrs	0	2	MIL	NO	PSR	No	No
329.003.00080	Asthenia	FATIGUE	04JAN96	39, ., -36	Not Stated	0	CON	SEV	NO	PBU	No	No
	Dizziness	DIZZINESS	04JAN96	39, ., -36	Not Stated	0	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	04JAN96	39, ., -36	Not Stated	0	CON	MIL	NO	PSR	No	No

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329.003.00080	Headache	HEADACHES	03JAN96	38, ., -37	Not Stated	0	CON	MIL	NO	PSR	No	No
	Respiratory Disorder	COLD SYMPTOMS	23DEC95	27, ., -48	12 Days	0	1	MIL	NO	UNR	No	No
329.003.00085	Dry Mouth	DRY MOUTH	22DEC94	45, ., -26	4 Days	0	1	MIL	NO	PSR	No	No
329.003.00086	Dizziness	DIZZINESS	12DEC94	15, -43,-264	Not Stated	0	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	01DEC94	4, -54,-275	Not Stated	0	CON	MIL	NO	PSR	No	No
	Fever	FEVER	02JAN95	36, -22,-243	02:00 Hrs	0		MIL	NO	UNR	Yes	No
	Rash	RASH ON BACK	13FEB95	78, 21,-201	72 Days	0	CON	MOD	NO	PSR	Yes	No
	Respiratory Disorder	COLD {SYMPTOMS}	12DEC94	15, -43,-264	3 Days	0	CON	MIL	NO	UNR	Yes	No
			15MAY95	169, 112,-110	5 Days	0	CON	MIL	NO	UNR	Yes	No
329.003.00094	Asthenia	WEAKNESS	11DEC95	49, ., -24	02:00 Hrs	0	1	MOD	NO	PSR	No	No
			12DEC95	50, ., -23	Not Stated	0	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS	11DEC95	49, ., -24	02:00 Hrs	0	1	MOD	NO	PSR	No	No
	Dyspepsia	STOMACH ACIDITY	24NOV95	32, ., -41	Not Stated	0	CON	MIL	NO	PSR	Yes	No
	Headache	HEADACHE	11DEC95	49, ., -24	02:00 Hrs	0	1	MOD	NO	PSR	No	No
			12DEC95	50, ., -23	Not Stated	0	CON	MIL	NO	PSR	No	No
	Rash	RASH {MINOR OF UNKNOWN CAUSES}	28OCT95	5, ., -68	24:00 Hrs	0	1	MIL	NO	PBU	No	No
329.003.00252	Asthenia	FATIGUE	25APR96	16, ., -54	20 Days	0	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	29APR96	20, ., -50	1 Mins	0	1	MIL	NO	PSR	No	No

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329.003.00252	Dyspnea	SHORTNESS OF BREATH	21MAY96	42, ., -28	30 Mins	0	1	MIL	DCR	PSR	No	No
	Headache	HEADACHE	30APR96	21, ., -49	30 Mins	0	5	MIL	NO	PSR	No	No
			18MAY96	39, ., -31	02:00 Hrs	0	1	MOD	DCR	PSR	Yes	No
	Nausea	NAUSEA	30APR96	21, ., -49	30 Mins	0	5	MIL	NO	PSR	No	No
	Nervousness	IRRITABILITY	16MAY96	37, ., -33	13 Days	0	CON	MOD	DCR	PSR	No	No
329.003.00291	Abdominal Pain	STOMACH PAINS	09JUL96	7, -59,-113	01:00 Hrs	0	2	MIL	NO	PSR	No	No
	Arrhythmia	SINUS-ARRHYTHMIA	02OCT96	92, 27, -28	29 Days	0	1	MIL	NO	PBU	No	No
	Constipation	CONSTIPATION	21AUG96	50, -16, -70	Not Stated	0	1	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS	07AUG96	36, -30, -84	8 Days	0	1	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	28AUG96	57, -9, -63	8 Days	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	14JUL96	12, -54,-108	01:00 Hrs	0	1	MOD	NO	PSR	No	No
329.003.00315	Respiratory Disorder	COLD {SYMPTOMS}	18NOV96	7, ., -53	3 Days	0	1	MIL	NO	UNR	Yes	No
329.003.00316	Thrombocythemia	ELEVATED PLATELETS	11FEB97	57, ., -7	Not Stated	0	CON	MIL	NO	PBU	No	No
329.004.00016	Abdominal Pain	STOMACH CRAMPS	28MAR95	16, ., -22	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Allergic Reaction	COUGHING DUE TO ALLERGIES	30MAR95	18, ., -20	Not Stated	0	CON	MIL	NO	UNR	Yes	No
		HEADACHES DUE TO ALLERGIES	24MAR95	12, ., -26	Not Stated	0	CON	MOD	NO	UNR	Yes	No
		SNEEZING DUE TO ALLERGIES	24MAR95	12, ., -26	Not Stated	0	CON	MOD	NO	UNR	Yes	No

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Intent-to-Treat Population

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329.004.00016	Allergic Reaction	STUFFED SINUSES DUE TO ALLERGIES	24MAR95	12, ., -26	Not Stated	0	CON	MOD	NO	UNR	Yes	No
329.004.00018	Abnormal Vision	BLURRY VISION	20JUN95	49, ., -24	21 Days	0	CON	MOD	NO	PSR	No	No
	Allergic Reaction	RHINITIS, SNEEZING, ITCHY EYES (POLLEN ALLERGY)	12MAY95	10, ., -63	7 Days	0	CON	MOD	NO	UNR	Yes	No
	Anxiety	TENSION {ANXIOUS FEELING POST CONFRONTATION NON-MEDICATION RELATED}	28MAY95	26, ., -47	1 Days	0	1	SEV	NO	UNR	Yes	No
	Dry Mouth	DRY MOUTH	20JUN95	49, ., -24	21 Days	0	CON	SEV	NO	PSR	No	No
	Headache	HEADACHE	24MAY95	22, ., -51	02:00 Hrs	0	1	SEV	NO	UNR	Yes	No
		HEADACHES	22JUN95	51, ., -22	Not Stated	0	CON	MOD	NO	PSR	Yes	No
	Insomnia	INSOMNIA(WORSENING)	07MAY95	5, ., -68	20 Days	0	CON	SEV	NO	REL	No	No
	Nausea	NAUSEA	09MAY95	7, ., -66	5 Days	0	CON	MOD	NO	REL	No	No
	Vomiting	NAUSEA-VOMITING	01JUN95	30, ., -43	38 Days	0	CON	MIL	NO	PSR	No	No
329.004.00020	Nausea	NAUSEA	12NOV95	4, ., -12	3 Days	0	CON	MOD	NO	UNR	No	No
329.004.00213	Abdominal Pain	STOMACH ACHES	03AUG96	2, -53,-239	8 Days	0	CON	MIL	NO	PSR	No	No
			11AUG96	10, -45,-231	192 Days	0	CON	MOD	NO	UNR	Yes	No
	Back Pain	BACKACHE	02AUG96	1, -54,-240	8 Days	0	CON	MIL	NO	UNR	No	No
	Constipation	CONSTIPATION	08AUG96	7, -48,-234	5 Days	0	2	MIL	NO	PSR	No	No

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Intent-to-Treat Population

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329.004.00213	Constipation	CONSTIPATION	10AUG96	9, -46,-232	13 Days	0	CON	MIL	NO	UNR	No	No
	Diarrhea	DIARRHEA	07AUG96	6, -49,-235	4 Days	0	4	MIL	NO	PSR	No	No
			09FEB97	192, 138, -49	31 Days	0	CON	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	14SEP96	44, -11,-197	Not Stated	0	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES	04AUG96	3, -52,-238	227 Days	0	CON	MIL	NO	UNR	Yes	No
	Rash	RASH	20DEC96	141, 87,-100	8 Days	0	CON	MIL	NO	PBU	No	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION (COLD)	12AUG96	11, -44,-230	19 Days	0	CON	MIL	NO	UNR	Yes	No
	Trauma	HEAD INJURY WITH LACERATION TO SCALP (4 STITCHES) NO LOSS OF CONSCIOUSNESS (PUSHED ONTO SUBWAY TRACK)	05OCT96	65, 11,-176	5 Mins	0	1	MOD	NO	UNR	No	No
329.005.00005	Asthenia	SLIGHTLY TIRED	03NOV94	3, ., -6	14 Days	0	5	MIL	NO	PSR	No	No
	Dizziness	SLIGHTLY DIZZY	03NOV94	3, ., -6	14 Days	0	4	MIL	NO	PSR	No	No
	Tachycardia	ELEVATED HEART RATE	08NOV94	8, ., -1	2 Days	0	2	MOD	STP	PSR	No	No
329.005.00010	Dizziness	DIZZINESS	22DEC94	10, -48,-245	6 Days	0	4	MIL	NO	PSR	No	No
			20JAN95	39, -19,-216	24:00 Hrs	0	CON	MIL	NO	PSR	No	No
	Infection	FLU-NAUSEA,CRAMPS DIARRHEA,STOMACH ACHE	18JAN95	37, -21,-218	3 Days	0	CON	SEV	NO	UNR	No	No

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329.005.00010	Menstrual Disorder	2 MENSTRUAL CYCLES IN JULY-2 WEEKS APART	03JUL95	203, 146, -52	6 Days	0	CON	MOD	NO	PBU	No	No
			18JUL95	218, 161, -37	7 Days	0	CON	MOD	NO	PBU	No	No
	Trauma	FOOT/ANKLE (RUN OVER BY CAR INJURY-PAIN)	13APR96	488, 431, 233	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Urticaria	HIVES	02MAR95	80, 23,-175	6 Days	0	CON	MOD	NO	UNR	Yes	No
329.005.00012	Dry Mouth	DRY MOUTH (1/2 HOUR AFTER TAKING MEDICATION)	22DEC94	4, -56,-161	13 Days	0	CON	MIL	NO	REL	No	No
	Dyspepsia	UPSET STOMACH (1/2 HOUR AFTER TAKING MEDICATION)	22DEC94	4, -56,-161	13 Days	0	CON	MIL	NO	REL	No	No
	Headache	HEADACHE	24JAN95	37, -23,-128	04:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
	Infection	STOMACH FLU-(HEADACHE,NAUSEA/VOMITING AND DIARRHEA)	31DEC94	13, -47,-152	4 Days	0	CON	SEV	NO	UNR	No	No
		TOXOPLASMOSIS	01JUN95	165, 106, 0	Not Stated	0	CON	MOD	STP	UNR	Yes	No
329.005.00111	Allergic Reaction	"PUFFY",ITCHY,WATERY EYES {ALLERGIES}	04MAR95	53, -4, -57	9 Days	0	CON	SEV	NO	PBU	No	No
	Asthenia	FATIGUE	31JAN95	21, -36, -89	8 Days	0	CON	MIL	NO	PSR	No	No
	Back Pain	BACKACHE	07JAN95	-4, -60,-113	39 Days	0	12	MOD	NO	PBU	Yes	No
	Fever	FEVER	15FEB95	36, -21, -74	6 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	07JAN95	-4, -60,-113	39 Days	0	12	MOD	NO	PBU	Yes	No
			14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No

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329.005.00111	Headache	HEADACHE	16APR95	96, 40, -14	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Nausea	NAUSEA	15FEB95	36, -21, -74	4 Days	0	CON	MIL	NO	PSR	No	No
			16MAR95	65, 9, -45	2 Days	0	CON	MIL	NO	PBU	No	No
	Pain	FACE PAIN	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	15FEB95	36, -21, -74	6 Days	0	CON	MOD	NO	UNR	Yes	No
			16MAR95	65, 9, -45	2 Days	0	CON	SEV	NO	UNR	Yes	No
			16APR95	96, 40, -14	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Rash	RASH ON BOTH FOREARMS	30JAN95	20, -37, -90	6 Days	0	CON	MOD	NO	PBU	No	No
	Rhinitis	NASAL STUFFINESS	16FEB95	37, -20, -73	49 Days	0	CON	SEV	NO	PBU	Yes	No
		NOSE PAIN	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Sinusitis	SINUS INFECTION	17APR95	97, 41, -13	Not Stated	0	CON	SEV	STP	UNR	Yes	No
		SINUS STUFFINESS	16FEB95	37, -20, -73	49 Days	0	CON	SEV	NO	PBU	Yes	No
	Tooth Disorder	TEETH PAIN	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Vomiting	VOMITING DRY HEAVES	17APR95	97, 41, -13	20:00 Hrs	0	CON	SEV	NO	UNR	No	No
329.005.00114	Infection	STREP THROAT SORE THROAT AND FEVER	04FEB95	5, -53, -93	11 Days	0	CON	SEV	NO	UNR	Yes	No
	Tremor	HAND TREMORS	01MAR95	30, -28, -68	22 Days	0	CON	MIL	NO	REL	No	No
329.005.00115	Dry Mouth	DRY MOUTH	08FEB95	3, -69, -72	6 Days	0	CON	MIL	NO	REL	No	No
	Headache	HEADACHE	12FEB95	7, -65, -68	02:30 Hrs	0	CON	MIL	NO	PSR	No	No
		HEADACHES	14MAR95	37, -35, -38	02:00 Hrs	0	7	MIL	NO	PSR	No	No

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329.005.00115	Sinusitis	TOOTHACHE/QUESTIONABLE SINUS INFECTION	23FEB95	18, -54, -57	26 Days	0	CON	SEV	NO	UNR	Yes	No
	Wbc Abnormality	ATYPICAL LYMPHS	18APR95	72, 1, -3	1 Days	0	1	MIL	NO	PBU	No	No
	Weight Loss	WEIGHT LOSS (12 POUNDS)	10APR95	64, -8, -11	9 Days	0	CON	SEV	NO	UNR	No	No
329.005.00120	Cough Increased	COUGH	12SEP95	14, ., -44	8 Days	0	CON	MOD	NO	UNR	Yes	No
		COUGHING	23OCT95	55, ., -3	Not Stated	0	CON	MIL	NO	UNR	Yes	No
	Eosinophilia	INCREASED EOSINOPHILS	22AUG95	-8, ., -65	Not Stated	0	CON	MIL	NO	UNR	No	No
			26OCT95	58, ., 0	Not Stated	0	CON	MIL	NO	UNR	No	No
	Euphoria	LAUGHING A LOT {EUPHORIA}	19SEP95	21, ., -37	17 Days	0	3	MOD	NO	UNR	No	No
	Headache	HEADACHE	14SEP95	16, ., -42	30 Mins	0	1	MIL	NO	UNR	No	No
	Hyperglycemia	INCREASED GLUCOSE	22AUG95	-8, ., -65	Not Stated	0	CON	MIL	NO	UNR	No	No
			26OCT95	58, ., 0	Not Stated	0	CON	MIL	NO	UNR	No	No
	Kidney Function Abnormal	DECREASED UREA NITROGEN	22AUG95	-8, ., -65	66 Days	0	CON	MIL	NO	UNR	No	No
	Nervousness	NERVOUS	19SEP95	21, ., -37	2 Days	0		MIL	NO	UNR	No	No
			21SEP95	23, ., -35	8 Days	0	CON	MIL	NO	UNR	No	No
	Rhinitis	RUNNY NOSE	12SEP95	14, ., -44	7 Days	0	CON	MIL	NO	UNR	Yes	No
329.005.00253	Headache	HEADACHE	02FEB96	-6, ., -61	04:00 Hrs	0	2	MIL	NO	UNR	Yes	No
			26FEB96	19, ., -37	05:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			27FEB96	20, ., -36	03:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
			23MAR96	45, ., -11	04:30 Hrs	0	CON	MIL	NO	UNR	Yes	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00253	Infection	CHLAMYDIA	04MAR96	26, ., -30	9 Days	0	CON	MIL	NO	UNR	Yes	No
329.005.00254	Abdominal Pain	STOMACH ACHE	28FEB96	14, -42,-244	03:00 Hrs	0	CON	MOD	NO	UNR	No	No
	Arthralgia	SHOULDER PAIN IN AM	18MAR96	33, -23,-225	3 Days	0	3	MOD	NO	UNR	No	No
	Asthenia	TIRED	16MAR96	31, -25,-227	Not Stated	0	CON	MIL	NO	PSR	No	No
	Chest Pain	CHEST PAIN	28FEB96	14, -42,-244	03:00 Hrs	0	CON	MIL	NO	UNR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	09MAR96	24, -32,-234	12:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			28MAY96	104, 49,-154	06:30 Hrs	0	CON	SEV	NO	UNR	Yes	No
	Headache	HEADACHE	11FEB96	-4, -59,-261	03:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			16FEB96	2, -54,-256	5 Days	0	3	MIL	NO	PSR	No	No
			24FEB96	10, -46,-248	1 Days	0	2	MIL	NO	PBU	No	No
			08MAR96	23, -33,-235	02:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			07APR96	53, -3,-205	02:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			02SEP96	201, 146, -57	02:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
			03SEP96	202, 147, -56	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
329.005.00293	Acne	ACNE	26MAR97	15, ., -42	Not Stated	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	06APR97	26, ., -31	03:30 Hrs	0	1	MOD	NO	PBU	Yes	No
			19APR97	39, ., -18	01:00 Hrs	0	1	MOD	NO	PBU	Yes	No
			06MAY97	56, ., -1	45 Mins	0	1	MOD	NO	PBU	No	No
	Respiratory Disorder	RESPIRATORY CONGESTION	18MAR97	7, ., -50	8 Days	0	CON	MOD	NO	PBU	Yes	No
329.005.00298	Back Pain	BACK ACHE	12SEP96	114, 58,-134	3 Days	0	CON	MOD	NO	UNR	No	No
		BACK PAIN (OLD SOCCER INJURY)	23JUN96	33, -24,-215	03:00 Hrs	0	CON	MOD	NO	UNR	Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
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Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00298	Diarrhea	STOMACH ACHE WITH DIARRHEA	18MAY96	-4, -60,-251	4 Days	0	CON	SEV	NO	UNR	No	No
	Dizziness	DIZZINESS WHEN STANDING UP	09DEC96	202, 146, -46	3 Days	0	3	MIL	NO	PBU	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	06JUL96	46, -11,-202	2 Days	0	CON	MOD	NO	UNR	Yes	No
			04NOV96	167, 111, -81	24:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			07DEC96	200, 144, -48	3 Days	0	CON	MOD	NO	UNR	Yes	No
			07JAN97	231, 175, -17	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Epistaxis	NOSEBLEEDS	06JAN97	230, 174, -18	7 Days	0	8	SEV	NO	PSR	No	No
	Headache	HEADACHE	06NOV96	169, 113, -79	02:30 Hrs	0	CON	MOD	NO	UNR	No	No
	Hypertonia	STIFF NECK	29JUN96	39, -18,-209	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	COLD SYMPTOMS:STUFFY NOSE, SORE THROAT, FEVER	08DEC96	201, 145, -47	12 Days	0	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	30JUN96	40, -17,-208	2 Days	0	CON	MOD	NO	UNR	Yes	No
			28AUG96	99, 43,-149	8 Days	0	CON	MOD	NO	UNR	No	No
		SINUS HEADACHE AND CONGESTION	02JUN96	12, -45,-236	4 Days	0	CON	MOD	NO	UNR	Yes	No
	Trauma	CHARLEY HORSE LEFT LEG-THIGH	01OCT96	133, 77,-115	4 Days	0	CON	MOD	NO	UNR	Yes	No
		KNEE INJURY (SOCCER RELATED)	15JUL96	55, -2,-193	3 Days	0	CON	MOD	NO	UNR	Yes	No
		PAIN IN RIGHT LEG (FOLLOWING AUTOMOBILE ACCIDENT)	16JUN96	26, -31,-222	04:30 Hrs	0	CON	MOD	NO	UNR	Yes	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00298	Trauma	PULLED MUSCLE - LEFT SHIN (SOCCER INJURY)	17OCT96	149, 93, -99	06:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
329.005.00331	Back Pain	BACKACHE	20DEC96	30, ., -27	6 Days	0	CON	MIL	NO	UNR	No	No
			07JAN97	48, ., -9	2 Days	0	CON	MIL	NO	UNR	No	No
	Depersonalization	"SPACED OUT" FEELING	08DEC96	18, ., -39	5 Days	0	CON	MIL	DCR	PSR	No	No
	Dizziness	DIZZINESS	19DEC96	29, ., -28	5 Mins	0	CON	MIL	NO	PBU	No	No
		DIZZINESS IN AM	09DEC96	19, ., -38	4 Days	0	3	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	23NOV96	3, ., -54	5 Days	0	CON	MIL	NO	REL	No	No
	Headache	HEADACHE	21NOV96	1, ., -56	4 Days	0	4	MOD	NO	REL	Yes	No
			23NOV96	3, ., -54	1 Days	0	2	MIL	NO	PSR	No	No
			24NOV96	4, ., -53	1 Days	0	CON	MIL	NO	PSR	No	No
			30NOV96	10, ., -47	2 Days	0	2	MOD	NO	REL	Yes	No
			26DEC96	36, ., -21	02:30 Hrs	0	CON	MOD	NO	UNR	Yes	No
			09JAN97	50, ., -7	02:30 Hrs	0	CON	MIL	NO	PBU	No	No
	Nervousness	FIDGETINESS	23NOV96	3, ., -54	10:00 Hrs	0	CON	MIL	NO	PSR	No	No
	Sinusitis	SINUS INFECTION	17DEC96	27, ., -30	11 Days	0	CON	SEV	NO	UNR	Yes	No
329.005.00334	Albuminuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS POSITIVE PROTEIN]	27MAR97	56, ., 0	1 Days	0	CON	MOD	NO	UNR	No	No
	Back Pain	BACK ACHE	19MAR97	48, ., -8	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
		BACKACHE	20FEB97	21, ., -35	04:00 Hrs	0	CON	MOD	NO	UNR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.005.00334	Fever	FEVER - 102 DEGREES[FEVER]	19MAR97	48, ., -8	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	Gastrointestinal Disorder	FOOD POISONING	18MAR97	47, ., -9	3 Days	0	CON	SEV	NO	UNR	No	No
	Headache	HEADACHE	03MAR97	32, ., -24	02:30 Hrs	0	CON	MIL	NO	PBU	Yes	No
			12MAR97	41, ., -15	05:00 Hrs	0	CON	SEV	NO	PBU	Yes	No
	Pharyngitis	SORE THROAT	03FEB97	4, ., -52	8 Days	0	CON	MOD	NO	UNR	Yes	No
	Pyuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS MODERATE BACTERIA]	27MAR97	56, ., 0	1 Days	0	CON	MOD	NO	UNR	No	No
	Tooth Disorder	{TOOTH DISORDER}	29JAN97	-2, ., -57	01:00 Hrs	0	CON	SEV	NO	UNR	No	No
329.006.00037	Bronchitis	BRONCHITIS	06FEB95	10, ., -15	8 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	06FEB95	10, ., -15	Not Stated	0	CON	MOD	NO	REL	No	No
	Insomnia	INSOMNIA	06FEB95	10, ., -15	Not Stated	0	CON	MOD	NO	REL	No	No
	Nausea	NAUSEA	15FEB95	19, ., -6	Not Stated	0	CON	MIL	NO	REL	No	No
329.006.00042	Dyspepsia	INDIGESTION(MEXICAN SPICY FOOD)	31DEC95	25, -33,-213	3 Days	0	3	MOD	NO	UNR	No	No
		UPSET STOMACH	07JAN96	32, -26,-206	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	23MAR96	108, 51,-130	30 Mins	0	1	MOD	NO	PBU	Yes	No
			24APR96	140, 83, -98	01:30 Hrs	0	1	MOD	NO	PBU	Yes	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.006.00042	Headache	HEADACHE	09JUL96	216, 159, -22	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			11JUL96	218, 161, -20	06:00 Hrs	0	1	SEV	NO	UNR	Yes	No
			13JUL96	220, 163, -18	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
		HEADACHES	28DEC95	22, -36,-216	6 Days	0	7	MIL	NO	UNR	No	No
	Myalgia	MUSCLE ACHE	07JAN96	32, -26,-206	34:00 Hrs	0	1	MIL	NO	UNR	No	No
	Nausea	NAUSEA	07JAN96	32, -26,-206	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	Palpitation	HEART PALPITATION {ONE TIME ONLY}	18MAY96	164, 107, -74	1 Mins	0	1	MIL	NO	PBU	No	No
	Sinusitis	SINUS HEADACHE	07JAN96	32, -26,-206	5 Days	0	CON	MOD	NO	UNR	No	No
	Tooth Disorder	ORTHODONTIC PAIN	02JUL96	209, 152, -29	5 Days	0	CON	SEV	NO	UNR	Yes	No
	Vomiting	EMESIS	07JAN96	32, -26,-206	1 Mins	0	1	MOD	NO	UNR	No	No
329.007.00141	Angina Pectoris	ANGINA ON EXERTION	13SEP95	-8, ., -29	30 Days	0	2	MOD	STP	PBU	No	No
329.007.00144	Headache	HEADACHE	14JAN96	39, -18, -18	2 Days	0	1	MIL	NO	PSR	Yes	No
329.007.00266	Headache	HEADACHE	08MAR96	2, ., -69	04:00 Hrs	0	1	SEV	NO	PSR	No	No
	Hyperkinesia	AKATHISIA	11MAR96	5, ., -66	46 Days	0	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	08MAR96	2, ., -69	04:00 Hrs	0	1	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	27APR96	52, ., -19	13 Days	0	CON	MOD	NO	UNR	Yes	No
329.007.00267	Abdominal Pain	STOMACH ACHE,NO VOMITING	16MAY96	71, ., 15	04:00 Hrs	0	CON	MOD	NO	PBU	No	No
	Headache	HEADACHE	06MAR96	-1, ., -56	01:00 Hrs	0	1	MOD	NO	PSR	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.007.00311	Abdominal Pain	ABDOMINAL PAIN	09OCT96	7, -54,-197	01:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
	Arthralgia	KNEE PAIN (RIGHT KNEE)	18NOV96	47, -14,-157	5 Days	0	CON	MOD	NO	UNR	Yes	No
	Bronchitis	BRONCHITIS	17MAR97	166, 106, -38	15 Days	0	CON	MOD	NO	UNR	Yes	No
		BRONCHITIS SYMPTOMS: CONGESTION, COUGH	22OCT96	20, -41,-184	12 Days	0	CON	MOD	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	18OCT96	16, -45,-188	02:00 Hrs	0	1	MIL	NO	UNR	No	No
			23JAN97	113, 53, -91	2 Days	0	12	MOD	NO	UNR	Yes	No
	Infection	FLU SYMPTOMS	23JAN97	113, 53, -91	2 Days	0	CON	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	18OCT96	16, -45,-188	02:00 Hrs	0	1	MIL	NO	UNR	No	No
	Sinusitis	SINUS CONGESTION	26DEC96	85, 25,-119	2 Days	0	CON	MIL	NO	UNR	Yes	No
		SINUSITIS	23OCT96	21, -40,-183	31 Days	0	CON	MIL	NO	UNR	Yes	No
	Vomiting	VOMITING	23JAN97	113, 53, -91	2 Days	0	12	MOD	NO	UNR	Yes	No
329.008.00158	Breast Pain	BREAST SORENESS {FEMALE}	12SEP95	-1, -63,-106	16 Days	0		MIL	NO	UNR	No	No
329.008.00162	Asthenia	DROP IN ENERGY	20DEC95	50, -16,-210	8 Days	0	1	MIL	INC	PSR	No	No
	Bronchitis	BRONCHITIS	29NOV95	29, -37,-231	11 Days	0	1	MIL	NO	UNR	No	No
	Eye Disorder	EYE INFECTION	07DEC95	37, -29,-223	11 Days	0	1	MIL	NO	UNR	No	No
	Insomnia	DROP IN SLEEP	20DEC95	50, -16,-210	8 Days	0	1	MIL	INC	PSR	No	No
329.008.00191	Decreased Appetite	APPETITE DOWN	03FEB96	3, -59,-131	Not Stated	0	CON	MIL	NO	PSR	No	No
	Nervousness	RESTLESS AND JUMPY	28FEB96	28, -34,-106	Not Stated	0	CON	MIL	NO	PSR	No	No

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Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.008.00191	Somnolence	SLEEPINESS	03FEB96	3, -59,-131	Not Stated	0	CON	MOD	NO	PSR	No	No
329.009.00128	Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	18APR95	8, ., -14	Not Stated	0	CON	MIL	STP	PSR	No	No
329.009.00135	Diarrhea	DIARRHEA	21OCT95	20, ., -29	1 Days	0	CON	MIL	NO	UNR	No	No
	Nausea	NAUSEA	21OCT95	20, ., -29	2 Days	0	CON	MIL	NO	UNR	No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	30OCT95	29, ., -20	21 Days	0	CON	MIL	NO	PSR	No	No
	Vomiting	VOMITING	21OCT95	20, ., -29	2 Days	0	CON	MIL	NO	UNR	No	No
329.009.00136	Contact Dermatitis	CONTACT DERMATITIS LOWER AND UPPER HIP	10OCT95	8, ., -62	15 Days	0	CON	MIL	NO	PBU	No	No
	Headache	HEADACHE	04NOV95	33, ., -37	11 Days	0	3	MIL	NO	PBU	Yes	No
	Thirst	INCREASE IN THIRST	10OCT95	8, ., -62	15 Days	0	CON	MIL	NO	PSR	No	No
329.009.00169	Dizziness	SLIGHT DIZZINESS WHEN TAKING MEDS	19DEC95	50, -16, -47	Not Stated	0	CON	MOD	NO	PSR	No	No
	Infection	SCABIES	03DEC95	34, -32, -63	13 Days	0	CON	MOD	NO	UNR	Yes	No
	Insomnia	MILD INITIAL INSOMNIA	12DEC95	43, -23, -54	Not Stated	0	CON	MIL	NO	PSR	No	No
	Manic Reaction	HYPOMANIA	02JAN96	64, -2, -33	Not Stated	0	CON	SEV	STP	REL	No	No
	Somnolence	DAYTIME SLEEPINESS	22NOV95	23, -43, -74	17 Days	0		MIL	NO	PSR	No	No
329.009.00174	Constipation	CONSTIPATION	10DEC95	20, -38, -65	Not Stated	0		MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00174	Headache	HEADACHE	03DEC95	13, -45, -72	Not Stated	0		MOD	NO	PSR	Yes	No
	Infection	FLU(STOMACH ACHE)	03DEC95	13, -45, -72	5 Days	0	CON	MIL	NO	UNR	Yes	No
329.009.00197	Dizziness	DIZZY	18JAN96	21, -34,-227	1 Days	0	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	20AUG96	236, 182, -12	4 Days	0		MOD	NO	UNR	No	No
	Trauma	SCALP LACERATIONS (TOP OF HEAD)	17JUN96	172, 118, -76	2 Days	0	CON	MOD	NO	UNR	Yes	No
	Vomiting	VOMITING	20AUG96	236, 182, -12	4 Days	0	3	MIL	NO	UNR	No	No
329.009.00198	Abnormal Dreams	NIGHTMARE	03JAN96	2, ., -66	7 Days	0	6	MOD	NO	PSR	No	No
	Asthenia	FATIGUE	03JAN96	2, ., -66	Not Stated	0	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	08JAN96	7, ., -61	13 Days	0	CON	MIL	NO	PSR	No	No
	Nervousness	RESTLESSNESS	16JAN96	15, ., -53	8 Days	0	CON	MIL	NO	PSR	No	No
	Trauma	FACIAL CUTS {LEFT CHEEK}	18FEB96	48, ., -20	1 Days	0	CON	MOD	NO	UNR	Yes	No
329.009.00200	Av Block	SINUS ARRHYTHMIA(MOBITZ I)	06FEB96	15, ., -42	43 Days	0	2	MIL	NO	PBU	No	No
	Nausea	NAUSEA	20FEB96	29, ., -28	9 Days	0	CON	MIL	NO	PSR	No	No
	Rash	NON PAPULAR RASH (UPPER TORSO AND BACK)	19MAR96	57, ., 0	Not Stated	0	CON	MIL	NO	PBU	No	No
	Thirst	INCREASE IN THIRST	12FEB96	21, ., -36	3 Days	0	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00202	Abdominal Pain	STOMACH ACHES IN AM	08MAR96	18, ., -18	12 Days	0	CON	MOD	NO	PSR	No	No
		STOMACH CRAMPS(VIRAL)	22FEB96	3, ., -33	3 Days	0	CON	MIL	NO	PBU	No	No
	Diarrhea	DIARRHEA(VIRAL)	22FEB96	3, ., -33	3 Days	0	CON	MIL	NO	PBU	No	No
329.009.00238	Abnormal Dreams	VIVID DREAMING	26NOV96	15, ., -54	8 Days	0	CON	MIL	NO	PSR	No	No
	Av Block	SERIAL INCREASE PR INTERVAL	26NOV96	15, ., -54	15 Days	0	CON	MIL	NO	PSR	No	No
	Cough Increased	COUGH	23DEC96	42, ., -27	9 Days	0	CON	MIL	NO	UNR	Yes	No
	Headache	INCREASE HEADACHE	03DEC96	22, ., -47	Not Stated	0	CON	MOD	NO	PSR	Yes	No
	Nausea	NAUSEA	03DEC96	22, ., -47	Not Stated	0	CON	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	23DEC96	42, ., -27	9 Days	0	CON	MIL	NO	UNR	Yes	No
	Rhinitis	CONGESTION {NOSE}	23DEC96	42, ., -27	9 Days	0	CON	MIL	NO	UNR	Yes	No
329.009.00276	Decreased Appetite	DECREASED APPETITE	18MAR97	57, ., -14	Not Stated	0	CON	MIL	NO	PSR	No	No
	Fever	FEVER	13MAR97	52, ., -19	6 Days	0	CON	MIL	NO	PBU	Yes	No
	Headache	HEADACHES	04FEB97	15, ., -56	15 Days	0	CON	MIL	NO	PSR	No	No
	Infection	STOMACH VIRUS	31MAR97	70, ., -1	2 Days	0	CON	MIL	NO	PSR	Yes	No
	Nausea	NAUSEA	04FEB97	15, ., -56	29 Days	0	CON	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	20FEB97	31, ., -40	12:00 Hrs	0	CON	MIL	NO	PBU	No	No
			13MAR97	52, ., -19	6 Days	0	CON	MIL	NO	PBU	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.009.00276	Weight Loss	WEIGHT LOSS	13MAR97	52, ., -19	20 Days	0	CON	MIL	NO	PSR	No	No
329.009.00302	Maculopapular Rash	RASH ON WRIST ELBOWS,ANKLE,(MACULOPAPULAR)	03APR96	8, ., -7	Not Stated	0	CON	MOD	STP	PSR	No	No
	Nodal Arrhythmia	JUNCTIONAL ESCAPE PATTERN(EKG)	03APR96	8, ., -7	Not Stated	0	CON	MIL	NO	PSR	No	No
329.009.00306	Anemia	ANEMIA	03JUN96	-8, ., -77	Not Stated	0	CON	MIL	NO	UNR	Yes	No
	Vasodilatation	HOT FLASHES	02JUL96	22, ., -48	50 Days	0	CON	MIL	NO	PSR	No	No
329.009.00312	Back Pain	BACKACHES	06JAN97	64, ., -14	15 Days	0	CON	MIL	NO	PBU	No	No
	Headache	INCREASE IN HEADACHES	27DEC96	54, ., -24	Not Stated	0		MOD	NO	PSR	Yes	No
329.009.00330	Bradycardia	SINUS BRADYCARDIA	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	21OCT96	1, ., -14	Not Stated	0	CON	MOD	STP	REL	No	No
	Heart Malformation	POSSIBLE LEFT VENTRICULAR HYPERTROPHY	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	21OCT96	1, ., -14	Not Stated	0	CON	MOD	STP	REL	No	No
	Supraventricular Extrasystoles	OCCASIONAL PREMATURE ATRIAL COMPLEXES	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR	No	No
	Vomiting	VOMITING	01NOV96	12, ., -3	2 Days	0	2	MIL	STP	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.010.00263	Abdominal Pain	STOMACH ACHE HEADACHE {SIMULTANEOUS} [STOMACH ACHE]	08SEP96	31, ., -41	10 Mins	0	1	MIL	NO	PSR	No	No
	Arthralgia	SHOULDER PAIN RIGHT SHOULDER	11SEP96	34, ., -38	12:00 Hrs	0	1	MIL	NO	UNR	No	No
	Back Pain	BACK ACHE	07SEP96	30, ., -42	06:00 Hrs	0	1	MIL	NO	UNR	No	No
	Headache	HEADACHE	14AUG96	6, ., -66	03:00 Hrs	0	1	MIL	NO	PBU	Yes	No
			17AUG96	9, ., -63	02:00 Hrs	0	1	MIL	NO	PBU	Yes	No
			04SEP96	27, ., -45	15 Mins	0	1	MIL	NO	PBU	No	No
		STOMACH ACHE HEADACHE {SIMULTANEOUS} [HEADACHE]	08SEP96	31, ., -41	10 Mins	0	1	MIL	NO	PSR	No	No
	Pain	SIDE ACHE LEFT SIDE	10SEP96	33, ., -39	01:30 Hrs	0	1	MIL	NO	UNR	Yes	No
	Respiratory Disorder	COLD AND CONGESTION	22SEP96	45, ., -27	8 Days	0	CON	MIL	NO	UNR	Yes	No
	Ulcerative Stomatitis	MOUTH SORES	06OCT96	59, ., -13	8 Days	0	CON	MIL	NO	UNR	No	No
329.010.00277	Headache	HEADACHE	06AUG96	159, 103, 46	02:00 Hrs	0	1	MIL	NO	UNR	Yes	No
329.010.00282	Back Pain	BACKACHE	15AUG96	21, ., -58	12 Days	0	CON	MIL	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	19SEP96	56, ., -23	6 Days	0	20	MOD	NO	PSR	No	No
	Dysmenorrhea	CRAMPS (MENSTRUAL)	19SEP96	56, ., -23	12:00 Hrs	0	CON	MIL	NO	PBU	Yes	No
	Headache	HEADACHE	02SEP96	39, ., -40	30 Mins	0	1	MOD	NO	PBU	Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.011.00164	Back Pain	BACKACHE	11JAN96	21, ., -15	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	Dizziness	DIZZINESS	24JAN96	34, ., -2	06:00 Hrs	0	7	MIL	NO	PSR	No	No
	Headache	HEADACHE	11JAN96	21, ., -15	01:00 Hrs	0	1	MIL	NO	PBU	Yes	No
329.011.00210	Arrhythmia	SINUS ARRHYTHMIA	24OCT96	27, -40, -40	40 Days	0	2	MIL	NO	PBU	No	No
	Asthenia	FATIGUE	24OCT96	27, -40, -40	12 Days	0	CON	MIL	NO	PSR	No	No
	Chest Pain	CHEST PAIN	03OCT96	6, -61, -61	20 Mins	0	1	MIL	NO	PBU	No	No
	Headache	HEADACHE	03OCT96	6, -61, -61	20 Mins	0	1	MIL	NO	PBU	No	No
329.011.00285	Tooth Disorder	TOOTHACHE	04JUN96	18, ., -57	Not Stated	0	CON	MOD	NO	UNR	Yes	No
329.012.00027	Anxiety	ANXIETY	21DEC95	16, ., -21	Not Stated	0	CON	MOD	NO	PBU	Yes	No
	Back Pain	NECK SPASM	21DEC95	16, ., -21	Not Stated	0	CON	MOD	NO	PBU	Yes	No
	Otitis Media	OTITIS MEDIA(EAR INFECTION)	26NOV95	-10, ., -46	12 Days	0	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	COMMON COLD	15DEC95	10, ., -27	13 Days	0	CON	SEV	NO	UNR	Yes	No
329.012.00217	Asthma	RECURRENT ASTHMA	15JUN96	26, ., 1	5 Days	0	CON	MOD	NO	UNR	Yes	No
	Depression	DEPRESSION (WORSENING)	19JUN96	30, ., 5	8 Days	0	CON	SEV	NO	UNR	Yes	Yes
	Infection	FLU	13JUN96	24, ., -1	7 Days	0	CON	MOD	STP	UNR	Yes	No
	Respiratory Disorder	COMMON COLD	03JUN96	14, ., -11	10 Days	0	CON	MIL	NO	UNR	Yes	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
329.012.00218	Headache	HEADACHE (MODERATE)	08JUN96	-8, -66,-115	02:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			11JUL96	26, -33, -82	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
329.012.00224	Arthralgia	LEFT KNEE PAIN	03OCT96	18, -49,-149	18:00 Hrs	0	CON	MIL	NO	UNR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	09OCT96	24, -43,-143	Not Stated	0		MOD	NO	UNR	Yes	No
	Infection	STREP THROAT	08DEC96	84, 18, -83	11 Days	0	CON	MIL	NO	UNR	Yes	No
	Insomnia	DIFFICULTY FALLING TO SLEEP	01JAN97	108, 42, -59	1 Days	0	1	MIL	NO	PBU	Yes	No
	Respiratory Disorder	COLD SYMPTOMS	22SEP96	7, -60,-160	11 Days	0	CON	MIL	NO	UNR	No	No
	Tooth Disorder	TOOTHACHE	01OCT96	16, -51,-151	1 Days	0	CON	MIL	NO	UNR	Yes	No
329.012.00225	Asthma	BRONCHOSPASM	29MAR97	124, 60,-134	11 Days	0	CON	MOD	NO	UNR	Yes	No
	Hypesthesia	NUMB LEFT UPPER LEG	20MAR97	115, 51,-143	1 Days	0	1	MIL	NO	PBU	No	No
	Lymphadenopathy	SLIGHTLY ENLARGED NON-TENDER LEFT JUGULO-DIGASTRIC NODE	04APR97	130, 66,-128	59 Days	0	1	MIL	NO	UNR	No	No
	Otitis Media	EAR INFECTION LEFT	29MAR97	124, 60,-134	11 Days	0	CON	MOD	NO	UNR	Yes	No
	Trauma	SPRAINED WRIST LEFT	15JUL97	232, 168, -26	Not Stated	0	CON	MIL	NO	UNR	Yes	No

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Appendix E: Patient Data Listings of Vital Signs

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.001.00063	SC	02NOV94	-6, .	0	110	80	72	126	84	88	177.50	70.0
	BL	08NOV94	1, .	0	96	60	66	100	70	80	181.00	
	1	15NOV94	8, .	20	120	60	86	120	60	68	178.00	
	2	22NOV94	15, .	20	124	80	80	122	76	88	180.00	
	3	29NOV94	22, .	20	122	64	80	120	70	104	179.20	
	4	06DEC94	29, .	20	120	70	84	120	76	98	179.70	
	5	13DEC94	36, .	20	100	58	68	108	78	88	183.00	
329.001.00065	SC	07NOV94	-10, .	0	114	70	60	110	64	74	131.00	65.0
	BL	17NOV94	1, .	0	120	68	60	92	64	80	128.00	
	1	21NOV94	5, .	20	110	70	60	118	80	72	126.00	
329.001.00068	SC	01FEB95	-7, .	0	108	74	68	112	84	80	129.00	62.0
	BL	08FEB95	1, .	0	112	80	84	120	86	80	127.00	
	1	15FEB95	8, .	20	116	72	72	122	80	80	128.00	
	2	22FEB95	15, .	20	108	70	82	112	84	88	128.00	
	3	01MAR95	22, .	20	116	78	104	118	80	108	125.50	
	4	08MAR95	29, .	30	110	78	80	120	80	100	127.70	
	5	15MAR95	36, .	40	116	70	84	110	74	98	128.00	
	6	22MAR95	43, .	40	124	80	80	118	84	88	131.00	
	7	29MAR95	50, .	40	110	80	110	116	84	124 H	131.00	
	8	05APR95	57, .	40	120	80	104	114	82	120	131.00	
329.001.00072	SC	07MAR95	-13, .	0	104	70	72	100	70	88	152.00	73.5
	BL	20MAR95	1, .	0	108	68	72	98	60	88	153.50	
	1	27MAR95	8, .	20	90	60	66	88	60	84	151.00	
	2	03APR95	15, .	20	100	60	76	90	60	114	150.00	
	3	10APR95	22, .	20	104	60	72	94	62	88	150.50	
329.001.00121	SC	22MAR95	-13, -69	0	102	62	60	98	60	86	143.50	74.0
	BL	04APR95	1, -56	0	106	60	68	100	60	100	143.50	
	1	11APR95	8, -49	20	104	60	60	106	64	70	141.00	
	2	18APR95	15, -42	20	100	66	64	98	70	80	139.75	
	3	26APR95	23, -34	20	100	68	64	104	62	88	135.50	
	4	02MAY95	29, -28	30	100	60	64	100	64	80	139.00	
	5	09MAY95	36, -21	30	110	70	60	100	70	88	138.70	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.001.00121	6	16MAY95	43, -14	30	98	70	64	104	72	84	139.50	
	7	23MAY95	50, -7	30	100	60	66	108	64	68	138.00	
	8	30MAY95	57, 1	30	98	66	60	100	70	80	138.00	
	12	27JUN95	85, 29	30	108	62	80	110	60	112	143.70	
	16	24JUL95	112, 56	30	100	60	68	96	62	80	142.70	
	20	21AUG95	140, 84	30	108	66	72	100	62	92	144.00	
329.001.00205	SC	29JAN96	-9, .	0	100	70	68	98	68	88	132.30	60.3
	BL	07FEB96	1, .	0	100	66	82	96	70	90	131.00	
	1	14FEB96	8, .	20	100	70	80	100	70	92	132.00	
329.001.00206	SC	12FEB96	-9, .	0	122	80	68	124	86	76	158.00	70.5
	BL	21FEB96	1, .	0	118	76	72	122	86	80	157.50	
	1	28FEB96	8, .	20	112	70	68	118	78	84	155.00	
	2	06MAR96	15, .	20	118	74	66	120	80	72	157.00	
	3	13MAR96	22, .	20	104	70	68	100	68	74	155.50	
	4	20MAR96	29, .	30	108	70	68	112	74	76	160.00	
	5	26MAR96	35, .	40	110	70	80	110	68	96	156.50	
	6	03APR96	43, .	40	110	70	72	106	68	84	156.00	
	7	10APR96	50, .	40	114	68	76	120	70	84	161.00	
	8	17APR96	57, .	30	106	70	78	112	70	92	160.00	
329.002.00055	SC	09JUN94	-15, -70	0	110	70	85	110	75	88	175.00	65.0
	BL	23JUN94	-1, -56	0	115	75	80	120	70	85	174.00	
	1	30JUN94	7, -49	20	104	68	64	110	70	75	174.50	
	2	07JUL94	14, -42	20	105	68	86	90	75	92	175.00	
	3	14JUL94	21, -35	20	100	66	72	100	72	96	173.00	
	4	21JUL94	28, -28	30	102	50	92	98	68	112	171.00	
	5	28JUL94	35, -21	40	102	60	72	100	62	102	168.00	
	6	04AUG94	42, -14	40	98	68	80	94	60	102	169.50	
	7	11AUG94	49, -7	40	92	58	72	94	60	100	169.00	
	8	18AUG94	56, 1	40	90	60	54	90	68	72	166.00	
	12	15SEP94	84, 29	40	94	60	68	92	64	98	170.00	
	16	13OCT94	112, 57	40	100	60	60	104	54	80	171.50	
	20	10NOV94	140, 85	40	112	70	72	104	68	84	173.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00058	SC	08SEP94	-12, -70	0	102	70	88	104	70	92	203.50	62.6
	BL	20SEP94	1, -58	0	102	70	88	104	70	92	203.50	
	1	29SEP94	10, -49	20	100	74	88	94	66	94	198.50	
	2	07OCT94	18, -41	20	110	80	100	102	60	84	195.50	
	3	13OCT94	24, -35	20	102	84	88	100	82	80	196.00	
	4	20OCT94	31, -28	30	100	60	72	98	54	84	197.00	
	5	27OCT94	38, -21	40	104	86	88	100	84	80	199.00	
	6	03NOV94	45, -14	40	102	80	84	100	78	86	195.00	
	7	10NOV94	52, -7	40	100	60	92	102	78	102	194.50	
	8	17NOV94	59, 1	40	110	80	80	112	82	100	194.50	
	12	15DEC94	87, 29	40	100	70	84	100	70	88	194.00	
	16	13JAN95	116, 58	40	120	72	80	122	74	82	190.00	
329.002.00099	SC	23FEB95	-7, -62	0	110	68	70	108	68	80	192.25	67.0
	1	07MAR95	6, -50	20	122	70	70	118	70	90	190.50	
	2	14MAR95	13, -43	20	102	64	64	106	64	60	189.00	
	3	21MAR95	20, -36	20	110	70	80	106	70	80	189.25	
	4	28MAR95	27, -29	20	110	70	64	108	70	64	189.50	
	5	04APR95	34, -22	30	94	66	76	90	68	80	190.00	
	6	11APR95	41, -15	30	108	70	66	104	70	64	188.50	
	7	18APR95	48, -8	40	90	60	90	90	60	95	188.25	
	8	25APR95	55, -1	40	98	60	80	92	60	80	188.75	
	12	23MAY95	83, 28	40	96	60	88	96	60	82	192.00	
	16	27JUN95	118, 63	40	108	60	100	102	56	100	196.00	
	20	01AUG95	153, 98	40	102	68	87	104	70	80	200.00	
	24	31AUG95	183, 128	40	90	58	68	94	62	92	203.00	
	28	28SEP95	211, 156	40	112	70	66	110	72	68	208.00 H	
	32	26OCT95	239, 184	40	108	70	79	110	72	78	207.00 H	
329.002.00102	BL	13APR95	1, -54	0	88	70	80	92	70	84	102.50	60.0
	1	18APR95	6, -49	20	90	50	92	98	58	95	100.50	
	2	25APR95	13, -42	20	88	60	62	92	60	70	101.00	
	3	02MAY95	20, -35	20	102	70	88	98	68	86	100.00	
	4	09MAY95	27, -28	30	98	60	88	92	60	84	103.50	
	5	16MAY95	34, -21	40	94	60	92	98	60	80	102.50	
	6	23MAY95	41, -14	40	92	60	110	96	60	120	101.70	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00102	7	30MAY95	48, -7	40	90	58	86	88	56	90	103.00	
	8	06JUN95	55, 1	40	90	60	100	92	60	90	104.20	
	12	13JUL95	92, 38	40	110	60	86	106	64	100	103.50	
	16	10AUG95	120, 66	40	90	64	84	84	60	88	104.00	
	20	12SEP95	153, 99	40	84	60	80	86	62	74	105.50	
	24	10OCT95	181, 127	40	80	64	80	84	64	80	107.50	
	28	09NOV95	211, 157	40	92	60	100	88	60	92	109.50	
	32	05DEC95	237, 183	30	84	62	80	80	60	86	108.00	
329.002.00105	BL	27JUL95	1, .	0	110	78	62	112	80	84	162.00	69.3
	1	03AUG95	8, .	20	132	70	100	138	78	108	162.50	
	2	10AUG95	15, .	20	122	74	88	112	70	80	161.00	
	3	17AUG95	22, .	20	120	74	80	130	80	82	158.00	
329.002.00106	BL	27JUL95	1, .	0	86	68	72	84	62	90	148.00	68.0
	1	03AUG95	8, .	20	110	60	80	106	60	84	149.50	
	2	08AUG95	13, .	20	102	60	96	102	68	100	154.00	
	3	17AUG95	22, .	20	80	60	68	78	58	75	152.00	
	4	24AUG95	29, .	20	100	64	70	100	60	68	152.00	
	5	31AUG95	36, .	30	98	70	66	100	64	74	153.00	
	6	05SEP95	41, .	40	98	68	64	96	70	78	153.00	
	7	12SEP95	48, .	40	90	64	80	86	64	72	153.00	
329.002.00242	SC	26JAN96	-12, -70	0	130	80	92	120	70	88	166.48	65.0
	1	14FEB96	8, -51	20	100	70	88	105	65	92	162.07	
	2	21FEB96	15, -44	20	110	70	92	115	75	100	158.76	
	3	29FEB96	23, -36	20	110	70	96	115	75	100	161.41	
	4	06MAR96	29, -30	30	110	70	96	115	75	100	159.86	
	5	14MAR96	37, -22	30	105	70	76	110	80	80	156.56	
	6	20MAR96	43, -16	30	110	75	84	110	80	108	158.76	
	7	28MAR96	51, -8	40	110	70	88	120	80	100	159.86	
	8	05APR96	59, 1	40	110	70	88	120	80	100	159.86	
	12	08MAY96	92, 34	40	125	80	80	125	85	96	161.41	
	16	05JUN96	120, 62	40	125	80	80	125	85	92	161.63	
	20	10JUL96	155, 97#	0	116	62	77	108	58	79	159.20	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00245	SC	21MAR96	-7, .	0	100	60	66	96	64	70	131.00	66.0
	BL	28MAR96	1, .	0	98	60	60	90	62	70	127.00	
	1	04APR96	8, .	20	98	62	62	96	60	68	126.50	
329.002.00319	SC	23APR96	-7, -63	0	110	60	100	108	66	94	109.00	61.0
	1	07MAY96	8, -49	20	112	70	78	110	66	84	109.00	
	2	14MAY96	15, -42	20	128	68	70	120	70	64	111.50	
	3	21MAY96	22, -35	20	110	62	64	106	64	80	109.00	
	4	28MAY96	29, -28	30	110	70	66	106	72	68	111.00	
	5	04JUN96	36, -21	30	102	64	80	98	64	76	112.50	
	6	11JUN96	43, -14	30	100	68	64	98	68	72	115.00	
	7	18JUN96	50, -7	30	108	68	80	112	76	64	113.50	
	8	25JUN96	57, 1	30	112	70	72	100	74	80	114.00	
	12	23JUL96	85, 29	30	102	70	66	108	68	68	116.00	
	16	15AUG96	108, 52	30	98	60	80	98	62	88	115.00	
	20	24SEP96	148, 92	30	108	68	66	110	66	68	117.00 H	
	24	22OCT96	176, 120	30	104	66	64	106	64	68	113.50	
	28	19NOV96	204, 148	30	92	64	80	94	68	80	117.00 H	
	32	17DEC96	232, 176	30	100	70	76	98	70	72	113.00	
329.003.00075	SC	18JAN95	-7, -63	0	124	66	82	124	70	82	145.75	60.6
	BL	25JAN95	1, -56	0	120	76	88	118	80	85		
	1	01FEB95	8, -49	20	130	78	78	132	88	82	143.55	
	2	08FEB95	15, -42	20	130	88	72	126	86	76	142.22	
	3	15FEB95	22, -35	20	120	66	78	126	64	90	141.34	
	4	21FEB95	28, -29	30	116	88	80	112	90	70	142.44	
	5	01MAR95	36, -21	20	130	76	88	138	80	92	142.22	
	6	08MAR95	43, -14	20	120	82	72	126	80	82	143.10	
	7	15MAR95	50, -7	20	120	82	74	130	84	76	142.22	
	8	22MAR95	57, 1	20	130	76	72	118	84	78	143.33	
	12	19APR95	85, 29	20	112	78	72	128	88	84	141.56	
	16	17MAY95	113, 57	20	114	70	72	118	68	76	142.00	
	20	14JUN95	141, 85	20	124	70	72	110	72	72	141.12	
	24	12JUL95	169, 113	20	130	62	80	120	64	86	142.22	
	28	09AUG95	197, 141	20	120	80	72	110	70	76	140.68	
	32	13SEP95	232, 176	20	120	78	64	130	86	72	140.24	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00077	SC	01MAR95	-5, -64	0	138	70	76	138	72	72	132.30	68.9
	BL	06MAR95	1, -59	0	138	70	76	138	72	72	132.30	
	1	13MAR95	8, -52	20	134	86	76	148	78	90	134.51	
	2	20MAR95	15, -45	20	118	88	76	116	86	88	134.51	
	3	27MAR95	22, -38	20	124	82	82	126	76	88	137.37	
	4	05APR95	31, -29	30	128	84	78	126	88	78	136.27	
	5	12APR95	38, -22	30	128	66	80	134	78	86	138.47	
	6	19APR95	45, -15	30	130	76	80	138	84	84	138.03	
	7	26APR95	52, -8	30	120	82	84	130	80	90	139.58	
	8	03MAY95	59, -1	30	114	78	78	130	86	78	140.68	
	12	07JUN95	94, 35	30	126	76	78	122	80	80	136.71	
329.003.00081	BL	11DEC95	1, .	0	110	70	92	110	80	92	110.00	63.5
	1	18DEC95	8, .	20	92	50	100	110	60	102	111.79	
	2	28DEC95	18, .	20	104	64	86	106	70	96	109.15	
	3	03JAN96	24, .	20	104	58	92	104	66	102	111.35	
	4	10JAN96	31, .	30	104	70	102	106	80	114	110.25	
	5	17JAN96	38, .	30	104	58	104	110	70	108	113.56	
	6	24JAN96	45, .	30	104	60	96	110	62	108	113.34	
	7	31JAN96	52, .	40	100	58	100	94	56	112	110.69	
	8	07FEB96	59, .	40	110	66	84	102	74	82	111.79	
329.003.00087	SC	23JAN95	-8, .	0	110	70	84	110	70	84	135.00	67.0
	BL	30JAN95	-1, .	0	110	70	84	110	70	84	135.00	
329.003.00089	SC	24FEB95	-11, .	0	110	70	72	.	.	.	115.00	67.5
	BL	07MAR95	1, .	0	96	66	84	96	66	84	115.00	
	1	14MAR95	8, .	20	90	62	92	90	62	92	115.50	
	2	21MAR95	15, .	20	90	60	84	90	60	84	116.00	
	3	28MAR95	22, .	20	90	62	88	90	62	88	117.00	
	4	04APR95	29, .	20	90	60	84	90	60	84	117.00	
	5	11APR95	36, .	20	100	62	96	100	62	96	118.00	
	6	18APR95	43, .	20	100	60	92	100	60	92	116.50	
	7	25APR95	50, .	20	96	60	88	96	60	88	119.00	
	8	02MAY95	57, .	20	100	60	100	100	60	100	120.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00091	SC	14MAR95	-10, -64	0	108	64	72	110	70	72	126.00	67.0
	BL	24MAR95	1, -54	0	90	60	72	90	60	72	131.00	
	1	28MAR95	5, -50	20	90	56	72	90	56	72	131.00	
	2	04APR95	12, -43	20	100	60	84	100	60	84	130.00	
	3	11APR95	19, -36	20	100	60	84	100	60	84	131.50	
	4	18APR95	26, -29	20	90	60	84	90	60	84	132.00	
	5	25APR95	33, -22	30	110	60	80	100	60	80	133.00	
	6	02MAY95	40, -15	40	120	66	80	120	66	80	132.00	
	7	09MAY95	47, -8	40	116	64	84	116	64	84	132.00	
	8	16MAY95	54, -1	40	110	60	80	110	60	80	132.00	
	12	16JUN95	85, 31	40	110	60	76	110	60	76	131.50	
	16	14JUL95	113, 59	40	110	70	84	100	60	84	128.00	
	20	10AUG95	140, 86	40	106	66	72	100	66	72	132.00	
	24	05SEP95	166, 112	40	98	58	72	98	58	72	127.00	
	28	03OCT95	194, 140	40	96	54	80	96	54	80	128.00	
	32	07NOV95	229, 175	40	86	54	84	86	54	84	129.00	
329.003.00248	SC	14FEB96	-16, .	0	100	60	.	.	.	.	121.00	65.5
	BL	22FEB96	-8, .	0	80	50	64	80	50	64	129.00	
	1	05MAR96	5, .	20	88	54	64	80	50	64	125.00	
	2	12MAR96	12, .	20	94	58	68	94	58	68	124.00	
	3	19MAR96	19, .	20	90	60	72	90	60	72	125.00	
	4	26MAR96	26, .	30	96	56	80	90	56	80	126.00	
	5	02APR96	33, .	40	96	62	80	90	60	80	126.00	
	6	11APR96	42, .	40	94	60	80	90	60	80	122.00	
	7	16APR96	47, .	40	94	62	80	90	60	80	124.00	
	8	23APR96	54, .	30	86	62	80	80	60	80	123.00	
329.003.00250	SC	05MAR96	-9, -66	0	110	70	60	100	65	64	180.00	64.0
	BL	14MAR96	1, -57	0	100	60	96	100	60	96	186.00	
	1	19MAR96	6, -52	20	120	66	88	110	60	88	181.00	
	2	26MAR96	13, -45	20	100	60	84	100	60	84	179.00	
	3	02APR96	20, -38	20	110	62	96	100	60	96	180.00	
	4	12APR96	30, -28	30	118	76	96	110	70	96	181.00	
	5	16APR96	34, -24	30	114	72	88	110	70	88	183.00	
	6	23APR96	41, -17	40	112	68	96	110	68	96	181.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00250	7	30APR96	48, -10	30	110	70	88	110	70	88	182.00	
	8	09MAY96	57, -1	30	110	70	96	110	70	96	184.00	
	12	28MAY96	76, 19	30	94	58	88	90	60	88	182.00	
329.003.00292	BL	07AUG96	1, -58	0	126	56	80	130	56	80	143.10	60.6
	1	16AUG96	10, -49	20	138	74	86	142	62	88	141.56	
	2	21AUG96	15, -44	20	112	80	80	118	76	45 L	139.36	
	3	30AUG96	24, -35	20	122	50	80	128	54	82	139.80	
	4	04SEP96	29, -30	20	126	50	92	116	46	106	141.12	
	7	25SEP96	50, -9	20	128	58	95	132	48	98	142.88	
	8	04OCT96	59, 1	20	120	65	100	120	70	96	144.43	
329.003.00313	SC	08MAY96	-9, .	0	116	70	60	118	80	60	175.00	63.0
	BL	17MAY96	1, .	0	90	60	72	82	56	72	191.00	
	1	21MAY96	5, .	20	90	60	72	90	60	72	194.00	
	2	28MAY96	12, .	20	112	74	84	112	74	84	182.00	
329.004.00015	SC	30NOV94	-8, -65	0	100	68	80	110	70	84	109.37	62.6
	BL	07DEC94	-1, -58	0	100	68	60	96	70	80	116.87	
	1	14DEC94	7, -51	20	90	60	96	90	64	104	107.16 L	
	2	21DEC94	14, -44	20	100	60	88	100	64	100	106.06 L	
	3	28DEC94	21, -37	20	100	70	82	100	70	90	104.96 L	
	4	04JAN95	28, -30	20	90	60	74	90	60	80	102.53 L	
	5	11JAN95	35, -23	20	110	70	76	110	78	100	102.97 L	
	6	18JAN95	42, -16	20	98	60	80	90	68	96	105.18 L	
	7	25JAN95	49, -9	20	110	78	94	100	66	100	105.18 L	
	8	03FEB95	58, 1	20	104	68	80	100	66	84	105.84 L	
	12	27FEB95	82, 25	20	102	64	80	98	64	104	99.67 L	
	16	22MAR95	105, 48	20	108	76	72	106	72	72	102.97 L	
	20	19APR95	133, 76	20	90	60	68	90	60	70	103.64 L	
	24	17MAY95	161, 104	20	90	60	64	100	60	64	105.84 L	
	28	14JUN95	189, 132	20	100	60	60	100	64	64	106.94 L	
329.004.00017	SC	15MAR95	-7, -63	0	112	70	56	112	74	60	137.15	63.4
	BL	22MAR95	1, -56	0	90	60	64	100	68	70	135.17	
	1	30MAR95	9, -48	20	80	60	64	90	60	64	135.39	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.004.00017	2	06APR95	16, -41	20	90	60	68	100	70	70	133.84	
	3	13APR95	23, -34	20	100	60	70	100	60	74	134.95	
	4	20APR95	30, -27	20	100	60	72	110	60	78	137.59	
	5	26APR95	36, -21	30	100	60	64	110	70	68	135.39	
	6	03MAY95	43, -14	30	90	60	60	90	70	72	133.62	
	7	10MAY95	50, -7	30	90	60	64	100	60	68	132.96	
	8	17MAY95	57, 1	30	90	60	68	90	60	70	133.40	
	12	14JUN95	85, 29	30	100	60	70	110	80	70	131.64	
	16	13JUL95	114, 58	30	110	70	72	110	70	80	131.42	
	20	10AUG95	142, 86	30	110	70	60	105	70	68	135.61	
	24	06SEP95	169, 113	30	90	60	60	100	70	64	135.17	
	28	04OCT95	197, 141	30	90	60	64	100	68	68	138.92	
	32	01NOV95	225, 169	20	100	70	78	100	68	68	140.02	
329.004.00019	SC	24MAY95	-7, .	0	90	60	60	100	70	78	120.17	66.1
	BL	31MAY95	1, .	0	100	60	64	110	70	80	117.31	
	1	07JUN95	8, .	20	90	60	80	110	70	84	119.51	
	2	14JUN95	15, .	20	100	60	70	110	80	90	120.61	
329.004.00212	SC	24MAY96	-10, .	0	100	60	60	90	60	72	143.33	65.7
	BL	03JUN96	1, .	0	90	60	72	90	60	78	139.80	
	1	10JUN96	8, .	20	110	60	78	110	78	84	137.81	
	3	21JUN96	19, .	20	116	78	80	108	80	92	139.58	
	4	28JUN96	26, .	20	118	78	90	110	80	98	137.81	
329.004.00214	SC	27SEP96	-7, -67	0	120	90	68	120	90	80	128.99	60.6
	BL	04OCT96	1, -60	0	110	70	78	110	70	80	129.43	
	1	09OCT96	6, -55	20	125	70	84	120	80	84	128.11	
	2	15OCT96	12, -49	20	120	80	84	120	90	88	127.89	
	2	21OCT96	18, -43	20	110	70	78	110	90	98	127.89	
	4	01NOV96	29, -32	30	100	60	60	100	60	120	128.99	
	5	11NOV96	39, -22	30	110	70	98	100	70	120	126.35	
	6	18NOV96	46, -15	20	110	60	100	135	85	120	128.11	
	7	25NOV96	53, -8	20	110	60	78	110	70	84	126.79	
	8	03DEC96	61, 1	20	125	75	84	125	75	95	129.43	
	12	30DEC96	88, 28	20	110	60	88	110	76	96	128.99	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00002	SC	20MAY94	-5, -61	0	80	60	92	80	60	92	115.76	62.0
	BL	25MAY94	1, -56	0	100	70	88	90	70	88	112.90	
	1	01JUN94	8, -49	20	90	60	92	90	64	92	114.88	
	2	08JUN94	15, -42	20	98	60	80	90	60	80	113.78	
	3	15JUN94	22, -35	20	90	60	80	88	60	80	111.79	
	4	23JUN94	30, -27	30	90	60	72	88	60	60	115.54	
	5	30JUN94	37, -20	40	90	60	72	80	60	76	113.12	
	6	07JUL94	44, -13	40	90	60	88	88	60	88	115.10	
	7	14JUL94	51, -6	40	84	60	80	80	60	80	115.10	
	8	20JUL94	57, 1	40	90	60	88	80	60	88	110.47	
	12	17AUG94	85, 29	40	94	68	88	94	70	88	115.10	
	16	15SEP94	114, 58	40	90	70	92	90	60	92	113.56	
	20	18OCT94	147, 91	40	94	70	94	90	70	86	112.20	
329.005.00004	SC	22SEP94	-18, -77	0	130	70	62	124	70	62	143.00	68.0
	BL	10OCT94	1, -59	0	134	74	68	130	70	68	141.50	
	1	20OCT94	11, -49	20	130	70	62	124	70	62	142.00	
	2	27OCT94	18, -42	20	118	74	64	110	70	62	144.80	
	3	03NOV94	25, -35	20	120	70	60	90	70	60	145.40	
	4	10NOV94	32, -28	30	120	70	68	100	60	64	148.00	
	5	17NOV94	39, -21	40	124	80	84	120	80	80	150.50	
	6	23NOV94	45, -15	40	124	80	64	120	80	64	148.00	
	7	01DEC94	53, -7	40	112	70	60	100	60	64	152.90 H	
	8	08DEC94	60, 1	40	110	60	60	118	60	62	149.60	
	12	05JAN95	88, 29	30	118	62	76	110	60	90	153.50 H	
329.005.00008	SC	10NOV94	-6, -61	0	100	70	70	100	68	70	88.50	60.0
	BL	16NOV94	1, -55	0	100	70	80	110	70	80	91.00	
	1	23NOV94	8, -48	20	100	70	72	108	70	72	89.00	
	2	30NOV94	15, -41	20	98	70	76	110	70	80	89.50	
	3	07DEC94	22, -34	20	80	60	84	84	60	88	88.00	
	4	14DEC94	29, -27	30	100	60	80	100	60	88	89.00	
	5	21DEC94	36, -20	40	104	70	76	110	70	76	90.85	
	6	28DEC94	43, -13	40	90	60	84	90	60	88	91.29	
	7	03JAN95	49, -7	40	100	60	80	100	64	84	90.00	
	8	10JAN95	56, 1	30	90	60	72	94	64	80	92.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00008	12	06FEB95	83, 28	30	100	70	80	96	60	80	95.50	
	16	08MAR95	113, 58	30	100	60	80	100	60	88	98.20 H	
	24	10MAY95	176, 121#	0	94	64	88	90	60	88	101.50 H	
329.005.00011	SC	06DEC94	-7, -63	0	112	70	84	100	70	88	122.00	69.0
	BL	13DEC94	1, -56	0	100	70	80	100	70	84	122.00	
	1	20DEC94	8, -49	20	100	70	84	104	70	84	122.00	
	2	27DEC94	15, -42	20	90	60	84	90	60	84	119.00	
	3	03JAN95	22, -35	20	90	60	76	90	60	76	121.50	
	4	09JAN95	28, -29	30	92	60	88	88	60	88	119.50	
	5	17JAN95	36, -21	40	90	60	84	100	70	88	120.50	
	6	23JAN95	42, -15	40	90	60	100	90	60	100	121.00	
	7	31JAN95	50, -7	40	90	60	72	94	60	76	118.10	
	8	07FEB95	57, 1	40	104	70	84	100	60	88	118.50	
	12	09MAR95	87, 31	40	110	70	96	112	64	114	117.50	
	16	06APR95	115, 59	40	110	70	90	100	62	96	118.20	
	20	03MAY95	142, 86	30	100	64	88	98	60	92	119.00	
329.005.00109	SC	22DEC94	-8, -61	0	112	70	60	100	70	60	137.00	67.0
	BL	30DEC94	1, -53	0	98	60	76	90	60	76	137.50	
	1	05JAN95	7, -47	20	110	70	72	120	70	72	138.50	
	2	12JAN95	14, -40	20	100	60	76	108	60	72	137.50	
	3	19JAN95	21, -33	20	112	70	72	112	70	76	136.20	
	4	26JAN95	28, -26	20	120	80	80	110	76	84	136.00	
	5	02FEB95	35, -19	20	100	70	76	98	68	80	132.10	
	6	08FEB95	41, -13	20	90	60	68	100	60	72	135.50	
	7	16FEB95	49, -5	20	128	76	72	128	78	76	135.61	
	8	21FEB95	54, 1	20	118	74	72	110	72	74	134.00	
	12	23MAR95	84, 31	20	90	70	72	104	70	76	134.00	
	16	24APR95	116, 63	20	120	88	60	120	78	68	140.00	
	20	25MAY95	147, 94	20	120	80	68	120	78	72	137.70	
329.005.00112	SC	17JAN95	-9, -64	0	104	70	66	100	70	72	119.00	61.0
	BL	26JAN95	1, -55	0	100	70	68	98	70	68	115.00	
	1	01FEB95	7, -49	20	100	70	80	90	60	84	119.00	
	2	08FEB95	14, -42	20	100	70	76	104	70	76	119.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00112	3	15FEB95	21, -35	20	90	60	84	84	56	88	118.00	
	4	23FEB95	29, -27	20	98	60	84	100	70	84	118.00	
	5	01MAR95	35, -21	20	100	70	80	110	74	80	118.50	
	6	08MAR95	42, -14	20	120	78	100	120	82	110	122.00	
	7	15MAR95	49, -7	20	90	60	92	90	60	96	122.00	
	8	22MAR95	56, 1	20	94	64	76	92	60	80	123.00	
	12	19APR95	84, 29	20	110	74	80	104	70	88	124.00 H	
	20	21JUN95	147, 92#	0	100	70	80	104	72	84	124.50 H	
329.005.00116	SC	30JAN95	-8, -66	0	118	80	54	110	80	56	206.80	71.0
	BL	07FEB95	1, -58	0	112	80	68	90	72	64	206.50	
	1	13FEB95	7, -52	20	110	80	72	90	60	74	206.70	
	2	20FEB95	14, -45	20	110	70	72	104	60	74	204.10	
	3	27FEB95	21, -38	20	118	62	70	112	70	74	203.30	
	4	09MAR95	31, -28	20	104	78	84	100	74	88	201.00	
	5	16MAR95	38, -21	20	120	78	84	110	80	88	201.00	
	6	23MAR95	45, -14	20	118	70	76	110	70	80	201.50	
	7	30MAR95	52, -7	20	120	84	96	112	80	98	206.00	
	8	06APR95	59, 1	20	120	80	88	112	70	92	208.00	
	12	04MAY95	87, 29	20	100	74	72	98	70	80	211.00	
	16	31MAY95	114, 56	30	104	80	80	98	70	84	214.00	
	20	28JUN95	142, 84	20	90	60	68	88	60	64	212.20	
	24	26JUL95	170, 112#	0	118	80	80	110	74	84	212.00	
329.005.00119	SC	27JUN95	-14, -73	0	118	80	70	110	82	70	150.10	65.0
	BL	11JUL95	1, -59	0	128	80	70	120	80	88	153.20	
	1	18JUL95	8, -52	20	120	80	74	110	72	76	153.50	
	2	26JUL95	16, -44	20	120	82	80	118	88	80	152.60	
	3	02AUG95	23, -37	20	124	74	70	120	80	80	152.00	
	4	08AUG95	29, -31	30	110	64	72	110	64	86	151.00	
	5	15AUG95	36, -24	40	100	60	88	104	60	96	155.20	
	6	23AUG95	44, -16	40	128	80	94	120	80	106	156.80	
	7	29AUG95	50, -10	40	118	78	86	106	74	92	159.00	
	8	08SEP95	60, 1	40	122	80	88	120	72	96	158.00	
	12	03OCT95	85, 26	40	128	80	84	118	86	98	156.00	
	16	30OCT95	112, 53	40	120	80	92	118	68	108	155.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00119	20	28NOV95	141, 82	30	90	60	94	90	50	106	159.00	
329.005.00151	SC	29AUG95	-8, -65	0	110	60	82	108	64	86	112.46	63.0
	BL	06SEP95	1, -57	0	102	64	76	106	66	88	110.91	
	1	14SEP95	9, -49	20	110	60	68	90	60	68	109.00	
	2	20SEP95	15, -43	20	100	60	64	110	70	64	107.50	
	3	28SEP95	23, -35	20	100	60	70	90	62	70	108.00	
	4	03OCT95	28, -30	20	100	60	88	104	60	92	105.20	
	5	11OCT95	36, -22	20	90	50	84	96	56	96	107.00	
	6	19OCT95	44, -14	20	100	64	80	102	66	88	109.59	
	7	26OCT95	51, -7	20	108	70	84	100	60	88	108.50	
	8	02NOV95	58, 1	20	106	66	84	104	64	88	109.81	
	12	28NOV95	84, 27	20	98	50	88	98	48	92	111.00	
	16	02JAN96	119, 62	20	120	80	80	120	70	86	114.00	
	20	31JAN96	148, 91	30	104	70	84	98	68	88	114.00	
	24	27FEB96	175, 118	30	90	50	72	90	60	88	116.70	
	28	27MAR96	204, 147	30	100	60	78	94	60	76	118.41	
	32	01MAY96	239, 182	20	98	68	68	92	64	78	119.75 H	
329.005.00152	SC	12OCT95	-14, .	0	100	70	78	94	70	84	128.00	66.0
	BL	23OCT95	-3, .	0	104	70	76	100	70	84	128.50	
	1	02NOV95	8, .	20	100	60	72	90	60	76	126.00	
329.005.00257	SC	05MAR96	-6, -62	0	110	68	102	100	60	96	112.00	63.0
	BL	11MAR96	1, -56	0	90	60	76	90	60	70	112.50	
	1	18MAR96	8, -49	20	100	50	80	98	48	98	108.00	
	2	25MAR96	15, -42	20	90	60	86	88	58	96	109.00	
	3	01APR96	22, -35	20	100	70	74	102	68	86	111.00	
	4	08APR96	29, -28	20	110	80	70	110	86	80	112.00	
	5	15APR96	36, -21	20	100	60	72	90	52	90	110.00	
	6	22APR96	43, -14	30	110	64	84	110	68	80	112.00	
	7	29APR96	50, -7	30	100	60	80	100	60	80	112.75	
	8	06MAY96	57, 1	30	120	68	86	118	78	94	112.00	
	12	03JUN96	85, 29	30	100	70	74	106	80	90	117.25	
	16	08JUL96	120, 64	30	112	70	86	108	70	86	122.25 H	
	20	07AUG96	150, 94	30	122	72	80	120	80	84	124.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00257	24	27AUG96	170, 114	30	120	80	84	110	70	86	122.00 H	
	28	01OCT96	205, 149	30	118	70	78	118	80	84	123.00 H	
	32	21OCT96	225, 169	30	116	72	80	110	70	86	123.00 H	
329.005.00258	SC	06FEB96	-35, .	0	102	60	98	100	60	104	169.50	64.0
	BL	20FEB96	-21, .	0	118	70	100	110	70	104	171.70	
	1	19MAR96	8, .	20	100	60	98	98	68	102	171.00	
	2	26MAR96	15, .	20	120	78	80	110	70	98	168.50	
	3	02APR96	22, .	20	120	70	80	110	70	98	171.00	
	4	09APR96	29, .	30	112	76	82	110	80	100	169.00	
	5	18APR96	38, .	40	104	70	80	100	70	84	169.00	
	6	23APR96	43, .	40	126	70	84	122	76	102	171.50	
	7	30APR96	50, .	40	112	70	88	120	80	106	167.50	
	8	07MAY96	57, .	30	120	80	88	120	80	102	168.75	
329.005.00299	SC	28MAY96	-11, -71	0	118	82	72	116	78	78	123.20	63.0
	BL	04JUN96	-4, -64	0	120	80	64	120	80	76	124.00	
	1	18JUN96	11, -50	20	92	64	84	92	60	100	123.00	
	2	25JUN96	18, -43	20	92	64	84	92	60	96	125.75	
	3	02JUL96	25, -36	20	110	70	82	110	80	84	124.00	
	5	10JUL96	33, -28	20	90	68	80	92	56	88	124.00	
	6	22JUL96	45, -16	20	100	48 L	84	90	42 L	100	124.00	
	8	31JUL96	54, -7	20	110	60	80	90	54	84	127.20	
	8	07AUG96	61, 1	20	106	70	80	100	60	84	125.75	
	12	03SEP96	88, 28	20	120	70	72	120	76	86	128.75	
	16	01OCT96	116, 56	20	92	58	84	88 L	54	92	128.00	
	20	29OCT96	144, 84	30	104	60	82	100	60	88	131.25	
329.005.00300	SC	12SEP96	-7, .	0	90	60	60	90	58	62	96.20	62.0
	BL	19SEP96	1, .	0	80	50	60	88	50	62	96.50	
	1	26SEP96	8, .	20	80	50	74	84	60	78	95.50	
	2	03OCT96	15, .	20	88	60	64	84	58	68	94.20	
	3	10OCT96	22, .	20	98	60	80	104	50	86	94.75	
	4	17OCT96	29, .	20	90	60	60	80	60	64	97.50	
	5	24OCT96	36, .	20	70	50	60	90	60	62	95.70	
	6	31OCT96	43, .	20	80	60	60	58 L	54	60	95.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00300	7	07NOV96	50, .	20	80	60	60	78	50	62	95.70	
	8	14NOV96	57, .	20	90	60	60	80	58	64	99.00	
329.005.00333	SC	15JAN97	-8, .	0	122	70	82	124	78	86	123.00	64.0
	BL	23JAN97	1, .	0	126	60	80	128	80	88	123.40	
	1	31JAN97	9, .	20	118	70	74	120	74	76	123.70	
	2	06FEB97	15, .	20	132	74	60	128	70	64	125.20	
	3	13FEB97	22, .	20	124	74	88	118	70	100	124.00	
	4	20FEB97	29, .	20	124	70	80	120	70	80	124.70	
	5	26FEB97	35, .	20	120	80	68	120	80	74	124.00	
329.005.00336	SC	26FEB97	-6, .	0	114	74	64	100	70	68	119.00	65.0
	BL	04MAR97	1, .	0	100	70	64	90	60	68	119.70	
	1	12MAR97	9, .	20	100	70	68	98	60	68	118.70	
	2	19MAR97	16, .	20	104	70	60	90	60	64	116.50	
	3	25MAR97	22, .	20	88	64	68	80	60	72	120.50	
	4	02APR97	30, .	20	82	60	78	80	60	78	121.00	
	5	09APR97	37, .	20	80	60	84	88	60	88	124.00	
	6	16APR97	44, .	20	100	60	68	90	60	72	122.50	
	7	23APR97	51, .	20	110	70	78	90	60	80	123.00	
	8	30APR97	58, .	20	100	70	72	90	60	76	121.70	
329.006.00038	SC	01FEB95	-14, .	0	108	60	64	103	61	72	171.00	67.0
	BL	08FEB95	-7, .	0	90	60	80	90	60	80	171.00	
	1	22FEB95	8, .	20	110	80	68	128	68	72	164.49	
	2	03MAR95	17, .	20	100	70	.	110	80	.	166.92	
	3	08MAR95	22, .	20	90	60	60	100	60	80		
	4	15MAR95	29, .	20	100	60	60	100	70	80	161.00	
	5	22MAR95	36, .	20	90	70	60	100	60	100		
	6	29MAR95	43, .	20	110	70	80	120	70	.	168.68	
	7	05APR95	50, .	20	100	80	60	108	68	80	166.48	
329.006.00039	SC	03FEB95	-5, -66	0	100	60	68	107	66	88	142.22	64.6
	BL	10FEB95	3, -59	20	116	70	71	108	70	66	142.22	
	1	13FEB95	6, -56	20	100	60	60	103	66	60	143.33	
	2	22FEB95	15, -47	20	98	68	70	100	72	80	143.33	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.006.00039	3	01MAR95	22, -40	20	90	60	60	90	60	66	138.92	
	4	08MAR95	29, -33	20	110	70	68	102	70	80		
	5	17MAR95	38, -24	20	100	60	84	110	60	80	135.61	
	6	22MAR95	43, -19	20	88	58	70	85	62	90		
	7	29MAR95	50, -12	30	98	78	80	98	70	90	136.71	
	8	05APR95	57, -5	30	100	60	70	96	60	100	136.71	
	12	01MAY95	83, 22	20	108	78	80	90	60	80	143.33	
329.006.00260	SC	12JUL96	-6, -64	0	115	70	62	113	75	78	140.00	67.0
	BL	18JUL96	1, -58	0	115	80	68	110	70	74	140.00	
	1	26JUL96	9, -50	20	113	80	80	113	78	90	138.00	
	2	01AUG96	15, -44	20	113	75	84	115	80	90	136.50	
	3	07AUG96	21, -38	20	113	78	78	113	80	84	137.00	
	4	14AUG96	28, -31	30	100	70	78	100	80	102	133.00	
	5	21AUG96	35, -24	30	100	80	72	100	75	94	133.50	
	6	28AUG96	42, -17	30	100	70	70	100	80	80	133.50	
	7	04SEP96	49, -10	30	110	70	78	105	70	72	135.00	
	8	18SEP96	63, 5	30	100	70	72	115	70	80	137.00	
	12	09OCT96	84, 26	30	100	80	78	98	70	102	133.00	
	16	06NOV96	112, 54	30	100	75	66	100	75	78	134.00	
	20	05DEC96	141, 83	20	115	80	66	100	70	80	140.00	
329.006.00261	SC	07NOV96	-19, -77	0	100	60	72	98	60	72	172.50	66.0
	BL	22NOV96	-4, -62	0	113	70	70	113	80	74	171.00	
	1	03DEC96	8, -51	20	113	70	60	113	75	80	172.00	
	2	10DEC96	15, -44	20	115	70	72	116	80	66	173.50	
	3	17DEC96	22, -37	20	117	75	72	117	80	72	172.50	
	4	24DEC96	29, -30	30	160	80	70	160	80	72	173.00	
	5	02JAN97	38, -21	30	118	80	66	118	80	78	174.00	
	6	09JAN97	45, -14	30	120	80	72	120	80	78	178.00	
	7	15JAN97	51, -8	30	120	85	66	120	85	72	178.00	
	8	23JAN97	59, 1	30	115	75	66	112	80	72	178.50	
	12	20FEB97	87, 29	30	116	75	66	116	80	70	178.00	
	20	02APR97	128, 70	30	113	80	72	113	80	80	180.00	
329.007.00140	SC	07SEP95	-8, -63	0	104	60	64	102	64	68	74.00	54.0

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.007.00140	BL	14SEP95	-1, -56	0	110	60	72	104	62	76	74.00	
	1	21SEP95	7, -49	20	100	62	60	98	64	68	72.00	
	2	28SEP95	14, -42	20	96	60	60	92	62	68	71.00	
	3	05OCT95	21, -35	20	110	60	64	106	62	68	72.00	
	4	12OCT95	28, -28	20	104	70	68	102	72	72	72.00	
	5	18OCT95	34, -22	20	110	70	64	108	72	68	73.00	
	6	26OCT95	42, -14	20	100	60	64	98	62	68	70.00	
	7	02NOV95	49, -7	20	102	58	64	100	62	68	72.00	
	8	09NOV95	56, 1	20	104	72	64	100	74	73	73.00	
	12	22NOV95	69, 14	20	104	68	78	98	66	72	74.00	
329.007.00142	SC	12OCT95	-6, .	0	124	80	68	120	82	76	212.00	68.0
	BL	18OCT95	1, .	0	124	82	72	120	84	68	213.00	
	1	26OCT95	9, .	20	130	78	68	128	80	72	214.00	
	2	02NOV95	16, .	20	122	84	72	120	88	68	212.00	
	3	09NOV95	23, .	20	124	74	68	118	82	72	211.00	
	4	16NOV95	30, .	30	130	70	80	128	74	72	212.00	
	5	22NOV95	36, .	30	123	78	88	114	79	110	210.00	
	6	30NOV95	44, .	40	140	74	80	132	76	64	214.00	
	8	21DEC95	65, .#	0	128	82	88	132	88	88	214.00	
329.007.00145	SC	04JAN96	-7, -63	0	110	60	68	108	64	72	107.00	62.0
	BL	11JAN96	1, -56	0	110	68	76	108	70	80	106.00	
	1	18JAN96	8, -49	20	118	70	76	116	74	80	106.00	
	2	25JAN96	15, -42	20	118	64	72	116	68	64	106.00	
	3	01FEB96	22, -35	20	118	76	80	112	78	84	108.00	
	4	08FEB96	29, -28	30	112	68	76	110	72	88	107.00	
	5	12FEB96	33, -24	30	118	68	72	114	70	80	108.00	
	6	21FEB96	42, -15	30	114	68	80	112	70	72	107.00	
	7	26FEB96	47, -10	40	112	64	72	110	66	64	106.00	
	8	07MAR96	57, 1	40	120	60	80	118	66	72	107.00	
	12	04APR96	85, 29	40	114	74	64	110	76	72	106.00	
	16	02MAY96	113, 57	30	118	84	68	114	86	74	110.00	
	20	30MAY96	141, 85	20	118	70	68	116	74	76	112.00	
	24	27JUN96	169, 113	20	98	58	88	100	74	88	110.00	
	28	25JUL96	197, 141	20	110	62	58	104	66	58	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.007.00145	32	23AUG96	226, 170	20	118	68	72	108	60	68	111.00	
329.007.00265	SC	25JAN96	-7, .	0	110	62	66	118	70	70	140.00	64.0
	BL	01FEB96	1, .	0	112	68	68	110	72	72	140.00	
	2	15FEB96	15, .	20	116	64	64	112	66	72	136.00	
329.007.00268	SC	21MAR96	-11, -70	0	120	70	64	122	76	72	224.00	64.0
	BL	01APR96	1, -59	0	118	68	68	116	72	72	225.00	
	1	11APR96	11, -49	20	118	68	64	114	74	68	224.00	
	2	18APR96	18, -42	20	122	74	72	118	76	76	221.00	
	3	25APR96	25, -35	20	122	70	64	120	70	62	221.00	
	4	02MAY96	32, -28	20	120	74	72	118	82	76	223.00	
	5	09MAY96	39, -21	20	122	80	72	120	84	80	224.00	
	6	16MAY96	46, -14	30	124	78	60	122	80	64	220.00	
	8	30MAY96	60, 1	30	128	74	72	126	80	80	222.00	
	12	27JUN96	88, 29	30	104	72	70	92	58	70	221.00	
	16	01AUG96	123, 64	40	130	76	90	140	84	100	227.00	
	20	30AUG96	152, 93	40	124	92	90	130	80	92	231.00	
	24	30SEP96	183, 124	30	110	78	80	104	74	84	234.00	
	32	07NOV96	221, 162	30	122	76	78	124	76	80	244.00 H	
	32	05DEC96	249, 190	20	106	78	76	112	92	84	243.00 H	
329.007.00294	SC	20FEB97	-8, .	0	101	64	62	90	64	102	154.00	67.0
	BL	27FEB97	-1, .	0	119	64	85	102	69	108	161.00	
	1	10MAR97	11, .	20	106	63	71	114	68	98	161.00	
	2	17MAR97	18, .	20	109	69	78	106	69	92	159.00	
	4	28MAR97	29, .	20	99	63	88	102	63	76	164.00	
	5	03APR97	35, .	30	105	71	74	94	72	84	166.00	
	6	10APR97	42, .	20	106	72	78	114	74	84	165.00	
329.007.00309	SC	02JUL96	-13, -65	0	106	66	80	94	66	96	130.00	67.0
	BL	15JUL96	1, -52	0	106	60	78	100	78	110	130.00	
	1	18JUL96	4, -49	20	108	58	84	92	60	88	131.00	
	1	25JUL96	11, -42	20	120	58	60	104	68	64	128.00	
	2	01AUG96	18, -35	20	114	64	77	110	68	80	131.00	
	3	08AUG96	25, -28	20	128	76	104	140	78	100	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.007.00309	4	15AUG96	32, -21	20	118	60	102	120	62	100	130.00	
	6	23AUG96	40, -13	20	120	66	82	118	70	82	127.00	
	7	30AUG96	47, -6	20	110	70	60	112	70	68	126.00	
	7	05SEP96	53, 1	20	109	68	85	114	75	106	128.00	
	12	03OCT96	81, 29	20	112	64	86	118	68	80	130.00	
	16	31OCT96	109, 57	20	106	72	80	108	76	72	131.00	
	20	13DEC96	152, 100	20	104	53	80	103	59	87	128.00	
	24	09JAN97	179, 127	20	111	62	94	100	59	88	129.00	
	28	10FEB97	211, 159	30	115	61	79	115	74	98	130.00	
	32	13MAR97	242, 190	20	100	60	74	100	60	94	129.00	
329.007.00310	SC	19SEP96	-7, -67	0	100	72	80	100	78	76	116.00	60.0
	BL	26SEP96	1, -60	0	104	63	99	109	71	119	116.00	
	1	03OCT96	8, -53	20	110	78	76	108	76	80	114.00	
	2	10OCT96	15, -46	20	112	70	72	110	72	74	115.00	
	3	17OCT96	22, -39	20	102	64	60	100	68	60	115.00	
	5	28OCT96	33, -28	20	104	68	70	100	66	72	116.00	
	5	31OCT96	36, -25	20	100	72	72	98	68	68	114.00	
	6	08NOV96	44, -17	20	96	68	74	100	72	76	114.00	
	8	18NOV96	54, -7	20	101	51	70	96	52	80	116.00	
	8	25NOV96	61, 1	20	96	50	64	94	52	76	115.00	
	12	02JAN97	99, 39	20	98	73	81	100	78	101	109.00	
	20	14FEB97	142, 82	20	102	59	66	98	60	74	111.00	
	24	13MAR97	169, 109	20	103	63	78	98	66	93	113.00	
	28	17APR97	204, 144	20	101	51	78	98	69	89	119.00	
	32	15MAY97	232, 172	20	98	63	71	109	69	69	118.00	
	32	12JUN97	260, 200	20	102	54	86	100	65	97	119.00	
329.007.00318	SC	22NOV96	-10, .	0	116	68	85	112	70	76	120.00	65.0
	BL	02DEC96	1, .	0	111	61	84	101	72	86	123.00	
329.008.00157	SC	16AUG95	-14, -69	0	138	68	72	136	68	72	278.00	72.0
	BL	29AUG95	-1, -56	0	138	78	78	140	78	74	277.00	
	1	05SEP95	7, -49	20	138	78	66	138	76	66	277.00	
	2	12SEP95	14, -42	20	136	78	68	134	74	72		
	3	20SEP95	22, -34	20	136	80	78	138	84	78	277.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
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Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.008.00157	4	26SEP95	28, -28	20	136	82	66	134	82	62	278.00	
	5	04OCT95	36, -20	20	136	80	64	133	78	60	278.00	
	6	10OCT95	42, -14	20	122	74	64	120	74	64		
	7	16OCT95	48, -8	20	114	78	66	110	80	70	280.00	
	8	24OCT95	56, 1	20	120	78	72	118	72	72	279.00	
	12	23NOV95	86, 31	20	112	80	58	106	76	60	278.00	
	16	15DEC95	108, 53	20	102	72	72	95	70	78	281.00	
	20	23JAN96	147, 92	20	118	78	78	116	78	90	280.00	
	24	20FEB96	175, 120	20	118	74	90	122	70	96	280.00	
329.008.00160	SC	25OCT95	-7, -73	0	102	65	68	110	85	80	161.00	76.0
	BL	01NOV95	1, -66	0	110	70	84	102	75	92	159.00	
	1	10NOV95	10, -57	20	90	58	76	85	80	80	159.00	
	3	20NOV95	20, -47	20	110	58	84	105	65	88	160.00	
	4	27NOV95	27, -40	20	110	80	80	110	80	92	160.00	
	5	05DEC95	35, -32	20	110	75	80	107	78	92	158.00	
	6	13DEC95	43, -24	30	100	70	80	105	78	96	159.00	
	7	20DEC95	50, -17	30	110	65	76	100	78	84	156.00	
	8	27DEC95	57, -10	30	112	72	72	100	80	88	163.00	
	8	05JAN96	66, -1	30	110	50	84	110	78	100	160.00	
	12	31JAN96	92, 26	30	112	65	92	110	75	96	160.00	
	16	05MAR96	126, 60	30	115	60	84	120	80	84	164.00	
	24	09APR96	161, 95	30	110	80	100	90	60	96	168.00	
	28	16MAY96	198, 132	30	122	78	92	110	80	96	175.00 H	
	32	18JUN96	231, 165	30	120	75	108	110	85	100	175.00 H	
	32	23JUL96	266, 200	30	120	60	96	90	70	80	175.00 H	
329.008.00188	SC	14DEC95	-21, .	0	110	70	80	100	70	100	156.00	63.0
	BL	04JAN96	1, .	0	112	85	88	100	85	132	160.00	
	1	10JAN96	7, .	20	110	85	80	105	75	100	162.00	
	2	17JAN96	14, .	20	112	60	80	100	75	88	162.00	
	3	24JAN96	21, .	20	100	70	88	105	80	112	159.00	
	4	31JAN96	28, .	30	120	80	72	112	82	88	162.00	
	5	07FEB96	35, .	40	110	75	84	110	70	100	164.00	
	6	14FEB96	42, .	40	110	75	88	105	75	120	162.00	
	7	21FEB96	49, .	40	110	65	96	110	80	128	163.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.008.00188	8	27FEB96	55, .	40	110	80	80	108	75	96	165.00	
329.008.00271	SC	25JAN96	-46,-110	0	98	76	68	96	70	72	170.00	63.5
	BL	11MAR96	1, -64	0	98	74	68	96	70	70	172.00	
	1	18MAR96	8, -57	20	132	78	82	116	78	94	175.00	
	2	25MAR96	15, -50	20	115	73	74	126	84	86	174.00	
	3	01APR96	22, -43	20	129	75	76	128	78	67	173.00	
	4	08APR96	29, -36	20	135	73	69	125	66	80	172.00	
	5	15APR96	36, -29	30	124	78	69	127	85	75	168.00	
	6	22APR96	43, -22	40	133	78	76	129	78	73	168.00	
	7	02MAY96	53, -12	40	126	76	67	116	76	75	164.00	
	8	14MAY96	65, 1	40	92	66	73	123	87	87	163.00	
	12	10JUN96	92, 28	40	130	76	76	126	84	78	168.00	
	16	12JUL96	124, 60	40	120	70	76	110	80	92	167.00	
	20	09AUG96	152, 88	40	98	75	80	90	60	112	162.00	
	24	06SEP96	180, 116	40	105	80	80	90	70	100	160.00	
	28	07OCT96	211, 147	40	105	75	72	95	80	92	162.00	
	32	05NOV96	240, 176	30	120	80	80	120	80	84	164.00	
329.008.00275	SC	30APR96	-8, -63	0	100	70	80	110	80	100	166.00	64.0
	BL	07MAY96	-1, -56	0	100	60	100	110	70	76	166.00	
	1	15MAY96	8, -48	20	110	80	80	105	80	100	164.00	
	2	21MAY96	14, -42	20	110	82	100	90	65	76	163.00	
	3	28MAY96	21, -35	20	100	72	88	100	80	96	167.00	
	4	04JUN96	28, -28	30	108	72	66	98	70	90	170.00	
	5	11JUN96	35, -21	30	104	72	66	96	72	88	170.00	
	7	25JUN96	49, -7	40	98	70	72	96	70	88	165.00	
	8	02JUL96	56, 1	30	110	62	72	94	60	90	165.00	
	12	23JUL96	77, 22	30	110	70	78	90	62	108	163.00	
	16	20AUG96	105, 50	30	104	74	74	86	70	96	158.00	
	20	16SEP96	132, 77	30	100	74	72	92	68	96	154.00 L	
	24	21OCT96	167, 112	30	60 L	72	76	88	68	86	154.00 L	
	28	25NOV96	202, 147	30	98	88	78	94	56	90	154.00 L	
	32	16DEC96	223, 168	30	98	64	90	92	60	112	154.00 L	
329.009.00130	SC	12APR95	-6, -62	0	139	58	57	130	70	74	146.30	66.3

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00130	BL	18APR95	1, -56	0	128	56	76	144	71	90	147.60	
	1	25APR95	8, -49	20	135	60	64	137	69	94	145.00	
	2	02MAY95	15, -42	20	128	55	52	131	65	54	145.80	
	3	09MAY95	22, -35	20	130	53	65	137	64	86	145.80	
	4	16MAY95	29, -28	20	133	67	59	122	61	76	145.09	
	5	23MAY95	36, -21	20	130	61	72	131	62	102	145.10	
	6	30MAY95	43, -14	20	130	64	64	122	63	88	147.60	
	7	06JUN95	50, -7	20	129	64	66	130	72	82	148.62	
	8	13JUN95	57, 1	20	130	60	79	138	76	93	151.10	
	16	07AUG95	112, 56	20	.	.	.	138	73	85	162.70 H	
	20	19SEP95	155, 99	20	137	60	65	137	66	71	165.30 H	
	24	03OCT95	169, 113	20	139	66	59	123	76	67	162.40 H	
329.009.00131	SC	26APR95	-6, -62	0	130	64	63	114	56	62	160.90	66.8
	BL	02MAY95	1, -56	0	106	60	64	122	56	72	158.70	
	1	09MAY95	8, -49	20	107	53	63	122	63	84	157.60	
	2	16MAY95	15, -42	20	121	60	69	123	65	85	159.64	
	3	23MAY95	22, -35	20	121	68	66	106	57	71	157.50	
	4	30MAY95	29, -28	20	115	60	73	130	65	100	156.50	
	5	06JUN95	36, -21	20	124	55	64	130	68	80	158.98	
	6	13JUN95	43, -14	20	115	52	67	130	72	86	160.40	
	7	20JUN95	50, -7	20	115	71	70	124	65	67	162.20	
	8	27JUN95	57, 1	20	130	68	69	115	81	102	162.10	
	12	25JUL95	85, 29	20	124	65	70	123	76	84	163.80	
	16	24AUG95	115, 59	20	115	44	63	94	60	72	159.00	
	20	26SEP95	148, 92#	0	106	63	75	107	56	83	155.00	
329.009.00133	SC	07JUN95	-6, .	0	138	72	132	144	59	95	308.26	68.1
	BL	13JUN95	1, .	0	144	98	105	149	85	114	308.80	
	1	20JUN95	8, .	20	152	80	95	155	58	105	308.00	
	2	27JUN95	15, .	20	145	55	88	145	79	97	307.80	
	3	05JUL95	23, .	20	145	79	95	147	72	108	309.50	
	4	11JUL95	29, .	30	138	76	80	138	83	87	308.30	
	5	18JUL95	36, .	40	131	72	109	148	69	111	308.40	
	6	27JUL95	45, .	40	148	72	91	146	62	109	308.90	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00138	SC	02OCT95	-8, .	0	114	64	76	107	71	84	116.50	65.5
	BL	10OCT95	1, .	0	122	61	83	115	65	98	117.70	
	1	17OCT95	8, .	20	104	54	70	107	71	85	117.70	
329.009.00170	SC	26OCT95	-12, -69	0	135	86	112	126	86	115	101.60	65.5
	1	14NOV95	8, -50	20	130	68	112	146	96	133	101.60	
	2	21NOV95	15, -43	20	128	79	114	124	80	126	101.10	
	3	28NOV95	22, -36	20	128	90	109	114	79	109	100.30	
	4	05DEC95	29, -29	30	129	83	115	126	91	119	100.90	
	5	12DEC95	36, -22	40	106	70	97	116	68	108	100.60	
	6	21DEC95	45, -13	40	107	68	84	100	73	90	98.80	
	7	29DEC95	53, -5	30	124	90	108	116	84	105	100.60	
	8	03JAN96	58, 1	30	130	80	125	124	81	125	101.50	
	12	29JAN96	84, 27	30	105	65	105	99	57	100	103.40	
	16	26FEB96	112, 55	30	114	52	106	114	49 L	108	105.90	
	20	01APR96	147, 90	30	93	76	78	115	60	102	106.30	
	24	22APR96	168, 111	30	114	72	93	128	67	98	109.00 H	
	28	23MAY96	199, 142	30	113	96	74	111	74	99	113.40 H	
	32	24JUN96	231, 174	30	128	82	99	131	85	99	114.60 H	
329.009.00173	SC	08NOV95	-12, -75	0	131	68	84	129	68	86	145.80	64.2
	BL	20NOV95	1, -63	0	133	80	85	131	73	96	142.60	
	1	27NOV95	8, -56	20	130	64	80	132	67	84	147.10	
	2	04DEC95	15, -49	20	110	67	66	123	64	74	142.90	
	3	11DEC95	22, -42	20	117	59	80	115	69	83	144.60	
	4	18DEC95	29, -35	30	121	60	75	122	68	80	145.60	
	6	29DEC95	40, -24	30	131	65	87	122	56	88	144.30	
	7	08JAN96	50, -14	20	124	57	98	131	68	96	139.00	
	8	15JAN96	57, -7	20	131	69	88	122	74	94	140.10	
	8	22JAN96	64, 1	20	114	61	80	116	66	87	141.60	
	12	26FEB96	99, 36	20	100	50	80	124	61	85	139.00	
329.009.00193	SC	21NOV95	-7, .	0	121	63	89	127	65	101	131.90	63.8
	BL	28NOV95	1, .	0	111	51	90	130	64	100	134.60	
	1	05DEC95	8, .	20	127	64	80	129	63	79	132.40	
	2	12DEC95	15, .	20	115	57	76	114	57	93	132.90	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00193	3	19DEC95	22, .	20	105	65	91	117	65	119	133.20	
	4	27DEC95	30, .	30	123	57	95	122	60	103	136.10	
	5	05JAN96	39, .	30	109	46	91	99	52	103	134.00	
	6	09JAN96	43, .	30	123	53	94	122	60	108	139.00	
	7	16JAN96	50, .	30	114	52	93	122	62	72	137.50	
	8	24JAN96	58, .	20	114	64	103	134	69	105	139.20	
329.009.00196	SC	11DEC95	-7, .	0	148	85	102	146	76	106	237.00	65.0
	BL	18DEC95	1, .	0	137	75	90	138	71	91	232.40	
	1	27DEC95	10, .	20	146	80	90	138	77	100	231.00	
	2	02JAN96	16, .	20	144	79	75	140	79	86	233.80	
	3	08JAN96	22, .	20	153	87	88	153	87	98	237.90	
	4	15JAN96	29, .	30	146	80	87	146	80	90	237.50	
	5	22JAN96	36, .	30	137	83	74	129	85	85	235.90	
	6	29JAN96	43, .	30	138	77	91	139	66	94	236.00	
	7	05FEB96	50, .	30	137	72	95	150	90	96	239.50	
	8	12FEB96	57, .	20	117	66	100	114	60	102	234.10	
329.009.00201	SC	31JAN96	-6, .	0	106	51	85	122	67	110	151.80	67.0
	BL	06FEB96	1, .	0	127	53	87	130	95	112	150.80	
	1	13FEB96	8, .	20	130	69	85	158	74	102	151.40	
	2	20FEB96	15, .	20	124	57	86	120	61	97	152.40	
	3	28FEB96	23, .	20	118	59	93	121	65	108	153.90	
	4	05MAR96	29, .	20	131	63	101	114	64	105	154.30	
	5	12MAR96	36, .	20	131	80	90	129	65	103	158.90	
	6	19MAR96	43, .	20	125	78	100	131	85	106	157.20	
	7	26MAR96	50, .	30	124	49	90	122	68	97	158.40	
	8	02APR96	57, .	20	136	59	109	121	77	106	163.80 H	
329.009.00204	SC	13MAR96	-6, -62	0	108	59	93	102	64	98	113.20	63.0
	BL	19MAR96	1, -56	0	105	64	87	105	51	89	117.10	
	1	26MAR96	8, -49	20	145	73	89	136	96	100	115.80	
	2	02APR96	15, -42	20	110	56	80	111	63	83	114.40	
	3	09APR96	22, -35	20	106	53	74	97	56	84	115.90	
	4	16APR96	29, -28	20	116	58	88	123	58	102	116.60	
	5	23APR96	36, -21	20	115	50	78	109	62	89	118.10	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00204	6	30APR96	43, -14	20	123	50	86	104	67	86	119.70	
	7	07MAY96	50, -7	20	122	63	93	122	59	98	120.10	
	8	14MAY96	57, 1	20	114	61	80	114	63	80	117.90	
	12	11JUN96	85, 29	20	115	62	93	108	67	102	119.90	
	16	09JUL96	113, 57	20	119	57	91	115	67	105	121.60	
	20	13AUG96	148, 92	20	118	57	86	120	68	101	123.00	
	24	10SEP96	176, 120	20	118	58	90	105	66	106	126.10 H	
	28	14OCT96	210, 154	20	120	57	74	126	55	91	129.00 H	
329.009.00235	SC	10DEC96	-8, -62	0	119	66	82	107	70	109	121.70	65.0
	BL	17DEC96	-1, -55	0	112	66	86	98	65	109	121.60	
	1	23DEC96	6, -49	20	111	67	80	116	66	82	123.60	
	2	30DEC96	13, -42	20	104	59	76	110	63	74	122.20	
	3	06JAN97	20, -35	20	122	63	95	112	54	135	121.50	
	4	15JAN97	29, -26	20	99	57	93	106	61	100	119.40	
	5	20JAN97	34, -21	20	138	91	102	121	55	125	120.20	
	6	27JAN97	41, -14	20	114	60	97	104	66	133	118.00	
	7	03FEB97	48, -7	20	107	57	81	112	58	105	119.80	
	8	10FEB97	55, 1	20	121	60	86	112	70	117	122.20	
	12	17MAR97	90, 36	20	130	65	106	120	77	109	123.30	
	16	14APR97	118, 64	20	145	82	86	135	78	115	121.50	
329.009.00240	SC	03JAN97	-11, .	0	120	84	85	124	82	91	168.00	67.7
	BL	10JAN97	-4, .	0	138	65	80	128	74	93	171.40	
	1	21JAN97	8, .	20	122	56	67	112	66	73	172.50	
	2	28JAN97	15, .	20	108	57	76	114	64	81	168.10	
	3	04FEB97	22, .	20	127	64	71	123	71	88	171.80	
	4	11FEB97	29, .	20	117	46	72	114	68	81	167.40	
	5	18FEB97	36, .	30	123	58	88	115	65	103	173.80	
	6	25FEB97	43, .	30	129	64	89	121	71	106	173.00	
	7	04MAR97	50, .	30	121	63	85	112	66	96	173.20	
329.009.00303	SC	25MAR96	-8, -64	0	116	66	59	123	71	54	166.20	71.0
	BL	02APR96	1, -56	0	108	59	68	122	58	76	166.90	
	1	09APR96	8, -49	20	116	56	62	121	45	65	166.20	
	2	16APR96	15, -42	20	122	57	61	121	60	64	165.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00303	3	23APR96	22, -35	20	123	57	62	120	48	66	165.00	
	4	30APR96	29, -28	20	130	58	61	125	51	59	165.60	
	5	07MAY96	36, -21	20	130	58	62	121	63	60	165.00	
	6	14MAY96	43, -14	20	115	50	62	123	61	64	167.00	
	7	22MAY96	51, -6	20	115	65	72	123	65	72	166.90	
	8	28MAY96	57, 1	20	107	49	49	107	46	56	164.90	
	12	25JUN96	85, 29	20	138	69	75	133	65	72	166.26	
	16	30JUL96	120, 64	20	109	47	62	116	59	68	170.67	
	20	27AUG96	148, 92	20	122	52	64	128	58	70	169.60	
	24	25SEP96	177, 121	20	122	59	68	121	67	68	169.30	
	32	30OCT96	212, 156	20	116	58	67	117	71	72	170.20	
	32	10DEC96	253, 197	20	127	60	67	118	60	76	172.80	
329.009.00304	SC	03APR96	-6, -62	0	122	56	73	131	65	70	201.00	67.0
	BL	09APR96	1, -56	0	118	59	80	121	52	82	200.80	
	1	16APR96	8, -49	20	138	60	72	139	57	73	199.90	
	2	23APR96	15, -42	20	138	59	74	145	63	86	195.90	
	3	30APR96	22, -35	20	140	70	90	145	83	102	198.10	
	4	07MAY96	29, -28	30	132	71	91	139	73	100	197.20	
	5	14MAY96	36, -21	30	137	60	100	139	74	102	195.20	
	6	21MAY96	43, -14	30	138	65	91	68 L	56	109	198.70	
	7	28MAY96	50, -7	30	137	64	69	120	59	79	200.70	
	8	04JUN96	57, 1	30	130	64	99	128	60	102	198.70	
	12	02JUL96	85, 29	30	131	64	70	120	67	75	202.20	
	16	30JUL96	113, 57	30	113	52	78	120	54	98	213.00	
	20	27AUG96	141, 85	30	129	61	88	142	61	96	207.20	
	24	23SEP96	168, 112	30	118	57	88	91	56	89	207.40	
	28	21OCT96	196, 140	30	140	54	70	139	60	73	210.30	
329.009.00324	SC	21OCT96	-7, .	0	126	59	88	116	62	98	127.70	61.0
	BL	28OCT96	1, .	0	130	64	82	131	75	85	126.30	
	1	04NOV96	8, .	20	116	69	78	115	55	86	125.10	
	2	11NOV96	15, .	20	114	66	86	127	66	83	126.50	
	3	18NOV96	22, .	20	114	64	77	106	67	80	123.40	
	4	25NOV96	29, .	20	119	59	89	77 L	55	94	124.80	
	5	02DEC96	36, .	20	115	65	85	107	73	100	127.30	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00324	6	09DEC96	43, .	20	114	72	85	106	57	86	124.90	
	7	16DEC96	50, .	20	122	73	88	108	61	84	123.20	
	8	27DEC96	61, .	20	115	62	86	132	68	89	124.00	
329.009.00328	SC	30SEP96	-7, .	0	123	67	70	112	85	79	85.30	59.5
	BL	07OCT96	1, .	0	111	68	71	112	76	86	86.60	
329.009.00329	SC	01OCT96	-8, .	0	108	62	59	101	67	65	122.30	66.1
	BL	09OCT96	1, .	0	119	56	64	128	62	88	121.60	
	1	16OCT96	8, .	20	123	58	57	122	60	67	120.70	
	2	23OCT96	15, .	20	126	57	66	125	64	71	120.30	
	3	29OCT96	21, .	20	123	57	54	129	71	58	123.50	
	4	05NOV96	28, .	20	124	65	73	114	63	97	119.10	
	5	12NOV96	35, .	20	107	58	50	107	64	62	121.70	
	6	19NOV96	42, .	30	130	64	64	133	63	80	122.20	
	7	26NOV96	49, .	30	114	61	54	115	61	66	120.50	
	8	03DEC96	56, .	30	115	58	62	121	60	66	120.90	
329.010.00182	SC	05DEC95	-14, .	0	.	.	.	.	.	.	137.50	71.0
	BL	19DEC95	1, .	0	110	80	68	112	87	84	140.50	
	3	12JAN96	25, .	20	118	72	72	122	82	84	135.50	
	4	19JAN96	32, .	20	118	75	66	124	70	74	130.00 L	
	SC	12DEC97	725, .#	0	118	70	82	118	75	94		
329.010.00278	SC	02FEB96	-7, -63	0	122	82	64	118	88	88	182.00	65.0
	BL	09FEB96	1, -56	0	127	78	.	118	70	118	184.50	
	1	16FEB96	8, -49	20	120	80	68	118	85	88	180.75	
	2	23FEB96	15, -42	20	124	78	60	118	70	88	181.00	
	3	01MAR96	22, -35	20	135	88	60	115	80	92	179.80	
	4	08MAR96	29, -28	20	118	83	68	120	88	96	179.50	
	5	15MAR96	36, -21	30	120	78	68	118	82	92	177.00	
	6	22MAR96	43, -14	40	110	78	62	104	72	72	179.50	
	7	29MAR96	50, -7	40	118	70	80	114	80	104	178.70	
	8	05APR96	57, 1	40	112	78	60	108	72	96	178.00	
	12	03MAY96	85, 29	40	123	58	72	115	72	85	182.00	
	16	31MAY96	113, 57	40	110	70	60	100	80	96	176.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.010.00278	20	27JUN96	140, 84	40	110	70	72	105	80	92	179.50	
	24	25JUL96	168, 112	40	105	80	72	100	75	88	178.00	
	28	22AUG96	196, 140	40	124	80	68	122	85	92	179.00	
	32	19SEP96	224, 168	40	100	65	76	100	70	96	181.50	
329.010.00280	SC	10MAY96	-7, -62	0	117	60	90	110	70	104	192.00	64.0
	BL	17MAY96	1, -55	0	117	60	90	110	70	104	192.00	
	1	24MAY96	8, -48	20	110	68	72	112	80	85	185.00	
	2	31MAY96	15, -41	20	112	80	76	108	60	98	182.00	
	3	07JUN96	22, -34	20	112	78	92	100	72	96	185.50	
	4	14JUN96	29, -27	20	100	70	80	110	78	98	186.00	
	5	21JUN96	36, -20	30	108	60	80	108	78	110	183.00	
	6	27JUN96	42, -14	40	100	70	80	100	80	84	185.00	
	7	03JUL96	48, -8	40	112	80	72	105	80	104	182.00	
	8	11JUL96	56, 1	40	105	70	80	120	80	88	183.00	
	12	21AUG96	97, 42#	0	.	76	78	110	80	92	193.00	
329.011.00283	SC	30JAN96	-9, -66	0	108	70	64	108	70	68	125.00	67.0
	1	14FEB96	7, -51	20	120	80	80	120	76	80	127.00	
	2	21FEB96	14, -44	20	110	76	60	108	76	62	124.70	
	3	29FEB96	22, -36	20	110	76	76	110	76	84	128.70	
	4	07MAR96	29, -29	20	108	70	76	108	70	76	128.20	
	5	15MAR96	37, -21	20	110	70	60	110	70	70	128.00	
	6	22MAR96	44, -14	20	110	60	76	104	60	70	127.20	
	7	28MAR96	50, -8	20	120	80	60	120	80	72	129.50	
	8	04APR96	57, -1	20	110	70	70	110	70	70	129.50	
329.011.00288	SC	01JUL96	-24, .	0	110	70	84	106	70	88	105.50	65.2
	BL	18JUL96	-7, .	0	110	68	88	110	70	96	105.50	
	1	01AUG96	8, .	20	110	56	70	106	60	76	103.20	
	2	09AUG96	16, .	20	110	60	80	100	60	80	103.00	
	4	19AUG96	26, .	20	104	70	80	100	70	90	104.20	
	5	29AUG96	36, .	20	100	70	80	104	70	80	103.20	
329.012.00025	SC	17OCT95	-7, .	0	114	80	82	118	80	92	114.66	65.0
	BL	24OCT95	1, .	0	110	74	72	114	80	76	114.66	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.012.00025	1	31OCT95	8, .	20	110	70	94	110	74	100	114.88	
	2	07NOV95	15, .	20	108	90	72	110	92	80	115.10	
	3	14NOV95	22, .	20	100	70	76	90	68	76	114.66	
	4	21NOV95	29, .	20	100	76	70	96	64	74	114.88	
	5	28NOV95	36, .	30	90	60	96	100	70	96	113.56	
	6	05DEC95	43, .	40	98	78	92	102	80	100	113.56	
	7	12DEC95	50, .	40	113	69	74	113	60	85	114.44	
	8	19DEC95	57, .	40	100	62	80	110	70	100	113.34	
329.012.00220	SC	04JUN96	-13, -73	0	122	82	76	128	90	80	179.93	66.9
	BL	14JUN96	-3, -63	0	110	80	60	110	70	68	179.49	
	1	22JUN96	6, -55	20	112	76	60	110	80	68	182.13	
	2	28JUN96	12, -49	20	120	80	68	124	84	64	183.24	
	3	05JUL96	19, -42	20	114	80	60	116	78	68	184.34	
	4	12JUL96	26, -35	30	110	74	68	120	70	84	186.32	
	5	19JUL96	33, -28	30	112	70	70	118	72	72	186.54	
	6	29JUL96	43, -18	30	118	78	82	114	74	80	186.54	
	7	06AUG96	51, -10	30	126	90	64	128	88	80	186.32	
	8	16AUG96	61, 1	30	120	80	80	130	90	86	185.22	
	12	13SEP96	89, 29	30	120	70	68	120	80	80	182.79	
	16	11OCT96	117, 57	30	120	82	84	122	84	100	180.37	
	20	08NOV96	145, 85	30	120	80	68	120	72	70	183.02	
	24	06DEC96	173, 113	0	120	80	76	120	70	82	184.12	
329.012.00222	SC	18JUN96	-10, -73	0	100	66	60	100	70	80	119.51	66.1
	BL	28JUN96	1, -63	0	110	70	80	112	76	72	121.05	
	1	05JUL96	8, -56	20	100	68	62	112	70	70	119.95	
	2	12JUL96	15, -49	20	110	70	72	110	62	68	119.07	
	3	19JUL96	22, -42	20	110	62	68	110	70	72	119.29	
	4	29JUL96	32, -32	20	114	70	64	110	68	62	119.51	
	6	06AUG96	40, -24	30	110	70	68	110	74	60	118.63	
	7	13AUG96	47, -17	30	108	76	82	100	80	80	119.51	
	8	20AUG96	54, -10	30	100	70	70	110	70	76	119.95	
	8	30AUG96	64, 1	30	130	78	68	122	74	70	119.51	
	12	27SEP96	92, 29	30	110	80	80	116	76	70	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PAROXETINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.012.00226	SC	26NOV96	-7, .	0	110	70	100	112	80	110	176.40	73.2
	BL	03DEC96	1, .	0	120	82	76	122	80	84	174.20	
	1	10DEC96	8, .	20	132	80	78	128	76	80	174.20	
	2	20DEC96	18, .	20	112	70	86	118	76	100	175.30	
329.012.00228	SC	04MAR97	-15, .	0	90	66	68	100	70	70	108.05	63.4
	BL	19MAR97	1, .	0	110	70	82	100	70	90	109.15	
	1	27MAR97	9, .	20	100	70	66	100	72	70	109.15	
329.012.00231	SC	26FEB97	-9, -70	0	110	70	68	112	80	72	156.56	63.4
	BL	07MAR97	1, -61	0	120	70	82	128	80	90	155.45	
	1	17MAR97	11, -51	20	110	80	60	120	80	72	157.88	
	2	24MAR97	18, -44	20	118	84	76	108	76	88	158.10	
	4	02APR97	27, -35	20	110	90	80	120	80	90	161.63	
	5	09APR97	34, -28	20	116	80	76	120	82	80	159.64	
	6	17APR97	42, -20	20	122	80	80	126	90	86	161.19	
	7	25APR97	50, -12	30	126	70	67	122	74	68	161.41	
	8	01MAY97	56, -6	30	116	76	74	114	78	78	162.95	
	8	07MAY97	62, 1	30	110	70	64	106	74	62	166.26	
	12	04JUN97	90, 29	30	120	80	72	120	86	72	166.92 H	
	16	30JUN97	116, 55	30	110	70	80	118	84	84	173.31 H	
	20	05AUG97	152, 91	20	128	80	80	120	80	80	176.18 H	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.001.00061	SC	19JUL94	-10, .	0	104	60	76	106	64	76	145.00	61.0
	BL	29JUL94	1, .	0	102	58	72	108	64	72	146.00	
	1	04AUG94	7, .	100	94	62	92	100	70	104	143.00	
	2	11AUG94	14, .	150	104	64	102	96	64	124 H	145.80	
	3	18AUG94	21, .	200	100	62	102	102	64	108	147.80	
	4	25AUG94	28, .	200	108	74	96	102	70	102	147.80	
	5	01SEP94	35, .	200	100	68	100	98	62	112	149.50	
329.001.00066	SC	14NOV94	-8, .	0	104	60	62	110	68	100	142.00	68.0
	BL	21NOV94	-1, .	0	98	60	68	92	70	80	142.00	
	1	28NOV94	7, .	100	114	74	100	100	70	120	135.00	
	2	05DEC94	14, .	100	120	68	96	118	78	124 H	140.50	
329.001.00067	SC	15NOV94	-7, .	0	108	60	78	110	60	96	105.50	64.5
	BL	22NOV94	1, .	0	100	64	64	88	60	88	106.00	
	1	29NOV94	8, .	100	112	76	88	118	84	92	105.00	
	2	06DEC94	15, .	100	96	70	92	92	68	118	105.50	
329.001.00070	SC	14FEB95	-8, .	0	108	70	76	112	74	88	76.00	58.0
	BL	22FEB95	1, .	0	104	70	82	110	70	92	76.00	
	1	28FEB95	7, .	100	100	60	100	98	60	120	76.00	
	2	08MAR95	15, .	150	98	60	100	100	70	108	74.00	
	3	15MAR95	22, .	150	100	60	102	92	62	118	74.00	
329.001.00122	SC	13JUN95	-7, -64	0	120	72	68	112	70	78	166.00	68.5
	BL	20JUN95	1, -57	0	110	60	64	102	70	74	166.00	
	1	27JUN95	8, -50	100	110	78	76	110	60	80	163.50	
	2	05JUL95	16, -42	150	102	70	80	110	70	104	164.00	
	3	11JUL95	22, -36	200	114	80	90	106	84	98	165.00	
	4	18JUL95	29, -29	200	110	74	88	120	80	108	164.00	
	5	25JUL95	36, -22	200	110	74	90	114	80	102	164.00	
	6	01AUG95	43, -15	200	120	80	78	112	86	96	166.00	
	7	08AUG95	50, -8	200	116	80	84	110	82	92	168.20	
	8	16AUG95	58, 1	200	120	76	96	120	80	98	171.00	
	12	12SEP95	85, 28	200	118	70	96	116	80	104	171.00	
	16	10OCT95	113, 56	200	110	80	82	108	76	84	171.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.001.00122	20	07NOV95	141, 84	200	120	70	88	112	80	112	179.00 H	
	24	05DEC95	169, 112	200	120	80	94	114	80	106	180.50 H	
329.002.00050	SC	10MAR95	-13, .	0	140	74	70	149	82	76	152.15	67.5
	BL	22MAR95	-1, .	0	135	75	88	135	75	96	154.00	
	1	29MAR95	7, .	50	115	70	92	115	70	104	154.00	
	2	05APR95	14, .	100	139	69	94	123	73	111	154.00	
	3	12APR95	21, .	150	120	80	104	120	85	112	153.00	
	5	28APR95	37, .	150	139	68	95	122	76	102	155.67	
329.002.00056	SC	24JUN94	-25, .	0	90	52	84	80	50	108	111.00	59.4
	BL	19JUL94	1, .	0	82	40	100	84	44	102	113.00	
	1	26JUL94	8, .	100	84	58	100	84	56	120	110.00	
	2	02AUG94	15, .	150	90	50	108	72	40	112	109.00	
	3	09AUG94	22, .	200	92	60	132 H	90	60	104	110.00	
	4	16AUG94	29, .	200	84	52	120	78	42	140 H	112.50	
329.002.00057	SC	11AUG94	-28, -85	0	98	62	72	88	60	88	162.50	66.5
	BL	08SEP94	1, -57	0	99	62	73	92	61	89	163.00	
	1	15SEP94	8, -50	100	90	60	88	84	60	84	160.50	
	2	22SEP94	15, -43	150	102	70	102	94	60	140 H	158.00	
	3	29SEP94	22, -36	200	90	60	100	94	60	100	158.00	
	4	06OCT94	29, -29	250	112	68	96	110	66	100	157.00	
	5	13OCT94	36, -22	300	104	60	100	88	50	102	159.50	
	6	20OCT94	43, -15	300	100	62	100	98	60	104	159.00	
	7	27OCT94	50, -8	300	102	64	100	94	62	102	160.00	
	8	03NOV94	57, -1	300	90	60	120	80	58	140 H	160.00	
	12	01DEC94	85, 28	300	110	60	100	90	60	128 H	163.00	
	16	29DEC94	113, 56	300	104	64	100	102	60	120	157.00	
329.002.00098	SC	20DEC94	-14, .	0	98	58	88	96	58	92	127.50	61.0
	BL	03JAN95	1, .	0	98	58	88	96	58	92	127.50	
	1	10JAN95	8, .	100	100	58	84	95	60	104	127.00	
	2	18JAN95	16, .	150	118	68	84	110	68	88	126.00	
	3	24JAN95	22, .	200	108	66	84	100	64	86	126.00	
	4	31JAN95	29, .	250	110	72	100	106	72	104	127.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00098	5	07FEB95	36, .	300	116	78	74	106	74	80	128.00	
	6	14FEB95	43, .	250	118	78	108	116	78	112	127.00	
	7	21FEB95	50, .	250	118	70	70	120	72	76	127.00	
	8	02MAR95	59, .	250	102	64	100	102	68	100	127.00	
329.002.00100	BL	07MAR95	1, -58	0	130	70	96	132	70	98	144.00	
	1	14MAR95	8, -51	100	116	70	78	112	70	90	145.00	
	2	21MAR95	15, -44	150	120	80	90	118	80	96	148.00	
	3	28MAR95	22, -37	200	120	80	80	114	80	80	146.25	
	4	04APR95	29, -30	200	116	78	110	120	78	112	147.25	
	5	11APR95	36, -23	250	110	80	84	114	80	86	145.25	
	6	18APR95	43, -16	250	118	80	100	112	80	114	147.75	
	7	25APR95	50, -9	250	110	62	98	108	62	100	147.50	
	8	04MAY95	59, 1	250	108	78	90	100	76	98	148.75	
	12	30MAY95	85, 27	250	126	80	100	108	80	112	146.50	
	16	27JUN95	113, 55#	0	112	80	100	118	80	116	145.25	
329.002.00103	SC	11APR95	-9, -65	0	110	64	65	110	64	66	116.50	60.0
	BL	20APR95	1, -56	0	94	62	68	90	62	68	115.00	
	1	27APR95	8, -49	100	92	62	70	90	60	68	114.00	
	2	02MAY95	13, -44	150	100	70	70	100	70	72	117.25	
	3	09MAY95	20, -37	200	102	70	100	102	70	92	114.25	
	4	16MAY95	27, -30	200	112	80	80	112	76	80	116.50	
	5	25MAY95	36, -21	200	98	68	60	90	64	74	115.00	
	6	30MAY95	41, -16	250	102	70	80	98	70	100	115.00	
	7	06JUN95	48, -9	250	100	66	88	96	60	84	111.25	
	8	15JUN95	57, 1	250	94	68	72	80	64	70	110.50	
	12	13JUL95	85, 29	250	102	70	88	96	68	80	112.00	
	16	10AUG95	113, 57	250	100	68	90	100	64	84	114.00	
329.002.00104	SC	28APR95	-6, -62	0	100	60	94	98	58	90	128.50	67.0
	1	11MAY95	8, -49	100	120	68	80	118	66	84	127.70	
	2	18MAY95	15, -42	150	106	74	76	100	70	80	130.50	
	3	25MAY95	22, -35	200	110	76	81	100	70	74	130.00	
	4	01JUN95	29, -28	250	122	80	92	120	72	100	126.00	
	5	09JUN95	37, -20	300	90	60	88	102	64	80	128.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00104	6	16JUN95	44, -13	300	90	66	80	82	64	74	129.00	
	7	22JUN95	50, -7	300	88	60	90	80	60	100	128.20	
	8	29JUN95	57, 1	300	122	76	100	100	70	68	130.00	
	12	25JUL95	83, 27	300	110	70	109	90	64	94	130.00	
	16	29AUG95	118, 62	300	102	76	90	96	60	130 H	128.00	
	20	03OCT95	153, 97	300	94	68	84	80	68	78	131.00	
	28	06NOV95	187, 131	300	108	70	106	112	72	80	129.50	
	32	06DEC95	217, 161	300	120	72	100	110	74	84	130.50	
	32	02JAN96	244, 188	250	110	60	100	108	60	92	127.50	
329.002.00243	SC	27FEB96	-16, .	0	94	64	68	92	60	64	112.50	62.0
	1	21MAR96	8, .	100	98	66	66	98	64	68	111.00	
	2	28MAR96	15, .	150	90	60	78	88	60	64	111.00	
	3	04APR96	22, .	150	90	62	74	88	64	76	113.00	
329.002.00244	SC	14MAR96	-7, -64	0	122	72	84	120	70	80	141.00	63.0
	BL	21MAR96	1, -57	0	110	66	80	112	70	98	143.00	
	1	28MAR96	8, -50	100	120	78	78	118	70	70	142.00	
	2	04APR96	15, -43	150	122	74	89	120	76	82	143.00	
	3	11APR96	22, -36	200	112	70	99	110	72	110	143.00	
	4	18APR96	29, -29	250	106	74	106	100	72	100	144.00	
	5	25APR96	36, -22	200	110	64	75	108	68	80	145.00	
	6	02MAY96	43, -15	250	120	70	84	116	70	86	144.00	
	7	09MAY96	50, -8	300	110	70	94	112	70	88	144.50	
	8	16MAY96	57, -1	300	104	68	106	92	70	104	144.20	
329.002.00321	BL	23MAY96	1, .	0	96	64	64	100	70	66	112.00	65.0
	1	30MAY96	8, .	50	88	64	66	88	64	80	114.00	
329.002.00322	SC	06JAN97	-3, .	0	120	84	80	120	80	86	136.00	68.5
	1	16JAN97	8, .	100	120	68	108	114	68	130 H	136.00	
	2	23JAN97	15, .	150	120	76	80	110	70	84	135.00	
	3	30JAN97	22, .	200	90	70	86	88 L	70	82	132.00	
	4	04FEB97	27, .	200	112	68	80	108	70	74	134.00	
	5	13FEB97	36, .	200	125	70	110	100	90	132 H	132.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00073	SC	11JAN95	-8, .	0	110	72	86	112	72	88	138.92	63.8
	BL	18JAN95	-1, .	0	100	70	82	90	68	87	140.00	
	1	25JAN95	7, .	100	110	68	100	100	70	120	136.70	
	2	03FEB95	16, .	150	114	74	92	96	70	120	135.61	
	3	07FEB95	20, .	200	114	72	120	96	78	132 H	136.27	
	4	14FEB95	27, .	200	112	78	92	102	66	120	134.73	
	5	22FEB95	35, .	250	116	82	116	114	90	130 H	135.61	
	6	01MAR95	42, .	250	128	72	114	116	68	128 H	134.73	
	7	08MAR95	49, .	250	100	76	120	104	80	140 H	128.11 L	
329.003.00076	SC	24JAN95	-7, -62	0	126	66	80	132	66	86	200.66	65.4
	BL	31JAN95	1, -55	0	114	76	76	110	72	80	197.70	
	1	07FEB95	8, -48	100	118	82	100	120	78	118	201.76	
	2	14FEB95	15, -41	150	126	80	88	130	78	112	198.01	
	3	21FEB95	22, -34	200	110	78	117	104	70	112	200.66	
	4	27FEB95	28, -28	200	128	68	112	120	80	118	201.76	
	5	06MAR95	35, -21	200	128	76	102	124	80	112	202.20	
	6	13MAR95	42, -14	200	130	66	96	132	82	108	203.52	
	7	20MAR95	49, -7	200	112	84	96	110	80	112	206.17	
	8	27MAR95	56, 1	200	124	80	112	130	82	120	206.17	
	12	03MAY95	93, 38	200	116	60	86	114	66	100	205.07	
	16	31MAY95	121, 66	200	114	60	92	104	68	112	205.07	
	20	28JUN95	149, 94	200	102	60	110	104	68	122 H	209.92	
	28	02AUG95	184, 129	200	124	70	100	120	76	104	206.39	
	32	06SEP95	219, 164	200	122	68	120	120	74	120	209.25	
	32	11OCT95	254, 199	0	120	52	100	130	64	108	218.30 H	
329.003.00079	BL	03MAY95	1, .	0	112	78	64	100	70	84	152.15	68.1
	1	10MAY95	8, .	100	110	74	78	100	80	86	150.38	
	2	19MAY95	17, .	150	124	74	90	112	80	112	149.28	
329.003.00082	SC	11DEC95	1, .	0	108	66	56	110	67	93	120.00	63.5
	2	28DEC95	18, .	100	100	65	70	110	70	90	118.50	
	3	03JAN96	24, .	150	116	60	88	104	58	118	119.07	
	4	11JAN96	32, .	200	132	63	93	121	55	89	120.25	
	5	17JAN96	38, .	250	124	80	92	114	74	116	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00088	SC	06FEB95	-22, .	0	.	.	.	110	62	84	109.00	52.3
	BL	28FEB95	1, .	0	90	60	80	90	60	80	113.00	
	1	09MAR95	10, .	100	90	60	96	90	60	96	111.00	
	2	14MAR95	15, .	100	96	56	100	96	56	100	111.00	
	3	21MAR95	22, .	200	90	60	96	90	60	96	112.00	
	4	30MAR95	31, .	200	80	50	96	80	50	96	111.00	
	5	04APR95	36, .	200	82	50	96	82	50	96	110.00	
	6	11APR95	43, .	200	84	58	96	84	58	96	109.00	
329.003.00090	SC	08MAR95	-6, .	0	100	60	70	100	60	72	137.00	64.0
	BL	14MAR95	1, .	0	70	44	80	70	44	80	140.00	
	2	28MAR95	15, .	100	96	60	84	96	60	84	139.00	
	3	04APR95	22, .	150	100	60	80	100	60	80	138.00	
	4	11APR95	29, .	200	96	60	84	90	60	84	140.00	
	5	18APR95	36, .	200	96	60	84	80	60	84	137.50	
	6	25APR95	43, .	200	90	60	84	90	60	84	139.50	
	7	02MAY95	50, .	200	100	60	88	100	60	88	138.00	
	8	09MAY95	57, .	200	96	56	84	96	56	84	139.00	
	8	16MAY95	64, .	150	92	58	96	92	58	96	140.00	
329.003.00092	SC	13APR95	-20, -78	0	104	60	68	104	62	72	99.00	60.5
	BL	02MAY95	-1, -59	0	94	56	72	94	56	72	102.00	
	1	11MAY95	9, -50	50	88	56	76	88	56	76	101.00	
	2	16MAY95	14, -45	100	90	60	96	90	60	96	101.50	
	3	26MAY95	24, -35	200	90	60	88	90	60	88	99.50	
	4	02JUN95	31, -28	200	90	64	96	90	64	96	99.50	
	5	06JUN95	35, -24	200	100	60	88	.	.	.	100.00	
	6	13JUN95	42, -17	200	106	66	88	106	66	88	98.50	
	7	20JUN95	49, -10	200	100	60	84	100	60	84	99.00	
	8	30JUN95	59, 1	200	100	60	84	100	60	84	99.50	
	12	08AUG95	98, 40	200	96	62	84	90	62	84	97.00	
	16	05SEP95	126, 68	200	92	66	84	90	66	84	98.00	
	20	26SEP95	147, 89	200	96	62	96	90	60	96	101.00	
	28	07NOV95	189, 131	200	90	58	88	90	58	88	98.00	
	32	05DEC95	217, 159	200	90	60	84	90	60	84	103.00	
	32	02JAN96	245, 187	200	100	60	84	100	60	84	102.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00093	SC	08JUN95	-13, -76	0	106	70	64	110	70	70	127.00	61.5
	BL	20JUN95	-1, -64	0	90	60	84	90	60	84	125.00	
	1	27JUN95	7, -57	100	90	60	84	90	60	84	122.50	
	2	06JUL95	16, -48	100	90	60	84	90	60	84	125.00	
	4	21JUL95	31, -33	150	86	60	84	80	60	84	125.00	
	5	25JUL95	35, -29	200	92	56	88	90	56	88	125.00	
	6	01AUG95	42, -22	250	84	54	100	86	54	100	126.00	
	7	10AUG95	51, -13	300	86	54	96	80	54	96	126.00	
	8	22AUG95	63, -1	300	90	60	88	86	60	88	126.00	
	16	03OCT95	105, 42#	0	90	60	80	90	60	80	128.00	
329.003.00247	SC	05JAN96	-27, -81	0	90	62	.	.	.	.	132.00	70.5
	BL	30JAN96	-2, -56	0	100	60	72	100	60	72	130.00	
	1	06FEB96	6, -49	50	100	60	72	100	60	72	130.00	
	2	13FEB96	13, -42	150	96	60	84	80	56	84	131.00	
	3	20FEB96	20, -35	150	98	56	88	100	56	88	131.00	
	4	27FEB96	27, -28	200	96	68	112	90	64	112	130.00	
	5	07MAR96	36, -19	200	102	60	96	102	60	96	135.00	
	6	12MAR96	41, -14	200	96	62	96	96	60	96	132.00	
	7	21MAR96	50, -5	200	94	60	96	94	60	96	132.00	
	8	26MAR96	55, 1	200	90	60	84	90	60	84	131.00	
	12	30APR96	90, 36	200	100	60	84	96	60	88	135.00	
	16	21MAY96	111, 57	200	90	60	96	90	60	96	131.00	
329.003.00249	SC	01MAR96	-6, .	0	90	60	78	90	58	76	176.00	63.3
	BL	07MAR96	1, .	0	86	60	88	86	60	88	176.00	
	1	12MAR96	6, .	100	90	60	84	90	60	84	176.00	
	2	19MAR96	13, .	150	100	70	96	100	70	96	177.00	
	3	26MAR96	20, .	200	92	56	84	90	56	84	175.00	
	4	02APR96	27, .	250	100	60	84	90	60	88	176.00	
	5	09APR96	34, .	300	106	70	84	100	66	84	178.00	
	6	16APR96	41, .	300	106	72	96	100	66	96	180.00	
	7	23APR96	48, .	300	98	78	88	90	74	88	176.00	
	8	30APR96	55, .	250	100	70	96	96	70	96	177.00	
329.003.00289	SC	12FEB96	-16, -72	0	110	56	76	104	62	76	118.63	63.0

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00289	1	06MAR96	8, -49	100	114	82	84	102	72	84	119.07	
	2	13MAR96	15, -42	150	94	70	108	88	68	120	118.41	
	3	20MAR96	22, -35	200	102	70	96	98	70	112	117.53	
	4	27MAR96	29, -28	200	104	70	94	94	76	112	114.66	
	5	03APR96	36, -21	200	94	64	96	84	66	112	113.12	
	6	10APR96	43, -14	200	98	70	82	86	66	96	114.66	
	7	17APR96	50, -7	200	100	66	98	92	62	112	116.87	
	8	24APR96	57, 1	200	106	74	84	98	68	82	118.41	
	12	22MAY96	85, 29	200	104	74	102	90	70	108	113.78	
	16	20JUN96	114, 58	200	90	62	92	84	64	100	115.10	
	20	19JUL96	143, 87	200	99	65	86	93	66	90	105.80 L	
	24	16AUG96	171, 115	200	80 L	60	100	84	60	104	102.09 L	
	28	13SEP96	199, 143	200	92	58	80	82	64	90	106.06 L	
	32	11OCT96	227, 171	150	88	60	68	86	64	70	108.93 L	
329.003.00290	SC	06MAR96	-5, .	0	122	70	90	128	72	112	176.18	66.1
	1	20MAR96	10, .	100	150	76	112	160	86	124	175.08	
	2	22MAR96	12, .	100	136	70	104	160	88	118		
329.003.00314	SC	15OCT96	-7, .	0	100	60	70	.	.	.	145.00	65.5
	BL	22OCT96	1, .	0	106	64	84	106	64	84	148.00	
	1	29OCT96	8, .	100	90	60	96	90	60	96	147.00	
	2	05NOV96	15, .	150	100	60	96	100	60	96	147.00	
	3	14NOV96	24, .	200	104	64	84	104	64	84	151.00	
	5	26NOV96	36, .	200	110	70	84	110	70	84	150.00	
	6	03DEC96	43, .	200	106	70	96	100	70	96	152.00	
	7	10DEC96	50, .	200	112	74	84	112	74	84	152.00	
	8	17DEC96	57, .	200	110	76	84	110	76	84	153.00	
	8	23DEC96	63, .	250	110	60	80	105	60	80	150.00	
329.003.00317	SC	12DEC96	-7, .	0	110	70	80	108	64	88	120.00	62.3
	BL	17DEC96	-2, .	0	110	70	96	110	70	96	122.00	
	1	23DEC96	5, .	50	90	60	96	90	60	110	119.00	
	3	07JAN97	20, .	150	115	80	88	115	70	96	118.50	
	4	14JAN97	27, .	200	110	80	96	100	80	96	118.00	
	5	21JAN97	34, .	200	110	80	88	100	80	88	118.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00317	6	28JAN97	41, .	250	110	80	92	100	80	92	118.00	
	7	04FEB97	48, .	300	110	74	84	110	74	84	118.00	
	8	11FEB97	55, .	250	120	70	84	120	70	84	116.00	
329.004.00013	SC	05JUL94	-14, -73	0	90	60	78	100	60	84	132.30	68.5
	BL	19JUL94	1, -59	0	108	70	60	104	70	64	131.86	
	1	26JUL94	8, -52	100	104	56	84	104	58	88	133.62	
	2	02AUG94	15, -45	150	104	78	74	96	76	88	132.30	
	3	09AUG94	22, -38	200	110	84	80	108	80	96	134.06	
	4	15AUG94	28, -32	200	115	80	78	100	75	100	136.71	
	5	23AUG94	36, -24	200	112	82	88	112	80	116	136.93	
	6	31AUG94	44, -16	200	120	82	92	100	72	104	136.71	
	7	08SEP94	52, -8	200	100	80	100	98	80	100	136.27	
	8	16SEP94	60, 1	200	102	82	92	104	82	108	138.92	
	12	11OCT94	85, 26	200	114	82	84	112	80	96	141.12 H	
	16	08NOV94	113, 54	250	110	80	90	120	90	100	144.43 H	
	20	06DEC94	141, 82	250	110	80	80	110	80	88	148.84 H	
	24	10JAN95	176, 117	250	110	70	80	110	70	100	151.04 H	
	28	07FEB95	204, 145	250	112	84	88	110	82	96	153.25 H	
	32	10MAR95	235, 176	200	112	84	92	116	86	92	153.03 H	
329.004.00014	SC	22NOV94	-7, .	0	100	68	70	110	80	80	145.31	72.8
	BL	29NOV94	1, .	0	100	60	78	100	60	80	147.51	
	1	05DEC94	7, .	100	130	70	84	120	70	88	142.44	
	2	13DEC94	15, .	100	100	60	80	100	70	88	138.03	
329.004.00211	SC	24JAN96	-9, .	0	80	60	60	90	60	68	102.53	63.0
	BL	01FEB96	-1, .	0	100	60	64	100	60	72	102.53	
	1	08FEB96	7, .	50	100	60	60	100	60	70	100.33	
	2	16FEB96	15, .	150	100	70	78	90	70	80	102.53	
	3	23FEB96	22, .	200	100	70	70	100	70	74	101.87	
	4	29FEB96	28, .	200	100	72	80	100	70	80	103.64	
	5	07MAR96	35, .	200	100	60	78	110	80	88	104.96	
	6	14MAR96	42, .	200	90	60	70	100	60	90	104.08	
	7	25MAR96	53, .	200	90	60	80	90	60	84	98.12	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.004.00215	SC	12MAR97	-8, .	0	98	64	60	98	70	64	103.19	58.3
	BL	20MAR97	1, .	0	98	50	76	98	45	76	102.31	
	1	27MAR97	8, .	100	105	60	84	100	60	88	99.23	
	2	03APR97	15, .	150	100	65	92	95	50	100	99.23	
	3	10APR97	22, .	200	100	60	100	95	50	108	98.78	
	4	15APR97	27, .	200	110	70	104	98	65	112	98.12	
	5	24APR97	36, .	200	108	70	104	100	68	108	99.89	
	6	29APR97	41, .	200	108	65	96	104	70	104	97.68	
329.005.00003	SC	12SEP94	-8, .	0	106	70	80	108	70	84	116.50	60.0
	BL	20SEP94	1, .	0	110	78	82	110	80	90	116.70	
	1	27SEP94	8, .	100	112	72	106	102	80	116	114.60	
	2	04OCT94	15, .	100	106	70	106	102	70	110	112.20	
329.005.00006	SC	27OCT94	-8, -68	0	110	70	72	108	68	72	145.00	68.0
	BL	03NOV94	-1, -61	0	100	70	60	90	70	62	141.90	
	1	14NOV94	11, -50	100	110	70	76	100	68	78	141.00	
	2	21NOV94	18, -43	150	110	70	64	100	70	64	141.00	
	3	28NOV94	25, -36	200	118	74	76	110	70	76	140.24	
	4	05DEC94	32, -29	250	100	60	70	90	60	72	142.00	
	5	12DEC94	39, -22	300	110	60	64	110	70	68	141.50	
	6	19DEC94	46, -15	300	100	64	80	90	60	94	139.00	
	8	27DEC94	54, -7	300	106	68	92	94	70	104	138.92	
	8	03JAN95	61, 1	300	104	70	90	90	60	94	139.14	
	12	02FEB95	91, 31	300	108	70	88	110	60	92	140.00	
	16	27FEB95	116, 56	300	104	70	84	100	70	88	145.31	
	20	05APR95	153, 93	300	120	70	92	104	70	96	147.00	
329.005.00007	SC	02NOV94	-7, -70	0	110	70	64	104	68	74	135.00	64.0
	BL	09NOV94	1, -63	0	110	70	74	100	70	72	132.30	
	2	23NOV94	15, -49	100	110	70	72	100	68	72	132.95	
	3	30NOV94	22, -42	150	100	70	74	94	68	74	132.52	
	4	07DEC94	29, -35	200	100	68	90	90	60	92	129.00	
	5	14DEC94	36, -28	250	110	80	80	94	70	80	127.80	
	6	21DEC94	43, -21	300	114	70	100	88	64	100	128.20	
	7	28DEC94	50, -14	250	110	80	100	100	70	104	129.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00007	8	04JAN95	57, -7	250	100	70	104	104	68	108	128.00	
	8	11JAN95	64, 1	250	104	74	86	90	70	92	128.10	
	12	15FEB95	99, 36	250	120	80	104	110	80	108	126.00	
	20	22MAR95	134, 71	250	120	70	80	98	60	88		
	24	19APR95	162, 99	250	104	70	100	100	60	104	127.00	
	28	17MAY95	190, 127	250	104	70	100	90	60	104	129.00	
	32	09AUG95	274, 211#	0	104	74	92	100	70	98	129.50	
329.005.00009	SC	07DEC94	-5, .	0	110	70	76	104	70	80	146.00	63.0
	BL	12DEC94	1, .	0	100	70	80	100	60	88	145.00	
	1	19DEC94	8, .	100	110	70	84	116	70	96	143.00	
	2	27DEC94	16, .	150	110	70	100	100	70	100	143.00	
	3	03JAN95	23, .	200	110	70	92	104	74	92	143.00	
	4	11JAN95	31, .	250	110	70	90	94	60	94	145.00	
	5	18JAN95	38, .	300	108	62	80	100	62	100	144.65	
	6	25JAN95	45, .	250	100	70	84	94	70	88	144.43	
	7	31JAN95	51, .	250	110	80	80	100	80	80	144.21	
	8	07FEB95	58, .	250	100	88	96	94	70	104	145.00	
329.005.00110	SC	04JAN95	-7, .	0	98	54	80	106	66	88	124.36	67.0
	BL	11JAN95	1, .	0	100	70	72	100	60	80	123.00	
	1	18JAN95	8, .	100	110	72	70	98	64	90	120.00	
	2	25JAN95	15, .	100	110	70	74	100	70	78	122.00	
329.005.00113	SC	20JAN95	-10, .	0	110	70	68	100	70	72	145.00	67.0
	BL	30JAN95	1, .	0	90	60	80	100	70	84	143.33	
	1	08FEB95	10, .	100	110	70	72	100	60	74	145.20	
	2	16FEB95	18, .	150	104	70	88	104	68	100	141.34	
	3	23FEB95	25, .	200	110	70	72	100	70	80	140.00	
	4	02MAR95	32, .	200	100	70	80	84	60	80	140.00	
329.005.00117	SC	06MAR95	-12, .	0	120	84	82	116	80	86	245.64	52.0
	BL	16MAR95	-2, .	0	124	84	84	100	80	88	246.96	
	1	27MAR95	10, .	100	108	80	98	122	90	98	245.86	
	2	03APR95	17, .	150	114	68	98	118	70	108	249.20	
	3	10APR95	24, .	200	120	70	102	110	70	110	248.40	

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\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00117	4	17APR95	31, .	200	110	70	100	114	70	108	246.50	
	5	24APR95	38, .	200	100	58	96	98	50	104	246.20	
	6	01MAY95	45, .	200	114	68	98	120	76	108	243.87	
	7	08MAY95	52, .	200	100	72	92	90	60	106	239.46	
	8	15MAY95	59, .	200	98	68	90	90	60	96	237.26	
329.005.00118	SC	09MAY95	-8, .	0	116	70	64	112	72	70	151.00	65.0
	BL	17MAY95	1, .	0	110	68	60	108	70	66	151.90	
	1	24MAY95	8, .	100	100	70	80	98	64	84	152.20	
	2	30MAY95	14, .	150	116	70	86	108	70	96	152.59	
	3	06JUN95	21, .	200	108	74	98	98	60	98	151.92	
	4	14JUN95	29, .	250	114	78	84	116	80	94	153.47	
	5	20JUN95	35, .	300	110	70	94	98	64	110	154.00	
	6	27JUN95	42, .	250	112	76	98	104	70	108	153.00	
329.005.00153	BL	25JAN96	1, -56	0	110	62	72	102	64	80	174.20	
	1	01FEB96	8, -49	100	102	64	96	96	60	104	171.99	
	2	08FEB96	15, -42	150	98	70	104	90	68	108	172.65	
	3	15FEB96	22, -35	200	102	70	108	96	72	112	174.64	
	4	22FEB96	29, -28	250	98	74	112	92	74	116	176.40	
	5	29FEB96	36, -21	250	110	72	104	100	68	112	179.71	
	6	06MAR96	42, -15	250	120	82	96	122	80	116	179.93	
	7	14MAR96	50, -7	250	116	70	104	114	70	112	179.93	
	8	21MAR96	57, 1	250	108	72	84	100	72	104	180.59	
	12	17APR96	84, 28	300	106	66	100	100	68	108	184.12	
	16	15MAY96	112, 56	300	116	76	96	108	72	104	188.50 H	
	20	12JUN96	140, 84	300	120	80	100	116	74	108	187.20 H	
	24	10JUL96	168, 112	300	102	72	108	96	70	112	193.00 H	
	28	05AUG96	194, 138	300	106	78	100	96	78	104	191.20 H	
	32	04SEP96	224, 168	250	114	72	108	114	70	112		
329.005.00255	SC	26FEB96	-7, .	0	120	80	60	120	78	76	150.20	69.0
	BL	04MAR96	1, .	0	100	60	86	90	50	82	149.30	
	1	11MAR96	8, .	100	110	78	86	100	70	96	151.00	
	2	18MAR96	15, .	150	104	80	76	100	70	76	149.00	
	3	25MAR96	22, .	200	102	66	96	100	60	108	149.50	

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Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00255	4	01APR96	29, .	250	112	80	86	100	70	104	148.50	
	5	08APR96	36, .	300	112	70	106	118	80	110	153.50	
	6	15APR96	43, .	250	110	80	90	110	76	100	145.00	
	7	23APR96	51, .	250	110	80	90	120	84	102	150.50	
	8	29APR96	57, .	200	90	60	96	90	60	100	147.25	
329.005.00256	SC	20FEB96	-14, -70	0	96	58	86	90	56	94	111.00	64.0
	BL	05MAR96	1, -56	0	98	66	88	92	60	98	110.50	
	1	12MAR96	8, -49	100	98	70	88	90	60	104	110.50	
	2	21MAR96	17, -40	150	90	60	88	90	58	90	111.00	
	3	26MAR96	22, -35	200	88	50	82	80	48	104	111.00	
	4	02APR96	29, -28	250	100	60	94	94	58	108	111.00	
	5	11APR96	38, -19	250	100	60	98	90	58	108	111.50	
	6	16APR96	43, -14	250	110	60	96	100	56	108	111.50	
	7	23APR96	50, -7	300	110	70	102	100	60	108	111.50	
	8	30APR96	57, 1	300	100	60	98	100	60	104	113.00	
	12	28MAY96	85, 29	300	80	40 L	96	80	40 L	96	114.50	
	16	02JUL96	120, 64	250	90	60	92	80	52	90	113.00	
329.005.00295	SC	21MAR96	-7, .	0	110	70	80	100	70	84	120.50	61.0
	BL	28MAR96	1, .	0	110	72	76	104	70	80	120.50	
	1	04APR96	8, .	100	120	78	88	110	68	94	119.20	
	2	11APR96	15, .	150	100	70	84	90	60	88	119.50	
	3	18APR96	22, .	200	100	68	88	94	60	88	119.00	
	4	24APR96	28, .	200	118	80	94	110	70	100	120.00	
	6	06MAY96	40, .	200	116	70	86	110	68	86	121.75	
	6	09MAY96	43, .	250	120	70	96	110	70	100	122.50	
	7	16MAY96	50, .	250	110	70	92	100	70	96	125.00	
	8	22MAY96	56, .	250	110	70	104	104	70	110	124.00	
329.005.00297	SC	28MAR96	-22, .	0	124	80	80	114	78	80	184.50	69.0
	BL	19APR96	1, .	0	118	72	80	120	70	80	180.00	
	1	26APR96	8, .	100	114	74	88	112	78	92	180.50	
	2	02MAY96	14, .	150	120	80	88	110	80	90	181.50	
	4	14MAY96	26, .	200	130	70	90	120	70	98	181.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00332	SC	05DEC96	-7, .	0	104	70	58	100	68	64	119.00	67.0
	BL	12DEC96	1, .	0	100	70	60	110	70	60	118.70	
	1	19DEC96	8, .	100	120	82	60	112	80	64	120.00	
	2	26DEC96	15, .	150	104	70	68	100	64	72	123.00	
	3	02JAN97	22, .	200	108	68	78	100	60	80	120.70	
	4	09JAN97	29, .	250	100	70	76	100	68	78	121.00	
	5	16JAN97	36, .	300	110	80	76	100	70	76	122.70	
	6	23JAN97	43, .	300	120	80	68	112	80	72	123.70	
	7	30JAN97	50, .	300	112	80	80	110	70	88	123.50	
	8	06FEB97	57, .	250	118	84	80	112	80	84	122.50	
329.005.00335	SC	20FEB97	-8, .	0	100	70	60	100	70	64	111.50	65.0
	BL	28FEB97	1, .	0	100	70	64	100	68	68	111.50	
	1	07MAR97	8, .	100	104	78	76	104	70	76	110.50	
	2	14MAR97	15, .	150	108	70	92	90	60	84	113.50	
	3	21MAR97	22, .	200	110	72	72	94	60	74	109.50	
	4	27MAR97	28, .	250	98	70	96	80	60	96	110.70	
	5	03APR97	35, .	200	110	80	104	100	70	88	113.20	
	6	10APR97	42, .	200	112	76	76	90	60	76	112.70	
	7	17APR97	49, .	200	110	80	100	100	70	88	113.00	
	8	24APR97	56, .	200	114	70	80	90	60	80	113.70	
329.006.00040	SC	10FEB95	-6, .	0	113	72	72	110	70	72	102.75	63.4
	BL	15FEB95	-1, .	0	118	70	72	110	70	84	102.75	
	1	22FEB95	7, .	50	110	80	88	106	76	90	102.97	
	2	01MAR95	14, .	50	90	60	132 H	90	60	140 H	103.00	
329.006.00041	SC	22MAR95	-14, -78	0	100	75	65	100	78	68	151.48	71.3
	BL	05APR95	1, -64	0	98	68	60	98	68	66	151.50	
	1	10APR95	6, -59	100	98	55	60	100	58	80	151.50	
	2	19APR95	15, -50	150	110	65	70	100	80	90	156.50	
	3	24APR95	20, -45	200	120	70	88	116	70	100	152.00	
	4	01MAY95	27, -38	200	110	65	80	100	80	100	154.00	
	5	08MAY95	34, -31	200	110	75	78	90	75	90	154.00	
	6	15MAY95	41, -24	200	108	70	78	90	75	95	154.50	
	7	24MAY95	50, -15	250	110	80	90	100	70	102	154.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.006.00041	8	31MAY95	57, -8	250	108	85	85	100	80	109	160.50	
	12	05JUL95	92, 28	300	102	78	78	92	78	120	162.00	
	16	31JUL95	118, 54	300	110	70	80	108	80	72	166.00 H	
	20	24AUG95	142, 78	300	110	70	100	92	78	100	167.00 H	
	24	21SEP95	170, 106	300	114	80	72	90	78	114	167.00 H	
	28	24OCT95	203, 139	300	118	80	85	100	80	90	170.00 H	
	32	21NOV95	231, 167	250	115	90	90	112	90	96	172.00 H	
329.007.00139	SC	04MAY95	-4, .	0	96	60	72	94	64	76	78.00	56.5
	BL	05MAY95	-3, .	0	96	60	77	94	64	76	78.00	
	1	18MAY95	11, .	100	102	68	72	98	70	76	75.00	
	2	25MAY95	18, .	100	102	68	80	98	70	84	76.00	
	6	19JUN95	43, .#	0	102	62	64	100	64	76	78.00	
329.007.00143	SC	26OCT95	-14, .	0	120	72	72	118	76	74	212.00	63.0
	BL	09NOV95	1, .	0	120	72	72	116	74	68	215.00	
	1	16NOV95	8, .	100	120	70	76	118	74	80	212.00	
	2	22NOV95	14, .	100	125	78	84	112	72	120	211.00	
329.007.00146	SC	18JAN96	-7, -60	0	130	80	88	128	86	96	228.00	63.0
	BL	25JAN96	1, -53	0	130	80	88	128	84	80	226.00	
	1	01FEB96	8, -46	100	138	84	88	136	88	96	227.00	
	2	05FEB96	12, -42	150	138	86	72	132	88	88	234.00	
	3	12FEB96	19, -35	200	130	84	76	128	88	68	231.00	
	4	19FEB96	26, -28	250	126	84	72	126	88	80	231.00	
	5	26FEB96	33, -21	250	128	82	76	130	86	84	232.00	
	6	04MAR96	40, -14	250	124	82	88	122	86	96	232.00	
	7	11MAR96	47, -7	200	128	86	84	126	90	96	234.00	
	8	18MAR96	54, 1	200	128	86	88	126	88	96	231.00	
	12	15APR96	82, 29	250	120	82	72	124	86	88	235.00	
	16	13MAY96	110, 57	200	128	88	88	124	92	96	234.00	
	20	06JUN96	134, 81	200	130	86	98	132	90	100	232.00	
	24	08JUL96	166, 113	200	116	84	104	124	92	96	234.00	
	28	05AUG96	194, 141	200	140	92	100	138	88	92	237.00	
	32	09SEP96	229, 176	200	126	98	106	128	99	126 H	235.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.007.00269	SC	04APR96	-7, .	0	138	80	64	132	86	72	239.00	68.0
	BL	11APR96	1, .	0	120	74	80	126	80	88	241.00	
	1	18APR96	8, .	100	132	82	96	130	84	92	237.00	
	2	25APR96	15, .	100	138	76	96	130	80	92	239.00	
	3	02MAY96	22, .	100	130	76	76	.	.	.	238.00	
329.007.00270	SC	02MAY96	-7, .	0	116	70	64	112	72	72	135.00	68.0
	BL	09MAY96	1, .	0	108	74	64	106	76	68	137.00	
	1	16MAY96	8, .	100	108	64	68	106	72	72	135.00	
	2	23MAY96	15, .	150	114	68	68	110	70	76	135.00	
	3	30MAY96	22, .	200	114	70	72	112	72	68	133.00	
	4	06JUN96	29, .	200	110	70	72	108	74	76	135.00	
	5	13JUN96	36, .	200	118	72	64	114	76	68	132.00	
	6	20JUN96	43, .	200	110	72	68	108	80	72	129.00	
	7	27JUN96	50, .	200	108	68	88	102	62	88	130.00	
329.007.00307	SC	09MAY96	-7, .	0	120	72	76	118	76	84	146.00	61.0
	BL	16MAY96	1, .	0	122	72	84	118	74	88	148.00	
	1	23MAY96	8, .	100	120	80	80	118	84	78	145.00	
	2	30MAY96	15, .	150	132	84	82	128	88	88	149.00	
	3	06JUN96	22, .	200	120	76	92	118	80	98	148.00	
	4	13JUN96	29, .	200	124	82	88	120	84	94	154.00	
	5	20JUN96	36, .	200	140	88	92	136	90	98	154.00	
	8	25JUL96	71, .#	0	124	74	98	130	88	108	151.00	
329.007.00308	SC	27JUN96	-5, .	0	102	68	74	102	70	74	142.00	71.0
	BL	02JUL96	1, .	0	100	64	72	102	60	72	142.00	
329.008.00159	SC	06SEP95	-7, -69	0	100	70	92	100	73	96	104.00	62.0
	BL	13SEP95	1, -62	0	103	70	68	100	65	80		
	1	19SEP95	7, -56	100	96	62	.	96	62	.	101.00	
	2	27SEP95	15, -48	150	96	62	.	94	64	.	101.00	
	3	03OCT95	21, -42	200	94	60	72	92	60	72	101.00	
	4	10OCT95	28, -35	250	100	78	84	92	62	88	101.00	
	5	16OCT95	34, -29	250	110	72	108	96	70	104	101.00	
	6	24OCT95	42, -21	250	102	78	118	100	76	118	101.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.008.00159	7	31OCT95	49, -14	200	116	78	100	100	76	122 H	101.00	
	8	14NOV95	63, 1	200	110	65	88	110	56	120	102.00	
	16	26DEC95	105, 43	200	102	74	80	96	70	90	100.00	
	20	23JAN96	133, 71	200	104	76	72	98	68	84	104.00	
329.008.00161	SC	31OCT95	-16, -71	0	110	72	60	.	.	.	261.00	73.0
	BL	16NOV95	1, -55	0	118	78	78	118	72	80	263.00	
	1	22NOV95	7, -49	100	104	78	74	100	76	78	263.00	
	2	29NOV95	14, -42	150	106	78	72	96	72	78	266.00	
	3	07DEC95	22, -34	200	118	74	72	110	78	86	259.00	
	4	15DEC95	30, -26	200	114	78	78	100	72	72	265.00	
	6	27DEC95	42, -14	200	120	80	72	118	78	90	268.00	
	7	03JAN96	49, -7	200	122	78	66	118	74	84		
	8	10JAN96	56, 1	200	118	74	72	110	70	82	272.00	
329.008.00187	SC	15NOV95	-14, .	0	100	70	84	100	70	93	108.00	63.0
	BL	29NOV95	1, .	0	100	70	84	100	70	93		
	1	07DEC95	9, .	100	120	78	88	115	82	92	111.00	
	2	14DEC95	16, .	100	116	84	100	90	70	104	111.00	
	3	21DEC95	23, .	200	118	78	104	104	78	116	113.00	
	4	28DEC95	30, .	200	110	70	108	100	70	120	109.00	
	5	04JAN96	37, .	200	124	98	100	118	90	100	115.00	
	6	11JAN96	44, .	250	110	82	108	104	80	116	112.00	
	7	18JAN96	51, .	200	110	78	100	110	82	100	112.00	
	8	26JAN96	59, .	200	100	70	104	100	76	108	113.00	
329.008.00192	SC	14FEB96	-20, .	0	114	66	84	104	60	96	126.00	65.0
	BL	05MAR96	1, .	0	110	72	72	98	64	90	126.00	
	1	11MAR96	7, .	50	100	70	78	94	62	90	133.00	
	2	18MAR96	14, .	100	102	70	78	94	70	90	133.00	
	3	25MAR96	21, .	200	102	60	90	92	60	120	131.00	
	4	03APR96	30, .	200	102	70	90	94	68	98	133.00	
	5	12APR96	39, .	200	100	68	72	96	68	90	130.00	
329.008.00272	SC	19MAR96	-15, -71	0	106	62	60	100	68	66	120.00	61.0
	BL	03APR96	1, -56	0	102	70	72	94	68	82	122.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.008.00272	1	10APR96	8, -49	50	102	72	78	96	64	96	120.00	
	2	17APR96	15, -42	100	102	70	78	96	66	84	120.00	
	3	26APR96	24, -33	150	102	70	84	98	68	108	122.00	
	4	01MAY96	29, -28	200	98	64	90	102	64	102	123.00	
	5	07MAY96	35, -22	200	116	72	90	98	66	96	125.00	
	7	22MAY96	50, -7	200	110	78	108	100	80	116	127.00	
	8	29MAY96	57, 1	200	110	75	100	110	80	108	128.00	
	12	26JUN96	85, 29	200	112	78	90	106	78	102	131.00 H	
	16	24JUL96	113, 57	200	118	96	96	100	58	110	135.00 H	
	20	21AUG96	141, 85	200	112	76	108	114	80	138 H	141.00 H	
	24	18SEP96	169, 113	200	168	72	72	116	60	96	145.00 H	
329.008.00273	SC	19APR96	-28, -91	0	120	85	80	120	85	92	152.00	72.0
	BL	17MAY96	1, -63	0	120	80	96	105	83	102	153.00	
	1	24MAY96	8, -56	100	110	85	112	105	82	136 H	150.00	
	2	31MAY96	15, -49	150	112	84	92	108	85	100	150.00	
	3	10JUN96	25, -39	200	100	80	96	100	80	112	147.00	
	4	17JUN96	32, -32	200	110	85	96	100	85	108	145.00	
	5	24JUN96	39, -25	250	110	80	100	110	80	108	145.00	
	6	01JUL96	46, -18	300	124	79	104	131	81	104	140.00 L	
	8	11JUL96	56, -8	300	112	82	106	110	80	120	138.00 L	
	8	19JUL96	64, 1	300	105	85	96	100	80	100	140.00 L	
	16	04SEP96	111, 48	300	110	85	104	110	80	112	140.00 L	
329.009.00127	SC	03APR95	-7, .	0	104	66	62	105	55	68	79.90	58.0
	BL	10APR95	1, .	0	114	54	75	.	.	.	79.70	
	1	17APR95	8, .	100	112	61	78	119	53	91	80.90	
	2	24APR95	15, .	150	111	62	74	111	63	83	78.20	
	3	01MAY95	22, .	200	115	54	74	118	78	72	79.60	
	4	08MAY95	29, .	200	127	52	79	111	82	89	77.60	
	5	15MAY95	36, .	200	118	57	91	111	68	103	78.30	
329.009.00132	SC	17MAY95	-6, -63	0	114	77	54	112	70	79	111.35	62.0
	BL	23MAY95	1, -57	0	117	58	85	123	72	94	112.90	
	1	30MAY95	8, -50	100	131	68	79	108	64	108	110.50	
	2	06JUN95	15, -43	150	114	63	95	113	67	106	111.79	

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\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00132	3	13JUN95	22, -36	200	115	69	103	123	80	106	114.00	
	4	20JUN95	29, -29	200	121	69	89	114	68	112	109.30	
	5	27JUN95	36, -22	200	122	71	91	122	72	105	110.30	
	6	05JUL95	44, -14	200	122	68	95	123	72	112	111.30	
	7	11JUL95	50, -8	200	114	64	93	116	72	105	109.50	
	8	19JUL95	58, 1	200	131	84	108	140	81	97	111.30	
	12	24AUG95	94, 37	200	116	79	96	115	72	96	112.50	
	16	15SEP95	116, 59	200	116	62	95	114	67	99	113.30	
	20	24OCT95	155, 98	200	114	67	95	116	62	99	112.50	
329.009.00134	SC	28JUN95	-8, .	0	114	60	76	115	76	93	122.50	66.0
	BL	06JUL95	1, .	0	122	68	93	128	73	119	122.50	
	1	14JUL95	9, .	100	114	56	95	106	72	111	122.70	
	2	19JUL95	14, .	150	122	72	101	122	75	105	124.70	
	3	26JUL95	21, .	200	114	76	93	121	84	112	122.20	
	4	03AUG95	29, .	200	115	76	98	122	72	114	123.90	
	5	08AUG95	34, .	200	122	76	115	115	80	117	123.50	
	6	15AUG95	41, .	200	122	90	108	131	84	108	124.00	
	7	24AUG95	50, .	200	136	81	88	129	82	101	124.20	
	8	29AUG95	55, .	150	115	69	94	104	88	115	122.80	
329.009.00137	SC	03OCT95	-7, .	0	101	53	100	111	64	115	87.30	62.0
	BL	10OCT95	1, .	0	99	54	85	98	57	101	88.30	
	1	17OCT95	8, .	100	114	60	98	106	60	101	86.50	
	2	24OCT95	15, .	150	120	72	105	109	64	114	85.70	
	3	31OCT95	22, .	200	111	60	88	102	63	.	84.80	
	4	07NOV95	29, .	200	93	50	108	84	52	117	85.10	
	5	14NOV95	36, .	200	106	56	101	91	56	126	85.60	
	6	21NOV95	43, .	200	118	69	102	98	54	114	86.00	
	7	28NOV95	50, .	200	99	60	112	98	52	111	84.90	
	8	05DEC95	57, .	150	130	59	111	103	56	119	85.90	
329.009.00171	SC	31OCT95	-7, .	0	131	69	79	135	74	109	200.60	62.0
	BL	07NOV95	1, .	0	116	60	98	116	59	97	201.90	
	1	14NOV95	8, .	50	122	71	93	115	74	105	199.30	

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\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00172	SC	06NOV95	-7, -64	0	125	71	100	147	76	115	126.50	64.0
	BL	13NOV95	1, -57	0	129	63	84	124	73	109	126.50	
	1	20NOV95	8, -50	100	122	70	129 H	115	57	137	123.60	
	2	27NOV95	15, -43	150	98	66	101	104	58	92	123.00	
	3	04DEC95	22, -36	200	126	81	92	121	69	96	125.00	
	4	11DEC95	29, -29	200	102	53	88	129	67	100	122.50	
	5	21DEC95	39, -19	200	117	67	108	108	56	.	121.40	
	6	27DEC95	45, -13	200	131	81	104	112	47 L	108	121.90	
	7	03JAN96	52, -6	200	115	61	102	102	56	110	121.70	
	8	09JAN96	58, 1	200	101	76	102	85 L	33 L	108	121.50	
	12	07FEB96	87, 30	200	99	49	104	91	37 L	108	122.80	
	16	04MAR96	113, 56	200	107	53	109	118	57	114	121.20	
	20	01APR96	141, 84	200	123	65	120	108	41 L	120	125.10	
	24	29APR96	169, 112	200	123	74	92	114	79	104	123.30	
	28	10JUN96	211, 154	200	123	77	112	106	68	115	122.40	
	32	08JUL96	239, 182	200	114	64	114	91	41 L	90	121.90	
329.009.00194	SC	28NOV95	-7, -63	0	109	58	66	98	69	68	90.40	56.8
	BL	05DEC95	1, -56	0	116	55	77	95	62	88	91.40	
	1	12DEC95	8, -49	100	105	53	88	104	54	83	90.20	
	2	19DEC95	15, -42	150	112	69	95	118	62	89	90.20	
	3	27DEC95	23, -34	200	114	65	98	108	62	111	91.30	
	4	02JAN96	29, -28	200	116	80	117	138	73	119	90.00	
	5	09JAN96	36, -21	200	109	57	105	106	62	109	91.00	
	6	16JAN96	43, -14	200	114	68	106	116	66	102	90.80	
	7	23JAN96	50, -7	200	107	62	106	100	56	108	91.10	
	8	30JAN96	57, 1	200	106	57	98	113	62	102	89.90	
	12	27FEB96	85, 29	200	93	48	97	114	48	87	89.90	
	16	02APR96	120, 64	200	95	60	88	97	65	87	87.00	
	20	30APR96	148, 92	200	106	53	81	111	52	83	86.70	
	24	04JUN96	183, 127	200	104	56	99	117	53	100	87.40	
329.009.00195	SC	06DEC95	-9, .	0	115	65	72	122	71	86	112.40	64.0
	BL	15DEC95	1, .	0	123	58	63	107	63	77	112.30	
	1	19DEC95	5, .	100	116	47	65	107	60	86	112.80	
	2	27DEC95	13, .	150	106	65	79	115	54	79	110.70	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00195	3	02JAN96	19, .	200	115	57	98	106	62	129 H	111.20	
	3	08JAN96	25, .	150	140	85	96	139	73	125 H		
329.009.00199	SC	10JAN96	-6, .	0	130	65	73	136	81	96	160.30	66.0
	BL	16JAN96	1, .	0	114	61	69	106	56	88	158.90	
	1	23JAN96	8, .	100	138	59	95	107	69	108	160.50	
	2	29JAN96	14, .	150	111	61	88	103	53	100	158.90	
	3	07FEB96	23, .	200	123	49	109	91	54	114	159.80	
	4	14FEB96	30, .	200	114	50	101	98	41	105	158.10	
	5	21FEB96	37, .	250	114	61	95	105	58	98	156.10	
	6	28FEB96	44, .	250	137	76	96	112	64	105	157.70	
	7	06MAR96	51, .	250	100	62	86	98	48	94	158.20	
	8	13MAR96	58, .	200	122	72	96	90	55	105	155.50	
329.009.00203	SC	28FEB96	-5, .	0	95	65	103	103	49	109	85.80	57.5
	BL	04MAR96	1, .	0	115	68	77	107	71	103	85.00	
	1	11MAR96	8, .	100	108	61	100	110	65	105	84.00	
	2	19MAR96	16, .	150	113	58	105	99	58	106	84.70	
	3	26MAR96	23, .	150	110	55	104	109	54	109	84.67	
329.009.00236	SC	17DEC96	-13, .	0	136	72	87	124	56	94	146.90	63.1
	BL	30DEC96	1, .	0	113	44	75	103	57	86	147.30	
	1	06JAN97	8, .	100	115	57	98	100	52	121 H	144.30	
	2	15JAN97	17, .	150	115	66	90	121	71	106	141.50	
	3	20JAN97	22, .	200	131	74	109	108	58	133 H	143.30	
	4	27JAN97	29, .	200	130	69	84	114	63	103	137.00	
329.009.00239	SC	11NOV96	-8, -65	0	122	60	54	113	62	53	148.90	65.5
	BL	18NOV96	-1, -58	0	114	60	53	123	57	74	149.40	
	1	25NOV96	7, -51	100	115	61	88	106	63	96	147.70	
	2	02DEC96	14, -44	150	115	69	85	112	60	109	146.80	
	3	09DEC96	21, -37	200	124	74	94	107	68	117	147.70	
	4	16DEC96	28, -30	200	121	66	86	113	58	115	149.10	
	5	23DEC96	35, -23	200	126	77	106	121	77	121 H	149.50	
	6	30DEC96	42, -16	200	113	75	100	115	73	102	143.40	
	7	06JAN97	49, -9	200	121	59	108	119	81	131 H	146.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00239	8	15JAN97	58, 1	200	120	74	68	131	82	91	143.40	
	12	18FEB97	92, 35	200	115	55	80	106	64	97	144.90	
	16	17MAR97	119, 62	200	114	52	65	105	54	80	149.80	
	20	14APR97	147, 90	200	126	62	64	122	66	65	144.40	
	24	12MAY97	175, 118#	0	114	65	59	115	65	71	153.60	
329.009.00262	SC	07FEB97	-10, .	0	122	69	54	134	75	68	145.40	62.3
	BL	17FEB97	1, .	0	126	83	74	131	79	84	145.90	
	1	24FEB97	8, .	100	129	63	77	120	70	112	141.20	
	2	03MAR97	15, .	150	130	85	91	120	72	119	143.60	
	3	07MAR97	19, .	200	131	75	90	113	63	119	141.90	
	4	17MAR97	29, .	200	127	85	103	119	65	129 H	139.20	
	5	24MAR97	36, .	200	147	91	106	147	84	112	136.70	
	6	31MAR97	43, .	200	143	83	96	122	74	117	136.90	
	7	07APR97	50, .	200	139	81	108	116	76	121 H	134.50 L	
	8	14APR97	57, .	200	139	74	102	116	79	114	135.70	
329.009.00264	SC	25OCT96	-7, .	0	138	73	71	129	82	83	171.00	62.5
	BL	01NOV96	1, .	0	109	72	102	122	66	82	171.00	
	1	08NOV96	8, .	100	121	79	108	.	.	.	170.30	
	1	11NOV96	11, .	150	145	80	105	126	87	140 H		
	2	18NOV96	18, .	200	130	88	104	130	68	133 H	168.00	
	3	25NOV96	25, .	200	145	88	117	120	73	145 H	168.00	
	4	02DEC96	32, .	200	137	76	115	104	57	137 H	169.40	
	6	11DEC96	41, .	200	135	86	126	123	61	150 H	165.80	
	6	16DEC96	46, .	200	144	91	137 H	125	72	140 H	169.60	
	7	23DEC96	53, .	200	128	66	131	115	55	148 H	169.10	
329.009.00301	SC	06MAR96	-13, -69	0	91	45	79	108	59	101	127.00	80.0
	BL	19MAR96	1, -56	0	93	45	75	95	57	75	129.00	
	1	26MAR96	8, -49	100	91	44	84	114	49	72	129.50	
	2	05APR96	18, -39	150	105	59	77	107	65	89	125.20	
	3	12APR96	25, -32	200	106	52	90	99	61	108	126.50	
	4	16APR96	29, -28	200	116	63	74	108	58	90	125.70	
	5	23APR96	36, -21	200	124	70	114	107	59	126 H	124.80	
	6	30APR96	43, -14	200	97	46	83	93	62	95	127.40	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00301	7	07MAY96	50, -7	200	101	53	86	115	62	92	128.60	
	8	14MAY96	57, 1	200	99	52	66	105	57	88	127.10	
	12	11JUN96	85, 29	200	107	56	66	107	75	78	129.70	
329.009.00305	SC	01MAY96	-6, -63	0	114	53	80	111	66	105	136.50	72.3
	BL	07MAY96	1, -57	0	108	54	86	107	53	89	135.90	
	1	14MAY96	8, -50	100	107	65	92	108	69	98	135.10	
	2	21MAY96	15, -43	150	96	54	94	99	37	98	133.80	
	3	28MAY96	22, -36	200	123	62	96	106	64	96	133.70	
	4	04JUN96	29, -29	200	126	76	100	93	47	132 H	135.60	
	5	11JUN96	36, -22	200	123	72	96	98	38	.	135.60	
	6	19JUN96	44, -14	200	115	65	96	103	53	120	133.90	
	7	25JUN96	50, -8	200	120	74	100	114	60	135 H	134.06	
	8	03JUL96	58, 1	200	105	60	115	95	53	140 H	134.50	
	12	06AUG96	92, 35	200	113	61	96	99	46	120	136.30	
	16	27AUG96	113, 56	200	114	56	89	105	55	123 H	134.30	
	20	24SEP96	141, 84	200	103	57	91	90	53	117	132.80	
	24	29OCT96	176, 119	200	115	65	88	100	50	126 H	137.00	
	28	03DEC96	211, 154	200	115	62	100	105	71	121 H	138.60	
	32	10JAN97	249, 192	200	122	65	98	106	68	125 H	137.40	
329.009.00325	SC	21AUG96	-6, -61	0	103	53	72	106	45	90	118.63	67.0
	BL	27AUG96	1, -55	0	108	53	65	96	55	97	116.00	
	1	03SEP96	8, -48	100	107	73	88	94	57	108	114.80	
	2	09SEP96	14, -42	150	113	67	109	100	65	114	114.44	
	3	16SEP96	21, -35	200	102	53	93	90	.	115	120.39	
	4	23SEP96	28, -28	200	112	56	103	99	51	131 H	115.32	
	5	30SEP96	35, -21	200	123	61	74	101	61	114	116.30	
	6	10OCT96	45, -11	200	121	63	93	107	59	119	117.40	
	7	14OCT96	49, -7	200	149	70	94	118	60	123	117.80	
	8	21OCT96	56, 1	200	130	68	93	128	58	119	117.20	
	12	18NOV96	84, 29	200	131	67	89	113	74	125	118.90	
	16	16DEC96	112, 57	200	113	60	87	92	47	131 H	118.20	
329.009.00326	SC	26AUG96	-10, -63	0	139	64	93	143	74	98	227.10	68.0
	BL	05SEP96	1, -53	0	152	81	91	158	87	108	227.70	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00326	1	09SEP96	5, -49	100	139	58	88	124	69	98	226.50	
	2	16SEP96	12, -42	150	136	63	88	95	70	98	223.60	
	3	23SEP96	19, -35	200	139	78	98	138	76	105	223.50	
	4	30SEP96	26, -28	200	125	65	111	105	57	126	222.00	
	5	07OCT96	33, -21	200	139	72	108	129	86	121	221.50	
	6	17OCT96	43, -11	200	141	67	98	124	51	112	215.30	
	7	24OCT96	50, -4	200	152	76	96	134	55	125	218.90	
	8	28OCT96	54, 1	200	139	70	106	123	86	105	215.50	
	12	25NOV96	82, 29	200	146	74	112	85 L	74	126	213.00	
	16	16DEC96	103, 50	200	.	.	.	.	.	.	211.10 L	
329.010.00279	SC	08MAR96	-14, -70	0	115	82	88	110	75	96	127.80	66.0
	BL	22MAR96	1, -56	0	170	70	75	106	85	92	129.00	
	1	29MAR96	8, -49	100	98	60	80	100	70	110	128.00	
	2	05APR96	15, -42	150	110	70	92	108	78	108	128.00	
	3	12APR96	22, -35	200	128	78	92	118	88	108	129.25	
	4	19APR96	29, -28	250	110	60	70	110	70	72	129.00	
	5	25APR96	35, -22	300	118	77	78	117	61	87		
	6	03MAY96	43, -14	300	118	70	65	115	80	74	129.20	
	7	10MAY96	50, -7	300	112	88	85	110	80	96	129.00	
	8	17MAY96	57, 1	300	120	80	85	114	85	90	128.50	
	12	14JUN96	85, 29	300	120	80	85	108	70	95	127.00	
	16	11JUL96	112, 56	300	115	70	84	110	70	88	125.50	
	20	08AUG96	140, 84	300	115	65	84	110	70	92	129.50	
	24	05SEP96	168, 112	300	115	70	72	118	75	88	128.00	
	28	02OCT96	195, 139	300	116	68	78	120	78	92	129.50	
	32	06NOV96	230, 174	250	114	68	82	110	68	96	129.50	
329.010.00281	SC	19JUL96	-7, -68	0	118	78	68	115	78	70	138.20	67.0
	BL	26JUL96	1, -61	0	110	80	62	108	76	80	138.20	
	1	02AUG96	8, -54	100	118	70	80	115	68	92	138.50	
	2	09AUG96	15, -47	150	122	74	68	120	72	74	138.50	
	3	19AUG96	25, -37	200	122	68	76	118	65	88	135.00	
	4	26AUG96	32, -30	250	118	80	64	118	78	72	133.00	
	6	04SEP96	41, -21	300	120	76	86	114	70	92	138.00	
	6	09SEP96	46, -16	300	120	78	80	118	74	88	136.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.010.00281	8	18SEP96	55, -7	300	116	78	92	112	72	98	138.50	
	8	25SEP96	62, 1	300	118	80	80	110	76	88	138.00	
	12	25OCT96	92, 31	300	122	72	84	118	66	92	141.00	
	16	20NOV96	118, 57	300	118	76	88	114	80	96	140.20	
	20	20DEC96	148, 87	300	116	72	88	112	76	96	137.50	
	24	03JAN97	162, 101	300	128	80	88	120	70	96	139.50	
329.011.00163	SC	18NOV95	-7, .	0	108	60	90	104	60	90	136.00	58.0
	BL	24NOV95	-1, .	0	110	60	76	110	68	80	134.00	
	1	01DEC95	7, .	50	90	50	90	90	52	92	134.20	
	2	11DEC95	17, .	100	90	50	90	92	50	90	134.70	
	3	18DEC95	24, .	150	110	76	94	110	76	96	130.00	
	5	27DEC95	33, .	200	110	70	80	110	70	80	130.70	
329.011.00208	SC	22AUG96	-15, -74	0	110	60	84	110	60	88	84.50	57.5
	BL	05SEP96	-1, -60	0	110	60	80	110	62	84	84.50	
	1	11SEP96	6, -54	50	108	62	80	110	60	84	82.00	
	2	17SEP96	12, -48	100	118	70	84	116	74	88	83.20	
	3	26SEP96	21, -39	150	110	80	90	110	84	86	83.20	
	4	03OCT96	28, -32	200	110	70	90	110	76	90	82.70	
	5	10OCT96	35, -25	250	108	70	80	110	70	84	83.00	
	6	17OCT96	42, -18	300	102	60	80	100	60	86	85.50	
	7	24OCT96	49, -11	300	110	70	96	110	76	100	84.70	
	8	03NOV96	59, -1	300	110	72	88	112	72	90	86.50	
329.011.00209	SC	23AUG96	-19, -81	0	120	90	80	120	90	80	122.00	64.0
	BL	10SEP96	-1, -63	0	118	88	86	120	90	88	122.00	
	1	19SEP96	9, -54	50	110	80	84	112	84	84	117.70	
	2	26SEP96	16, -47	100	120	90	90	114	88	96	115.00	
	3	03OCT96	23, -40	150	120	80	100	118	78	100	117.00	
	4	11OCT96	31, -32	200	118	72	96	116	74	100	117.00	
	5	17OCT96	37, -26	200	118	80	80	110	78	84	116.20	
	6	24OCT96	44, -19	200	118	78	80	110	76	88	116.70	
	7	01NOV96	52, -11	200	120	80	86	112	84	88	116.50	
	8	11NOV96	62, -1	250	120	76	84	120	80	92	115.50	
	12	18DEC96	99, 37	250	108	68	80	100	64	84	110.50 L	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.011.00284	SC	13MAR96	-9, -65	0	122	78	80	122	70	80	154.70	72.0
	BL	21MAR96	-1, -57	0	122	78	80	122	70	80	154.70	
	1	28MAR96	7, -50	50	120	78	76	120	80	80	151.70	
	2	05APR96	15, -42	100	108	70	80	110	70	88	151.70	
	3	11APR96	21, -36	150	110	80	90	110	86	96	152.00	
	4	19APR96	29, -28	200	110	80	80	118	80	90	152.20	
	5	25APR96	35, -22	200	110	70	80	110	76	80	153.00	
	6	02MAY96	42, -15	250	120	80	80	120	80	80	152.00	
	7	09MAY96	49, -8	250	120	78	80	120	84	86	152.00	
	8	16MAY96	56, -1	250	120	80	80	120	80	80	150.00	
	12	10JUN96	81, 25	250	110	72	80	116	70	88	147.00	
	16	08JUL96	109, 53	250	126	78	80	120	70	96	147.00	
	20	05AUG96	137, 81	250	122	88	76	120	84	80	147.50	
329.011.00286	SC	15MAY96	-22, -90	0	118	80	80	110	80	80	166.20	61.5
	BL	05JUN96	-1, -69	0	112	80	72	110	70	76	166.20	
	1	14JUN96	9, -60	50	110	80	65	100	70	65	164.00	
	2	21JUN96	16, -53	100	100	80	96	114	82	96	165.50	
	3	28JUN96	23, -46	150	106	82	92	110	80	90	164.00	
	5	08JUL96	33, -36	200	120	78	90	120	80	96	167.00	
	6	17JUL96	42, -27	250	118	80	88	120	80	92	164.20	
	7	24JUL96	49, -20	250	120	80	86	120	76	84	163.20	
	8	02AUG96	58, -11	300	116	80	84	120	80	88	160.00	
	8	09AUG96	65, -4	300	110	70	80	112	74	84	160.00	
	16	17SEP96	104, 36	300	110	70	88	110	72	84	160.50	
	20	24OCT96	141, 73	300	104	70	84	106	72	88	156.70	
	24	25NOV96	173, 105	300	110	70	86	110	74	90	153.70 L	
	28	30DEC96	208, 140	300	110	80	80	110	80	84	151.20 L	
329.012.00026	SC	09NOV95	-19, .	0	110	70	68	100	72	80	159.20	63.8
	BL	28NOV95	1, .	0	110	78	56	90	62	80	161.63	
	1	05DEC95	8, .	100	100	66	80	104	80	84	163.17	
329.012.00219	SC	24MAY96	-7, -67	0	100	70	64	110	70	72	167.36	78.7
	BL	31MAY96	1, -60	0	110	80	72	120	90	64	166.92	
	1	07JUN96	8, -53	100	110	70	80	100	80	100	165.38	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.012.00219	2	14JUN96	15, -46	150	120	80	68	110	80	60	163.39	
	3	24JUN96	25, -36	200	110	70	74	112	76	80	165.38	
	5	02JUL96	33, -28	200	104	70	60	102	80	68	167.36	
	6	09JUL96	40, -21	200	112	70	60	120	78	68	168.46	
	7	16JUL96	47, -14	200	120	80	84	110	80	74	169.12	
	8	23JUL96	54, -7	200	110	80	110	100	86	90	168.24	
	8	30JUL96	61, 1	200	112	76	74	120	70	84	168.02	
	12	30AUG96	92, 32	200	130	78	80	132	80	82	165.82	
	16	26SEP96	119, 59	200	118	76	100	120	80	90	170.23	
	20	25OCT96	148, 88	200	118	80	86	110	86	80	169.34	
	24	22NOV96	176, 116	200	122	80	80	120	70	74	168.24	
	28	20DEC96	204, 144	200	110	72	82	112	80	76	168.24	
	32	24JAN97	239, 179	200	126	82	64	120	80	72	170.89	
329.012.00221	SC	18JUN96	-7, -70	0	110	70	80	120	80	80	148.18	69.3
	BL	25JUN96	1, -63	0	114	80	64	110	80	80	147.96	
	1	02JUL96	8, -56	100	110	70	84	110	80	100	147.29	
	2	09JUL96	15, -49	150	110	78	72	118	76	80	144.87	
	3	16JUL96	22, -42	200	110	80	104	120	80	100	148.62	
	4	23JUL96	29, -35	250	124	80	88	118	90	92	148.18	
	5	30JUL96	36, -28	250	110	72	90	120	80	96	148.40	
	6	09AUG96	46, -18	200	110	80	96	100	70	100	150.16	
	8	19AUG96	56, -8	200	124	78	92	118	78	90	147.74	
	8	27AUG96	64, 1	200	120	74	84	118	74	90	147.96	
	12	23SEP96	91, 28	200	120	86	88	110	80	80	151.26	
	16	21OCT96	119, 56	200	110	80	88	100	80	100	154.35	
	20	04NOV96	133, 70	200	120	70	90	124	68	90	157.66	
329.012.00223	SC	23AUG96	-7, .	0	104	70	72	110	70	80	194.04	61.8
	BL	30AUG96	1, .	0	132	86	88	136	88	90	196.25	
	1	06SEP96	8, .	100	136	100	100	130	90	92	196.47	
	2	16SEP96	18, .	150	130	90	108	128	90	100	195.36	
	3	23SEP96	25, .	200	132	84	96	138	86	92	195.14	
	5	01OCT96	33, .	150	140	98	90	140	104	100	195.14	
329.012.00227	SC	12DEC96	-6, -75	0	130	70	60	130	76	70	153.25	70.1

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=IMIPRAMINE

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.012.00227	BL	18DEC96	1, -69	0	128	82	80	122	76	84	150.38	
	1	27DEC96	10, -60	100	128	80	80	126	78	90	150.38	
	3	06JAN97	20, -50	150	120	90	100	120	80	95	150.38	
	4	15JAN97	29, -41	200	124	80	92	120	78	94	150.38	
	5	24JAN97	38, -32	200	130	90	100	124	82	102	150.38	
	7	04FEB97	49, -21	200	126	90	90	122	80	92	151.04	
	8	14FEB97	59, -11	250	122	82	80	120	78	82	151.04	
	8	20FEB97	65, -5	250	130	80	82	120	86	88	152.15	
	8	25FEB97	70, 1	300	128	90	78	120	90	90	151.48	
	16	27MAR97	100, 31	300	136	90	90	134	90	100	156.56	
	20	25APR97	129, 60	300	152	80	96	152	80	105	159.42	
	24	26MAY97	160, 91	300	144	90	94	134	80	120	159.86	
	28	25JUN97	190, 121	300	130	90	100	120	90	110	157.44	
	32	21JUL97	216, 147	300	120	80	88	136	90	100	156.56	
	32	19AUG97	245, 176	250	120	70	90	128	70	96	157.66	
329.012.00230	SC	20FEB97	-8, -77	0	120	80	76	120	78	72	121.50	65.4
	BL	28FEB97	1, -69	0	120	76	80	120	78	82	121.28	
	1	07MAR97	8, -62	100	110	80	84	120	80	96	121.50	
	2	14MAR97	15, -55	150	124	70	60	110	70	100	122.38	
	3	24MAR97	25, -45	200	120	80	90	114	76	80	122.60	
	5	03APR97	35, -35	200	114	76	82	108	80	82	121.72	
	6	11APR97	43, -27	200	118	78	90	120	80	96	122.82	
	8	23APR97	55, -15	200	106	74	109	90	70	120	119.07	
	8	02MAY97	64, -6	250	106	74	100	104	70	116	123.04	
	8	08MAY97	70, 1	250	106	68	110	104	60	120	122.16	
	12	16MAY97	78, 9	100	106	58	102	100	68	120	122.38	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.001.00062	SC	06OCT94	-14, .	0	88	50	80	84	60	88	98.00	60.5
	BL	20OCT94	1, .	0	90	60	68	100	56	84	98.00	
	1	27OCT94	8, .	0	98	60	80	90	68	100	99.75	
	2	03NOV94	15, .	0	92	56	80	86	60	96	99.75	
	3	10NOV94	22, .	0	92	58	80	100	60	96	101.00	
329.001.00064	SC	04NOV94	-6, -60	0	120	60	80	130	70	84	165.00	71.5
	BL	10NOV94	1, -54	0	110	60	72	106	70	88	165.00	
	1	16NOV94	7, -48	0	104	68	68	122	70	80	165.00	
	2	22NOV94	13, -42	0	114	72	68	104	60	88	166.00	
	3	29NOV94	20, -35	0	110	70	68	128	70	80	166.00	
	4	06DEC94	27, -28	0	100	70	64	120	78	74	165.00	
	5	13DEC94	34, -21	0	108	70	70	106	66	84	165.00	
	6	20DEC94	41, -14	0	104	68	60	110	70	88	165.50	
	7	27DEC94	48, -7	0	114	70	66	120	72	72	167.00	
	8	03JAN95	55, 1	0	112	60	76	118	64	92	167.00	
	12	31JAN95	83, 29	0	116	80	68	110	74	84	169.80	
	16	28FEB95	111, 57	0	116	70	66	110	80	84	169.00	
	20	28MAR95	139, 85	0	100	70	64	112	78	82	169.20	
329.001.00069	SC	07FEB95	-9, .	0	110	60	64	104	60	80	125.00	70.5
	BL	16FEB95	1, .	0	112	72	60	106	68	72	127.00	
	1	23FEB95	8, .	0	100	70	80	104	70	100	125.00	
	2	02MAR95	15, .	0	112	70	68	118	78	80	127.00	
	3	09MAR95	22, .	0	110	74	66	110	80	100	123.00	
	4	16MAR95	29, .	0	110	70	66	116	80	84	127.00	
	5	23MAR95	36, .	0	106	66	64	98	60	88	123.00	
	6	30MAR95	43, .	0	110	72	72	108	80	100	126.50	
	7	06APR95	50, .	0	122	84	72	128	88	76	127.00	
	8	13APR95	57, .	0	110	70	72	116	80	88	132.00	
329.001.00071	SC	02FEB95	-21, .	0	100	60	80	104	66	100	97.00	61.8
	BL	23FEB95	1, .	0	90	58	72	100	60	92	99.00	
	1	02MAR95	8, .	0	110	60	84	106	60	100	95.00	
	2	09MAR95	15, .	0	100	54	82	102	60	88	96.50	
	3	16MAR95	22, .	0	104	60	76	110	70	84	95.70	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.001.00071	4	23MAR95	29, .	0	106	64	74	100	60	88	96.50	
	5	30MAR95	36, .	0	110	70	76	100	60	78	96.00	
	6	06APR95	43, .	0	104	64	96	100	80	100	98.00	
	7	13APR95	50, .	0	100	60	82	100	70	96	97.50	
	8	20APR95	57, .	0	100	60	72	106	68	76	97.50	
329.001.00123	SC	14DEC95	-21, .	0	122	68	64	120	70	84	183.00	69.3
	BL	04JAN96	1, .	0	108	72	64	110	70	78	185.00	
	1	12JAN96	9, .	0	112	70	80	110	70	100	185.50	
	2	18JAN96	15, .	0	104	64	82	108	70	68	184.00	
	3	25JAN96	22, .	0	100	60	78	102	70	80	182.75	
	4	01FEB96	29, .	0	120	70	66	116	70	80	186.50	
	5	08FEB96	36, .	0	106	62	68	114	72	70	187.00	
	6	15FEB96	43, .	0	120	70	62	110	68	92	187.50	
	7	22FEB96	50, .	0	102	68	66	90	60	96	184.00	
329.001.00207	SC	19FEB96	-9, .	0	120	76	76	116	72	80	217.00	70.5
	BL	28FEB96	1, .	0	118	70	72	120	78	80	215.00	
	1	06MAR96	8, .	0	120	78	84	120	76	98	220.00	
	2	13MAR96	15, .	0	116	70	92	124	80	100	220.00	
	3	20MAR96	22, .	0	122	76	84	118	82	92	217.50	
	4	26MAR96	28, .	0	112	62	80	116	70	90	217.50	
	5	03APR96	36, .	0	122	74	88	118	78	96	214.00	
	6	10APR96	43, .	0	122	80	88	116	82	96	217.50	
	7	17APR96	50, .	0	116	70	88	114	80	94	220.00	
	8	24APR96	57, .	0	114	72	84	118	78	94	213.50	
329.002.00049	SC	03MAR95	-6, .	0	110	65	64	110	80	96	210.00	75.0
	BL	08MAR95	-1, .	0	110	60	80	110	75	104	211.00	
	1	15MAR95	7, .	0	130	65	88	125	70	100	211.50	
	2	22MAR95	14, .	0	115	60	84	115	70	96	211.00	
	3	29MAR95	21, .	0	100	65	68	100	70	92	210.00	
	4	05APR95	28, .	0	100	70	72	100	70	84	211.00	
	5	12APR95	35, .	0	110	65	76	100	75	96	210.50	
	6	19APR95	42, .	0	100	68	82	112	68	105	212.56	
	7	27APR95	50, .	0	110	60	80	100	70	104	208.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00049	8	05MAY95	58, .	0	115	61	81	115	65	106	210.36	
329.002.00059	SC	03NOV94	-7, .	0	90	60	72	100	70	88	124.00	71.0
	BL	10NOV94	1, .	0	102	64	80	94	60	88	123.50	
	1	17NOV94	8, .	0	100	72	88	98	68	112	125.00	
	2	23NOV94	14, .	0	102	60	72	90	60	96	126.00	
	3	01DEC94	22, .	0	90	60	80	110	60	100	126.00	
	4	08DEC94	29, .	0	92	52	80	98	60	96	124.00	
	5	15DEC94	36, .	0	100	68	86	98	60	92	125.00	
	6	22DEC94	43, .	0	106	66	88	108	70	80	126.00	
	7	29DEC94	50, .	0	90	60	84	102	78	92	125.00	
	8	05JAN95	57, .	0	104	60	88	100	60	92	124.00	
329.002.00060	BL	31JAN95	1, -56	0	108	74	88	112	76	88	117.00	64.0
	1	07FEB95	8, -49	0	92	50	88	92	54	84	120.00	
	2	14FEB95	15, -42	0	90	60	80	90	62	80	119.00	
	3	21FEB95	22, -35	0	90	68	80	90	68	80	117.50	
	4	28FEB95	29, -28	0	96	64	84	92	64	84	118.00	
	5	07MAR95	36, -21	0	88	56	80	70 L	58	84	117.70	
	6	14MAR95	43, -14	0	110	64	84	106	64	82	120.00	
	7	21MAR95	50, -7	0	110	70	100	102	70	100	120.50	
	8	28MAR95	57, 1	0	104	64	74	94	60	74	120.20	
	12	25APR95	85, 29	0	100	62	90	100	60	90	117.30	
329.002.00097	SC	20DEC94	-14, -72	0	104	64	83	100	64	89	122.00	60.0
	1	10JAN95	8, -51	0	110	65	80	108	55	88	123.00	
	2	18JAN95	16, -43	0	100	64	100	106	68	106	123.00	
	3	24JAN95	22, -37	0	102	62	84	106	64	86	121.30	
	4	31JAN95	29, -30	0	104	60	84	100	60	90	122.75	
	5	07FEB95	36, -23	0	118	72	64	116	70	66	124.50	
	6	14FEB95	43, -16	0	118	80	72	115	78	84	123.50	
	7	21FEB95	50, -9	0	118	80	72	114	77	83	122.00	
	8	02MAR95	59, 1	0	104	70	70	100	70	70	124.00	
	12	30MAR95	87, 29	0	114	72	80	112	70	72	124.75	
	16	27APR95	115, 57	0	104	66	67	106	66	76	126.50	
	20	23MAY95	141, 83	0	114	70	78	114	70	98	126.25	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00097	24	29JUN95	178, 120	0	110	68	76	106	64	78	128.00	
	28	01AUG95	211, 153	0	110	70	90	108	66	96	133.00 H	
	32	05SEP95	246, 188	0	100	68	74	92	66	70	131.00 H	
329.002.00101	BL	20MAR95	-8, -66	0	.	.	.	.	.	.		68.0
	BL	28MAR95	1, -58	0	116	78	84	114	78	80	147.00	
	1	04APR95	8, -51	0	124	76	100	122	72	88	149.00	
	2	13APR95	17, -42	0	122	78	84	124	80	96	147.00	
	3	20APR95	24, -35	0	122	70	68	120	72	66	150.20	
	4	27APR95	31, -28	0	110	80	64	102	80	68	150.50	
	5	04MAY95	38, -21	0	122	70	86	110	70	100	152.70	
	6	11MAY95	45, -14	0	122	68	60	118	66	88	149.00	
	7	18MAY95	52, -7	0	102	64	60	100	60	68	150.00	
	8	25MAY95	59, 1	0	98	72	64	90	68	61	150.00	
	12	22JUN95	87, 29	0	108	60	88	102	60	88	145.20	
	12	27JUN95	92, 34	0	108	66	88	102	60	88	145.20	
329.002.00107	SC	18JAN96	-7, -63	0	112	74	70	110	72	68	167.00	65.0
	1	01FEB96	8, -49	0	108	78	66	106	76	60	172.00	
	2	08FEB96	15, -42	0	110	76	64	106	72	62	174.00	
	3	13FEB96	20, -37	0	108	74	64	110	76	80	173.00	
	4	20FEB96	27, -30	0	110	68	68	104	70	62	174.50	
	5	27FEB96	34, -23	0	106	70	66	100	66	62	174.00	
	6	05MAR96	41, -16	0	114	74	70	110	72	68	179.00 H	
	7	15MAR96	51, -6	0	106	72	64	104	70	64	179.50 H	
	8	21MAR96	57, 1	0	94	72	70	92	68	92	178.00	
	12	23APR96	90, 34	0	104	68	60	110	76	64	178.00	
	16	21MAY96	118, 62	0	106	64	64	100	68	78	177.00	
	20	20JUN96	148, 92	0	110	62	48	104	64	70	167.00	
	24	18JUL96	176, 120	0	110	62	60	100	60	62	162.00	
	32	29AUG96	218, 162	0	108	64	62	104	64	70	157.00	
	32	26SEP96	246, 190	0	100	62	60	94	60	78	156.00	
329.002.00241	SC	25JAN96	-12, -68	0	110	70	66	106	70	80	202.00	69.0
	BL	06FEB96	1, -56	0	110	72	64	110	70	80	202.00	
	1	13FEB96	8, -49	0	108	60	60	110	70	70	205.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00241	2	22FEB96	17, -40	0	110	60	62	108	60	66	205.00	
	3	27FEB96	22, -35	0	112	78	64	106	74	72	202.00	
	4	05MAR96	29, -28	0	110	70	62	104	68	60	205.00	
	5	12MAR96	36, -21	0	120	68	60	114	70	58	205.00	
	6	19MAR96	43, -14	0	120	64	64	112	60	68	205.00	
	7	26MAR96	50, -7	0	122	70	70	120	72	62	204.00	
	8	02APR96	57, 1	0	110	64	64	108	68	72	199.00	
	12	30APR96	85, 29	0	106	60	60	100	62	61	207.00	
329.002.00246	SC	01APR96	-17, .	0	126	74	62	120	70	66	190.00	61.0
	1	25APR96	8, .	0	122	68	72	120	64	66	191.00	
	2	02MAY96	15, .	0	122	66	72	120	68	80	187.00	
	3	09MAY96	22, .	0	104	64	76	100	60	72	189.00	
	4	16MAY96	29, .	0	108	85	88	115	88	95	189.50	
	5	23MAY96	36, .	0	110	80	70	118	78	88	189.00	
	6	30MAY96	43, .	0	108	62	88	110	66	88	194.00	
	7	04JUN96	48, .	0	102	64	88	98	62	90	191.00	
	8	18JUN96	62, .	0	130	70	74	124	72	86	194.00	
329.002.00320	BL	16MAY96	1, -61	0	94	62	96	78	60	115	154.00	
	1	23MAY96	8, -54	0	96	60	84	90	58	92	154.50	
	2	30MAY96	15, -47	0	106	62	68	90	60	72	155.50	
	3	04JUN96	20, -42	0	98	64	64	100	68	70	154.50	
	5	18JUN96	34, -28	0	122	70	68	120	74	64	155.00	
	6	25JUN96	41, -21	0	98	62	100	96	64	116	156.25	
	7	02JUL96	48, -14	0	120	64	80	116	66	102	158.00	
	8	09JUL96	55, -7	0	108	70	75	106	72	86	160.00	
	8	16JUL96	62, 1	0	108	70	84	110	74	100	160.00	
	12	13AUG96	90, 29	0	110	70	66	108	68	88	160.00	
	16	17SEP96	125, 64	0	92	70	80	90	68	86	159.40	
329.002.00323	SC	04NOV96	-8, -66	0	92	68	84	90	64	90	118.00	63.0
	BL	12NOV96	1, -58	0	92	68	84	90	64	90	118.00	
	1	19NOV96	8, -51	0	94	66	88	98	64	80	117.00	
	2	26NOV96	15, -44	0	102	78	84	100	78	78	109.00 L	
	3	05DEC96	24, -35	0	96	70	80	94	66	82	112.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.002.00323	4	10DEC96	29, -30	0	100	68	66	96	66	64	112.00	
	5	17DEC96	36, -23	0	98	60	90	94	62	84	114.00	
	6	26DEC96	45, -14	0	88	66	74	88	64	76	112.00	
	7	02JAN97	52, -7	0	102	72	80	104	60	84	112.00	
	8	09JAN97	59, 1	0	100	68	74	100	66	80	114.50	
	12	04FEB97	85, 27	0	102	64	74	102	60	84	116.00	
	16	04MAR97	113, 55	0	108	68	84	104	66	88	118.00	
	20	03APR97	143, 85	0	108	62	100	112	70	106	120.00	
	24	30APR97	170, 112	0	116	58	82	116	58	92	119.00	
	28	27MAY97	197, 139	0	110	70	72	110	80	100	118.50	
	32	12JUN97	213, 155	0	110	80	76	105	75	76	114.00	
329.003.00074	SC	18JAN95	-7, -63	0	110	66	76	106	58	76	91.07	61.4
	BL	25JAN95	1, -56	0	104	86	75	98	78	90	94.20	
	1	01FEB95	8, -49	0	110	76	72	108	80	82	95.48	
	2	08FEB95	15, -42	0	110	84	84	110	70	96	94.82	
	3	15FEB95	22, -35	0	100	70	76	100	78	88	95.70	
	4	21FEB95	28, -29	0	102	78	88	102	80	117	95.48	
	5	01MAR95	36, -21	0	100	72	76	110	66	84	96.36	
	7	15MAR95	50, -7	0	110	86	76	104	88	98	97.02	
	8	22MAR95	57, 1	0	104	74	68	100	78	92	96.80	
	12	19APR95	85, 29	0	106	76	72	92	70	104	98.34	
	16	17MAY95	113, 57	0	94	66	80	98	72	78	98.34	
	20	19JUN95	146, 90	0	100	72	60	94	76	80	97.46	
	24	24JUL95	181, 125	0	104	74	85	100	76	104	101.65 H	
	32	30AUG95	218, 162	0	108	74	68	96	70	88	103.19 H	
	32	11OCT95	260, 204	0	90	70	96	100	76	100	102.53 H	
329.003.00078	SC	11APR95	-15, .	0	110	65	72	110	65	72	195.00	68.5
	BL	26APR95	1, .	0	120	75	80	.	.	.	198.00	
	1	02MAY95	7, .	0	110	78	80	105	75	90	198.00	
	2	10MAY95	15, .	0	110	70	80	120	80	84	200.00	
	3	17MAY95	22, .	0	118	70	80	110	80	88	195.50	
	4	24MAY95	29, .	0	122	76	80	114	80	88	194.00	
	5	30MAY95	35, .	0	120	80	82	110	78	88	196.00	
	6	07JUN95	43, .	0	118	68	82	110	76	84	192.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00078	7	15JUN95	51, .	0	110	80	90	112	80	78	192.00	
	8	21JUN95	57, .	0	112	80	80	110	84	84	196.00	
329.003.00080	SC	22NOV95	-5, .	0	110	70	68	124	62	84	177.94	62.6
	1	04DEC95	8, .	0	122	72	80	110	80	96	178.61	
	1	07DEC95	11, .	0	124	64	94	120	62	100	179.27	
	3	18DEC95	22, .	0	114	58	88	110	66	100	177.50	
	5	29DEC95	33, .	0	134	48 L	98	112	60	106	181.03	
	5	04JAN96	39, .	0	128	58	86	126	74	90	179.05	
	6	10JAN96	45, .	0	122	58	82	110	48	88	179.71	
	7	17JAN96	52, .	0	122	68	82	120	74	100	181.47	
	8	24JAN96	59, .	0	120	64	102	110	60	112	179.27	
329.003.00085	SC	26OCT94	-13, .	0	110	70	110	100	80	120	199.00	63.8
	BL	07NOV94	-1, .	0	90	60	96	90	60	96	207.50	
	1	14NOV94	7, .	0	98	58	104	.	.	104	204.50	
	2	21NOV94	14, .	0	110	70	100	110	70	100	203.00	
	3	28NOV94	21, .	0	110	80	100	106	80	100	206.00	
	4	05DEC94	28, .	0	110	70	104	110	70	104	208.00	
	5	12DEC94	35, .	0	108	74	96	108	74	96	209.00	
	6	19DEC94	42, .	0	110	70	96	110	72	96	203.00	
	7	27DEC94	50, .	0	110	76	92	112	76	92	205.00	
	8	03JAN95	57, .	0	130	86	100	120	86	100	207.50	
329.003.00086	SC	09NOV94	-19, -76	0	127	70	71	123	76	78	93.70	58.0
	BL	21NOV94	-7, -64	0	78	54	64	78	54	64	100.00	
	1	05DEC94	8, -50	0	92	60	72	90	60	72	96.00	
	2	12DEC94	15, -43	0	88	62	72	88	62	76	96.00	
	3	19DEC94	22, -36	0	84	56	80	84	56	84	97.50	
	4	27DEC94	30, -28	0	76	48	72	76	48	72	97.00	
	5	03JAN95	37, -21	0	86	50	88	86	50	84	97.00	
	6	09JAN95	43, -15	0	86	56	70	86	56	70	96.50	
	7	17JAN95	51, -7	0	90	58	84	90	58	84	98.50	
	8	23JAN95	57, -1	0	84	56	72	84	56	76	98.00	
	12	13FEB95	78, 21	0	84	56	80	84	56	80	98.00	
	16	28MAR95	121, 64	0	86	54	72	86	54	72	100.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00086	20	25APR95	149, 92	0	84	54	80	84	54	80	100.00	
	28	30MAY95	184, 127	0	80	50	84	80	50	84	100.50	
	32	11JUL95	226, 169	0	82	52	84	80	50	84	100.00	
	32	17AUG95	263, 206	0	84	52	84	80	52	84	95.00	
329.003.00094	SC	20OCT95	-4, .	0	108	62	.	100	70	70	112.00	64.5
	BL	24OCT95	1, .	0	110	20	84	110	70	84	118.00	
	1	31OCT95	8, .	0	116	74	108	116	74	108	113.00	
	2	07NOV95	15, .	0	110	70	88	110	70	84	111.00	
	3	14NOV95	22, .	0	114	78	84	114	78	84	111.50	
	4	21NOV95	29, .	0	110	70	84	110	70	84	112.00	
	5	28NOV95	36, .	0	112	74	104	112	74	104	113.00	
	6	05DEC95	43, .	0	114	74	84	114	74	84	111.00	
	7	12DEC95	50, .	0	100	64	96	100	64	96	110.50	
	8	19DEC95	57, .	0	100	66	96	100	66	96	111.00	
329.003.00251	SC	19MAR96	-9, .	0	120	80	60	120	90	61	124.50	61.0
	1	04APR96	8, .	0	110	70	96	100	66	96	130.00	
	2	09APR96	13, .	0	112	64	96	106	56	96	131.00	
329.003.00252	SC	19MAR96	-22, .	0	100	68	68	100	64	66	106.00	66.5
	BL	09APR96	-1, .	0	100	60	88	100	60	88	109.00	
	1	16APR96	7, .	0	102	58	96	100	58	96	113.00	
	2	23APR96	14, .	0	90	56	.	100	56	104	113.00	
	3	30APR96	21, .	0	102	54	100	100	54	100	113.00	
	4	09MAY96	30, .	0	98	54	96	96	54	96	114.00	
	5	14MAY96	35, .	0	100	56	96	100	56	96	114.00	
	6	21MAY96	42, .	0	102	56	84	102	56	84	113.00	
	7	28MAY96	49, .	0	100	60	84	100	60	84	113.00	
	8	04JUN96	56, .	0	100	60	96	100	60	96	112.00	
329.003.00291	SC	01JUL96	-2, -67	0	100	58	84	102	60	84	101.65	62.2
	BL	03JUL96	1, -65	0	97	75	66	97	64	70		
	2	15JUL96	13, -53	0	109	68	84	105	64	96	102.53	
	3	24JUL96	22, -44	0	110	62	80	102	64	88	101.43	
	4	31JUL96	29, -37	0	108	56	92	104	58	92	103.19	

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Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.003.00291	5	07AUG96	36, -30	0	112	64	78	108	66	86	102.75	
	6	14AUG96	43, -23	0	108	60	86	100	62	104	102.09	
	7	21AUG96	50, -16	0	110	70	78	110	65	92	102.53	
	8	28AUG96	57, -9	0	102	62	84	108	58	90	102.75	
	8	04SEP96	64, -2	0	104	58	92	104	62	98	103.19	
	12	02OCT96	92, 27	0	104	60	92	108	62	98	100.99	
	16	30OCT96	120, 55	0	106	60	90	108	70	90	102.31	
329.003.00315	BL	05NOV96	-7, .	0	110	70	84	110	70	84	177.00	
	SC	12NOV96	1, .	0	112	62	80	110	68	84	173.00	65.0
	1	21NOV96	10, .	0	120	80	96	120	80	96	178.00	
	2	26NOV96	15, .	0	116	80	96	116	80	96	178.00	
	3	03DEC96	22, .	0	130	84	84	130	84	84	181.00	
	4	12DEC96	31, .	0	120	84	84	120	84	84	182.00	
	5	17DEC96	36, .	0	120	76	84	120	76	84	182.00	
	6	23DEC96	42, .	0	126	80	80	120	80	80	185.00	
	8	07JAN97	57, .	0	120	80	78	100	80	78	187.00	
329.003.00316	SC	05DEC96	-12, .	0	110	70	.	.	.	.	135.00	65.8
	BL	17DEC96	1, .	0	96	62	96	96	62	96	135.00	
	1	23DEC96	7, .	0	110	70	80	110	70	90	138.00	
	3	07JAN97	22, .	0	100	70	80	100	70	88	136.50	
	4	14JAN97	29, .	0	104	64	96	104	64	96	138.00	
	5	21JAN97	36, .	0	100	66	96	100	66	96	140.00	
	6	28JAN97	43, .	0	96	66	84	96	66	84	140.00	
	7	04FEB97	50, .	0	106	70	84	106	70	84	138.00	
	8	11FEB97	57, .	0	110	70	84	100	70	84	140.00	
329.004.00016	SC	01MAR95	-12, .	0	104	60	64	98	74	68	155.45	68.5
	BL	13MAR95	1, .	0	104	80	72	108	84	80	155.45	
	1	20MAR95	8, .	0	108	72	72	108	76	72	157.66	
	2	29MAR95	17, .	0	110	60	78	120	70	84	158.76	
	3	05APR95	24, .	0	112	72	80	114	84	80	157.66	
	4	12APR95	31, .	0	100	60	70	110	78	78	158.98	
	5	19APR95	38, .	0	110	68	84	110	70	84	159.20	

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\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.004.00018	SC	19APR95	-14, .	0	125	75	88	125	75	88	126.79	64.2
	BL	03MAY95	1, .	0	120	70	70	120	70	72	126.79	
	1	11MAY95	9, .	0	100	60	70	100	60	84	127.89	
	2	18MAY95	16, .	0	100	60	80	100	60	84	127.89	
	3	25MAY95	23, .	0	110	70	90	110	70	98	127.23	
	4	01JUN95	30, .	0	120	70	104	118	70	108	126.35	
	5	08JUN95	37, .	0	100	60	72	110	70	84	126.79	
	7	19JUN95	48, .	0	118	70	68	120	70	78	126.13	
	7	22JUN95	51, .	0	100	70	84	120	70	96	124.14	
	8	29JUN95	58, .	0	140	84	90	145	90	100	127.01	
329.004.00020	SC	02NOV95	-7, .	0	90	60	72	100	60	80	110.47	62.6
	BL	09NOV95	1, .	0	90	60	70	90	60	74	110.25	
	1	16NOV95	8, .	0	90	64	78	98	70	80	109.15	
	2	24NOV95	16, .	0	90	60	60	90	60	78	109.15	
329.004.00213	SC	18JUL96	-15, -69	0	98	78	90	110	98	100	191.17	63.8
	BL	01AUG96	-1, -55	0	100	70	74	110	78	80	190.73	
	1	08AUG96	7, -48	0	100	70	88	110	78	90	192.94	
	2	15AUG96	14, -41	0	100	60	84	110	78	90	194.04	
	3	21AUG96	20, -35	0	110	70	64	110	80	88	193.60	
	4	29AUG96	28, -27	0	124	64	92	110	68	100	196.25	
	5	03SEP96	33, -22	0	110	80	90	120	88	104	197.79	
	6	10SEP96	40, -15	0	120	88	80	110	70	90	195.36	
	7	17SEP96	47, -8	0	110	70	104	120	80	120	195.80	
	8	24SEP96	54, -1	0	120	70	84	120	80	100	196.25	
	12	22OCT96	82, 28	0	110	70	120	100	60	120	191.84	
	16	19NOV96	110, 56	0	120	70	80	110	70	84	196.25	
	20	20DEC96	141, 87	0	130	70	84	120	70	90	193.82	
	24	21JAN97	173, 119	0	120	66	84	116	70	88	198.01	
	28	18FEB97	201, 147	0	120	58	84	110	60	80	196.69	
	32	19MAR97	230, 176	0	115	60	68	114	58	76	195.58	
329.005.00001	SC	11APR94	-9, .	0	110	70	105	108	72	108	125.00	67.0
	BL	20APR94	1, .	0	114	80	92	110	78	96	125.91	
	1	27APR94	8, .	0	100	60	96	92	60	106	122.82	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00001	2	04MAY94	15, .	0	108	60	90	108	80	94	123.92	
	3	11MAY94	22, .	0	126	78	92	124	88	96	123.92	
	4	18MAY94	29, .	0	120	80	96	118	80	90	124.80	
	5	25MAY94	36, .	0	124	78	84	124	78	96	124.80	
	6	01JUN94	43, .	0	122	62	98	118	70	92	124.80	
	7	08JUN94	50, .	0	118	68	80	110	68	92	126.35	
	8	15JUN94	57, .	0	102	60	92	118	78	98	125.02	
329.005.00005	SC	24OCT94	-8, .	0	100	64	80	100	60	88	111.57	60.5
	BL	01NOV94	1, .	0	98	58	88	104	68	88	114.66	
	1	08NOV94	8, .	0	104	66	98	108	62	136 H	114.00	
329.005.00010	SC	07DEC94	-6, -63	0	100	72	68	94	60	72	121.00	69.0
	BL	13DEC94	1, -57	0	100	60	68	110	68	70	121.00	
	1	20DEC94	8, -50	0	100	70	78	100	70	78	120.00	
	2	27DEC94	15, -43	0	100	68	88	110	70	88	119.00	
	3	04JAN95	23, -35	0	100	60	76	90	60	78	122.16	
	4	11JAN95	30, -28	0	104	70	76	100	60	80	123.04	
	5	18JAN95	37, -21	0	102	70	72	110	70	72	123.70	
	6	25JAN95	44, -14	0	90	60	70	100	70	74	120.39	
	7	02FEB95	52, -6	0	104	60	74	90	60	76	121.00	
	8	08FEB95	58, 1	0	100	70	76	90	60	76	121.50	
	12	10MAR95	88, 31	0	90	60	76	94	60	78	123.00	
	16	13APR95	122, 65	0	100	70	80	90	64	84	120.70	
	20	10MAY95	149, 92	0	90	60	72	88	58	74	123.00	
	24	06JUN95	176, 119	0	100	60	70	100	58	76	120.39	
	32	12JUL95	212, 155	0	100	60	70	90	60	76	118.63	
	32	09AUG95	240, 183	0	80	60	72	80 L	60	78	120.50	
329.005.00012	SC	12DEC94	-7, -66	0	110	74	80	110	70	84	145.50	69.0
	BL	19DEC94	1, -59	0	100	70	84	110	70	88	145.00	
	1	27DEC94	9, -51	0	110	70	88	112	72	92	144.00	
	2	05JAN95	18, -42	0	120	80	92	118	70	94	143.50	
	3	12JAN95	25, -35	0	94	68	68	100	70	72	143.50	
	4	18JAN95	31, -29	0	118	74	72	100	70	74	144.00	
	5	25JAN95	38, -22	0	110	70	60	108	72	64	142.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00012	6	31JAN95	44, -16	0	112	70	60	120	82	64	140.10	
	7	08FEB95	52, -8	0	112	70	68	112	80	72	140.00	
	8	16FEB95	60, 1	0	110	60	78	100	60	80	145.00	
	12	27MAR95	99, 40	0	120	80	80	110	78	84	146.00	
	20	04MAY95	137, 78	0	110	64	64	100	70	68	149.30	
	24	31MAY95	164, 105	0	110	80	60	100	82	64	147.74	
329.005.00111	SC	05JAN95	-6, -62	0	94	64	84	100	70	88	132.50	65.0
	BL	11JAN95	1, -56	0	90	60	88	94	60	92	132.00	
	1	18JAN95	8, -49	0	100	68	92	120	70	98	132.00	
	2	25JAN95	15, -42	0	98	60	76	110	80	80	134.70	
	3	01FEB95	22, -35	0	90	60	72	98	70	74	132.20	
	4	08FEB95	29, -28	0	108	70	88	90	68	88	130.50	
	5	15FEB95	36, -21	0	90	60	72	84	60	72	133.50	
	6	22FEB95	43, -14	0	100	70	76	94	70	76	132.00	
	7	01MAR95	50, -7	0	110	70	70	90	60	90	132.50	
	8	08MAR95	57, 1	0	110	70	80	100	70	84	129.00	
	12	05APR95	85, 29	0	90	60	80	104	64	76	129.87	
	12	19APR95	99, 43	0	94	68	80	90	60	80	128.00	
	16	03MAY95	113, 57	0	90	68	80	90	60	84	128.50	
329.005.00114	SC	23JAN95	-8, -65	0	112	70	68	108	72	72	145.20	70.0
	BL	31JAN95	1, -57	0	80	60	72	70	50	72	145.00	
	1	07FEB95	8, -50	0	108	62	80	102	62	88	153.50	
	2	14FEB95	15, -43	0	110	80	60	90	70	64	154.50	
	3	21FEB95	22, -36	0	100	70	58	104	70	60	155.89 H	
	4	28FEB95	29, -29	0	110	70	70	90	60	72	157.00 H	
	5	09MAR95	38, -20	0	100	70	80	90	64	80	157.00 H	
	6	15MAR95	44, -14	0	104	80	80	100	70	84	155.00	
	7	22MAR95	51, -7	0	104	70	60	90	70	64	154.50	
	8	29MAR95	58, 1	0	100	70	68	92	70	72	153.00	
	12	26APR95	86, 29	0	90	60	70	98	68	74	155.10	
	16	17MAY95	107, 50	0	104	70	72	100	70	74	155.50 H	
329.005.00115	SC	27JAN95	-10, -81	0	118	76	78	110	74	82	144.00	64.0
	BL	06FEB95	1, -71	0	120	70	84	118	60	88	143.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00115	1	13FEB95	8, -64	0	104	70	80	110	70	84	143.70	
	2	20FEB95	15, -57	0	120	70	88	110	68	92	142.22	
	3	02MAR95	25, -47	0	124	80	88	118	70	88	146.00	
	5	10MAR95	33, -39	0	120	76	80	112	70	84	144.00	
	6	17MAR95	40, -32	0	112	70	76	110	64	80	144.70	
	7	28MAR95	51, -21	0	106	70	84	118	80	94	145.00	
	8	10APR95	64, -8	0	116	78	60	120	70	60	152.00	
	8	18APR95	72, 1	0	110	54	76	110	60	82	140.00	
	12	27APR95	81, 10	0	114	70	68	110	68	74	141.00	
329.005.00120	SC	22AUG95	-8, .	0	124	60	96	120	60	98	152.00	61.5
	BL	30AUG95	1, .	0	110	72	72	106	66	80	152.15	
	1	07SEP95	9, .	0	104	62	68	108	66	84	155.23	
	2	14SEP95	16, .	0	112	66	80	108	66	84	159.20	
	3	21SEP95	23, .	0	116	72	84	114	70	88	160.52	
	4	28SEP95	30, .	0	116	68	84	110	66	88	159.86	
	5	05OCT95	37, .	0	108	72	68	104	68	68	162.51	
	6	12OCT95	44, .	0	116	66	68	114	68	72	162.51	
	7	19OCT95	51, .	0	122	68	72	116	66	76	164.71 H	
	8	26OCT95	58, .	0	120	64	88	116	68	80	166.04 H	
329.005.00253	SC	31JAN96	-8, .	0	106	62	72	102	60	80	133.40	63.0
	BL	08FEB96	1, .	0	96	68	72	94	66	78	133.62	
	1	14FEB96	7, .	0	122	72	76	118	70	88	133.18	
	2	21FEB96	14, .	0	118	64	96	108	62	108	133.84	
	3	28FEB96	21, .	0	120	76	80	110	76	104	132.30	
	4	06MAR96	28, .	0	108	72	72	106	72	80	132.74	
	5	14MAR96	36, .	0	118	72	84	116	70	96	134.51	
	6	20MAR96	42, .	0	104	66	88	102	62	92	133.84	
	7	28MAR96	50, .	0	104	68	80	100	60	100	133.84	
	8	03APR96	56, .	0	112	66	76	106	62	88	129.00	
329.005.00254	SC	08FEB96	-7, -62	0	94	72	76	90	68	84	130.00	67.0
	BL	14FEB96	-1, -56	0	82	60	80	80	60	80	126.00	
	1	21FEB96	7, -49	0	104	68	80	90	60	76	130.00	
	2	28FEB96	14, -42	0	90	60	80	100	70	84	128.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00254	3	06MAR96	21, -35	0	80	60	76	78	58	80	130.00	
	4	13MAR96	28, -28	0	88	60	76	80	64	76	127.00	
	5	20MAR96	35, -21	0	90	60	76	90	60	80	129.50	
	6	27MAR96	42, -14	0	90	60	76	94	60	80	129.50	
	7	03APR96	49, -7	0	98	70	80	98	68	80	128.00	
	8	10APR96	56, 1	0	90	60	80	88	60	80	128.00	
	12	22MAY96	98, 43	0	104	70	80	98	60	84	125.00	
	16	12JUN96	119, 64	0	102	70	80	90	70	80	122.20	
	20	10JUL96	147, 92	0	112	70	76	110	70	80	122.50	
	28	12SEP96	211, 156	0	94	70	74	90	60	80	129.00	
	32	16OCT96	245, 190	0	90	60	80	90	64	84	128.50	
329.005.00293	SC	06MAR97	-6, .	0	108	70	70	106	70	74	175.00	63.0
	BL	12MAR97	1, .	0	122	78	80	108	70	96	171.75	
	1	19MAR97	8, .	0	110	80	68	110	80	78	174.00	
	2	25MAR97	14, .	0	120	74	90	116	68	106	173.25	
	3	02APR97	22, .	0	120	80	92	110	70	100	173.25	
	4	09APR97	29, .	0	124	80	90	118	80	98	175.00	
	5	16APR97	36, .	0	120	84	80	110	80	90	174.00	
	6	23APR97	43, .	0	128	74	90	118	78	104	172.00	
	7	30APR97	50, .	0	120	82	94	126	76	102	174.50	
	8	07MAY97	57, .	0	120	70	90	120	82	100	172.50	
329.005.00298	SC	15MAY96	-7, -63	0	110	80	68	112	80	68	149.50	64.0
	BL	22MAY96	1, -56	0	118	80	74	112	80	76	147.70	
	1	30MAY96	9, -48	0	90	60	60	90	56	64	147.50	
	2	06JUN96	16, -41	0	118	80	60	114	80	60	146.20	
	3	12JUN96	22, -35	0	110	60	58	104	68	60	148.00	
	4	19JUN96	29, -28	0	98	60	60	94	60	60	147.70	
	5	26JUN96	36, -21	0	118	70	54	110	60	58	148.20	
	6	03JUL96	43, -14	0	116	74	56	112	72	60	148.70	
	7	10JUL96	50, -7	0	100	60	64	110	70	72	146.50	
	8	17JUL96	57, 1	0	104	64	60	90	60	62	147.70	
	16	19SEP96	121, 65	0	104	60	54	112	60	64	147.50	
	20	17OCT96	149, 93	0	90	64	60	90	60	60	148.00	
	24	14NOV96	177, 121	0	92	60	60	90	50	62	148.70	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.005.00298	28	12DEC96	205, 149	0	104	78	64	110	76	64	150.00	
	32	13JAN97	237, 181	0	100	60	60	100	60	64	149.00	
329.005.00331	SC	14NOV96	-7, .	0	100	70	84	90	70	88	163.00	66.0
	BL	21NOV96	1, .	0	90	60	84	90	60	88	162.50	
	1	27NOV96	7, .	0	120	70	88	112	70	100	164.70	
	2	04DEC96	14, .	0	110	70	84	104	70	88	164.00	
	3	12DEC96	22, .	0	100	70	88	110	74	84	164.00	
	4	19DEC96	29, .	0	104	70	92	112	70	96	163.00	
	6	02JAN97	43, .	0	124	80	80	120	70	84	166.70	
	7	10JAN97	51, .	0	100	64	80	90	60	84	162.00	
	8	16JAN97	57, .	0	100	70	74	90	60	80	162.50	
329.005.00334	SC	24JAN97	-7, .	0	112	70	72	100	70	76	174.00	63.0
	BL	29JAN97	-2, .	0	112	78	84	110	70	88	173.00	
	1	06FEB97	7, .	0	120	80	88	118	80	96	172.50	
	2	13FEB97	14, .	0	112	70	80	114	80	84	173.00	
	3	21FEB97	22, .	0	118	70	78	112	70	80	175.50	
	4	26FEB97	27, .	0	112	70	64	100	60	68	170.00	
	5	06MAR97	35, .	0	118	80	80	104	80	80	171.00	
	6	13MAR97	42, .	0	98	60	80	98	60	80	173.00	
	7	21MAR97	50, .	0	114	70	76	90	60	80	167.50	
	8	27MAR97	56, .	0	98	70	72	90	60	76	167.50	
329.006.00037	SC	20JAN95	-8, .	0	135	68	82	.	.	.	144.43	65.0
	BL	27JAN95	-1, .	0	128	70	88	132	70	92	144.43	
	1	03FEB95	7, .	0	125	78	85	.	.	.	144.43	
	2	13FEB95	17, .	0	120	76	84	120	70	72	142.22	
	4	22FEB95	26, .	0	110	80	72	130	70	78	142.22	
329.006.00042	SC	01DEC95	-6, -63	0	120	90	84	120	90	96	226.01	65.4
	BL	06DEC95	-1, -58	0	123	90	90	125	95	90		
	1	13DEC95	7, -51	0	120	80	96	120	85	120	233.00	
	2	20DEC95	14, -44	0	125	90	90	125	85	120	234.00	
	3	27DEC95	21, -37	0	125	85	80	120	80	110	235.00	
	4	03JAN96	28, -30	0	120	90	70	120	95	90	233.30	

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\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.006.00042	5	10JAN96	35, -23	0	120	90	78	120	90	78	237.40	
	6	17JAN96	42, -16	0	120	90	68	118	80	76	235.50	
	7	23JAN96	48, -10	0	120	90	65	120	94	80	235.00	
	8	02FEB96	58, 1	0	120	94	80	120	94	78	236.00	
	12	29FEB96	85, 28	0	120	90	78	118	90	90	236.50	
	16	26MAR96	111, 54	0	125	95	74	125	95	82	240.00	
	20	23APR96	139, 82	0	120	90	80	120	90	80	238.00	
	24	21MAY96	167, 110	0	120	85	62	120	85	60	242.00 H	
	28	18JUN96	195, 138	0	120	90	70	120	90	80	250.00 H	
	32	16JUL96	223, 166	0	125	85	74	120	80	90	248.00 H	
329.006.00259	SC	22APR96	-32, .	0	125	75	66	120	75	66	136.00	67.0
	BL	22MAY96	-2, .	0	120	70	78	110	70	110	132.00	
	1	30MAY96	7, .	0	110	70	66	118	84	78	131.00	
	2	06JUN96	14, .	0	125	70	78	120	75	68	132.00	
	3	13JUN96	21, .	0	120	70	60	113	70	94	130.00	
	4	20JUN96	28, .	0	110	70	72	110	75	80	128.50	
	5	27JUN96	35, .	0	115	75	60	115	70	76	128.50	
	6	03JUL96	41, .	0	120	80	66	115	80	70	128.00	
	7	10JUL96	48, .	0	120	70	68	115	70	90	128.50	
	8	17JUL96	55, .	0	115	70	60	118	70	60	130.00	
329.007.00141	SC	14SEP95	-7, .	0	128	78	76	124	80	80	181.00	66.0
	BL	21SEP95	1, .	0	128	78	81	126	80	87	183.00	
	1	28SEP95	8, .	0	128	70	80	122	76	84	184.00	
	2	05OCT95	15, .	0	128	78	72	126	80	68	184.00	
	3	12OCT95	22, .	0	126	82	80	122	84	76	185.00	
329.007.00144	SC	30NOV95	-7, -63	0	132	52	76	122	70	56	155.00	60.0
	BL	07DEC95	1, -56	0	120	70	72	110	70	80	158.00	
	1	14DEC95	8, -49	0	110	70	68	92	72	88	160.00	
	2	21DEC95	15, -42	0	136	64	76	112	56	88	162.00	
	3	28DEC95	22, -35	0	124	72	76	104	74	88	159.00	
	4	04JAN96	29, -28	0	128	70	80	124	76	76	160.00	
	5	11JAN96	36, -21	0	120	74	80	118	78	78	165.00	
	6	18JAN96	43, -14	0	126	70	68	120	74	72	168.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.007.00144	7	25JAN96	50, -7	0	128	82	72	126	84	80	165.00	
	8	01FEB96	57, 1	0	118	80	76	120	82	72	166.00	
329.007.00266	SC	29FEB96	-7, .	0	118	76	72	116	78	68	98.00	61.0
	BL	07MAR96	1, .	0	108	58	60	106	62	68	99.00	
	1	14MAR96	8, .	0	108	70	72	104	74	76	98.00	
	3	25MAR96	19, .	0	112	64	72	110	66	80	100.00	
	3	28MAR96	22, .	0	114	64	72	110	68	76	103.00	
	4	04APR96	29, .	0	110	74	76	108	76	80	103.00	
	5	11APR96	36, .	0	118	76	72	114	78	74	105.00	
	6	18APR96	43, .	0	112	64	68	110	70	72	103.00	
	8	29APR96	54, .	0	110	62	56	106	70	64	102.00	
	8	02MAY96	57, .	0	108	72	60	104	74	68	102.00	
329.007.00267	SC	29FEB96	-7, .	0	120	80	64	118	82	64	258.00	73.0
	BL	07MAR96	1, .	0	120	76	72	118	78	76	258.00	
	1	14MAR96	8, .	0	128	70	84	126	78	88	263.00	
	2	21MAR96	15, .	0	130	76	72	128	82	76	262.00	
	3	28MAR96	22, .	0	120	82	76	118	86	80	260.00	
	4	04APR96	29, .	0	132	86	80	130	88	88	257.00	
	5	11APR96	36, .	0	130	74	68	124	80	78	257.00	
	6	18APR96	43, .	0	120	78	68	118	82	72	257.00	
	7	25APR96	50, .	0	120	74	80	118	80	76	257.00	
	8	02MAY96	57, .	0	120	72	64	118	76	72	257.00	
329.007.00311	SC	26SEP96	-7, -67	0	102	75	69	123	72	68	118.00	65.0
	BL	03OCT96	1, -60	0	120	78	72	118	76	74	122.00	
	1	10OCT96	8, -53	0	120	78	74	118	74	78	120.00	
	2	17OCT96	15, -46	0	114	66	83	104	66	100	119.00	
	4	28OCT96	26, -35	0	120	74	72	122	76	68	121.00	
	4	31OCT96	29, -32	0	118	66	84	120	70	88	119.00	
	5	07NOV96	36, -25	0	116	72	72	118	78	76	123.00	
	6	14NOV96	43, -18	0	118	74	72	120	68	76	123.00	
	7	22NOV96	51, -10	0	110	74	60	118	76	64	123.00	
	8	02DEC96	61, 1	0	110	65	85	118	81	68	122.00	
	12	02JAN97	92, 32	0	123	57	73	114	62	81	127.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.007.00311	16	30JAN97	120, 60	0	118	59	66	122	66	73	127.00	
	24	13MAR97	162, 102	0	110	80	83	110	76	86	130.00	
	28	11APR97	191, 131	0	108	70	68	106	68	72	126.00	
329.008.00158	SC	06SEP95	-7, -69	0	110	92	76	110	92	96	156.00	62.0
	BL	13SEP95	1, -62	0	112	75	100	110	82	108		
	1	19SEP95	7, -56	0	118	82	96	105	90	100	158.30	
	2	27SEP95	15, -48	0	108	85	92	110	90	100	156.00	
	3	03OCT95	21, -42	0	112	75	76	110	82	92	158.00	
	4	10OCT95	28, -35	0	110	70	68	110	85	76	155.00	
	5	16OCT95	34, -29	0	112	80	84	120	85	104	156.00	
	6	24OCT95	42, -21	0	110	78	72	100	80	88	154.00	
	7	31OCT95	49, -14	0	110	84	72	104	90	96	154.00	
	8	14NOV95	63, 1	0	105	70	80	100	70	100	153.00	
	16	26DEC95	105, 43	0	110	80	72	110	85	100	156.00	
	20	23JAN96	133, 71#	0	108	78	68	110	80	80	155.00	
329.008.00162	SC	26OCT95	-6, -71	0	102	70	66	.	.	.	132.00	74.0
	1	10NOV95	10, -56	0	100	68	88	96	70	100		
	3	20NOV95	20, -46	0	100	70	76	110	75	84	134.00	
	4	29NOV95	29, -37	0	100	60	80	100	68	88	133.00	
	5	07DEC95	37, -29	0	100	58	76	100	60	88	132.00	
	6	14DEC95	44, -22	0	103	75	96	100	70	100	130.00	
	7	20DEC95	50, -16	0	90	58	56	95	70	76	133.00	
	8	27DEC95	57, -9	0	105	65	72	105	70	88	131.00	
	8	05JAN96	66, 1	0	100	55	68	90	60	88	137.00	
	16	09FEB96	101, 36	0	100	70	80	80	50	100	133.00	
	20	08MAR96	129, 64	0	90	62	68	90	65	84	136.00	
	24	01MAY96	183, 118	0	90	60	84	88	60	80	132.00	
	32	05JUN96	218, 153	0	110	55	76	90	60	88	132.00	
	32	02JUL96	245, 180	0	128	70	68	138	79	78	133.00	
329.008.00191	SC	12JAN96	-20, -81	0	104	74	67	.	.	.	119.00	60.0
	BL	01FEB96	1, -61	0	108	68	72	96	64	78	117.00	
	2	12FEB96	12, -50	0	108	72	78	96	66	86	119.00	
	3	20FEB96	20, -42	0	102	68	84	92	58	104	121.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.008.00191	4	27FEB96	27, -35	0	98	64	82	88	58	90	119.00	
	5	05MAR96	34, -28	0	102	68	72	98	58	78	119.00	
	6	12MAR96	41, -21	0	102	64	72	99	56	90	119.00	
	7	18MAR96	47, -15	0	102	70	90	94	64	94	119.00	
	8	26MAR96	55, -7	0	102	70	78	98	68	90	120.00	
	8	02APR96	62, 1	0	102	62	78	94	64	90	119.00	
	12	01MAY96	91, 30	0	94	60	84	90	60	90	121.00	
	16	05JUN96	126, 65	0	96	64	72	89	60	84	120.00	
329.009.00128	SC	05APR95	-6, .	0	121	65	91	84	74	101	114.88	62.2
	BL	11APR95	1, .	0	115	61	98	122	54	114	111.60	
	1	18APR95	8, .	0	123	66	98	107	68	96	111.50	
	2	25APR95	15, .	0	115	53	85	114	68	90	112.50	
329.009.00129	SC	22MAR95	-20, .	0	115	42	68	108	50	79	187.80	69.3
	BL	11APR95	1, .	0	131	53	64	130	49	68	189.50	
	1	18APR95	8, .	0	131	53	58	137	89	64	188.70	
	2	25APR95	15, .	0	115	54	64	123	57	64	186.70	
	3	02MAY95	22, .	0	114	57	67	123	60	69	189.40	
	4	09MAY95	29, .	0	106	40	59	108	56	75	187.50	
	5	16MAY95	36, .	0	123	49	57	115	49	65	190.07	
329.009.00135	SC	25SEP95	-7, .	0	113	74	89	122	60	100	133.60	71.0
	BL	02OCT95	1, .	0	113	63	78	.	.	.	131.60	
	1	09OCT95	8, .	0	118	56	83	124	59	91	132.70	
	2	16OCT95	15, .	0	119	60	80	121	70	88	131.70	
	3	23OCT95	22, .	0	123	56	86	122	56	88	133.90	
	4	30OCT95	29, .	0	122	64	74	122	56	80	132.40	
	5	06NOV95	36, .	0	107	82	86	123	68	105	133.50	
329.009.00136	SC	26SEP95	-7, .	0	131	56	109	105	72	115	287.60	66.5
	BL	03OCT95	1, .	0	119	76	102	124	66	115	299.60	
	1	10OCT95	8, .	0	132	57	81	84 L	63	114	296.40	
	2	17OCT95	15, .	0	124	48 L	90	102	73	117	288.90	
	3	24OCT95	22, .	0	101	50	86	114	56	115	292.80	
	4	03NOV95	32, .	0	109	54	54	117	67	86		

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00136	5	07NOV95	36, .	0	133	80	66	131	50	103	294.00	
	6	14NOV95	43, .	0	124	60	84	109	55	111	287.40	
	7	21NOV95	50, .	0	116	62	74	110	82	100	293.80	
	8	28NOV95	57, .	0	125	57	86	105	49	96	296.00	
329.009.00169	SC	25OCT95	-6, -71	0	110	57	70	110	69	67	80.90	56.0
	BL	31OCT95	1, -65	0	108	52	94	111	57	98	80.20	
	1	07NOV95	8, -58	0	92	42	74	99	45	90	80.40	
	2	14NOV95	15, -51	0	113	63	86	110	56	106	81.90	
	3	21NOV95	22, -44	0	110	53	80	106	53	79	83.40	
	4	28NOV95	29, -37	0	106	56	102	107	57	106	83.00	
	5	05DEC95	36, -30	0	119	54	74	112	61	75	83.30	
	6	12DEC95	43, -23	0	99	45	86	98	46	97	83.10	
	7	19DEC95	50, -16	0	108	57	84	99	57	95	84.10	
	8	27DEC95	58, -8	0	95	53	76	98	52	93	82.50	
	12	23JAN96	85, 20	0	122	68	108	107	44	111	86.20 H	
329.009.00174	SC	14NOV95	-7, -64	0	115	60	64	123	85	98	219.20	65.5
	BL	21NOV95	1, -57	0	132	74	91	124	66	105	219.60	
	1	28NOV95	8, -50	0	125	77	101	135	72	111	222.40	
	2	05DEC95	15, -43	0	145	89	84	158	84	105	218.90	
	3	12DEC95	22, -36	0	135	66	81	136	71	100	223.00	
	4	19DEC95	29, -29	0	129	79	106	137	67	114	222.40	
	5	27DEC95	37, -21	0	145	88	105	138	72	126	224.00	
	6	02JAN96	43, -15	0	123	68	80	147	78	86	224.10	
	7	09JAN96	50, -8	0	136	83	104	150	85	109	222.40	
	8	17JAN96	58, 1	0	138	83	108	149	76	104	220.40	
	12	31JAN96	72, 15	0	114	68	95	122	70	105	221.70	
329.009.00197	SC	20DEC95	-9, -63	0	118	54	88	110	59	115	99.40	58.0
	BL	29DEC95	1, -54	0	106	49	86	124	60	95	97.80	
	1	02JAN96	5, -50	0	92	40	72	101	55	86	98.60	
	1	08JAN96	11, -44	0	102	50	79	107	50	96	100.00	
	3	16JAN96	19, -36	0	100	38	71	97	49	81	99.60	
	4	23JAN96	26, -29	0	94	43	81	100	46	83	101.60	
	5	30JAN96	33, -22	0	115	68	81	116	49	105	100.30	

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\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00197	6	06FEB96	40, -15	0	82	47	96	86 L	53	100	99.70	
	7	13FEB96	47, -8	0	89	40	75	90	52	84	98.80	
	8	20FEB96	54, -1	0	90	47	91	98	52	120	99.10	
	12	19MAR96	82, 28	0	100	49	83	107	42	95	100.00	
	16	23APR96	117, 63	0	99	53	71	99	57	94	99.60	
	20	21MAY96	145, 91	0	97	63	76	83 L	61	90	102.30	
	24	25JUN96	180, 126	0	114	61	98	112	63	112	106.94 H	
	28	16JUL96	201, 147	0	106	53	93	105	52	100	107.40 H	
	32	20AUG96	236, 182	0	103	44	89	98	62	84	109.20 H	
329.009.00198	SC	19DEC95	-14, .	0	116	66	86	123	68	94	103.00	61.5
	BL	02JAN96	1, .	0	112	63	91	115	66	95	103.90	
	1	08JAN96	7, .	0	113	67	91	108	65	93	102.80	
	2	16JAN96	15, .	0	107	57	81	105	59	88	105.60	
	3	23JAN96	22, .	0	108	65	80	115	64	81	105.90	
	4	30JAN96	29, .	0	131	65	94	124	64	115	104.50	
	5	06FEB96	36, .	0	97	50	86	106	48	105	104.60	
	6	13FEB96	43, .	0	132	70	91	126	75	90	105.10	
	7	20FEB96	50, .	0	99	52	76	99	53	97	105.00	
	8	27FEB96	57, .	0	106	59	86	106	57	88	105.70	
329.009.00200	SC	17JAN96	-6, .	0	115	76	70	121	79	74	118.20	62.0
	BL	23JAN96	1, .	0	122	72	81	.	.	.	121.40	
	1	02FEB96	11, .	0	110	60	79	114	59	78	119.30	
	2	06FEB96	15, .	0	110	80	91	123	69	106	123.00	
	3	13FEB96	22, .	0	100	62	105	122	60	101	120.20	
	4	20FEB96	29, .	0	122	83	84	107	69	105	119.90	
	5	28FEB96	37, .	0	107	56	86	112	77	95	120.20	
329.009.00202	SC	14FEB96	-6, .	0	101	65	83	107	71	93	103.80	62.0
	BL	20FEB96	1, .	0	114	75	88	102	59	98	105.30	
	1	27FEB96	8, .	0	100	50	86	106	60	90	103.70	
	2	08MAR96	18, .	0	107	56	86	113	66	102	104.80	
	4	19MAR96	29, .	0	110	71	79	122	75	84	105.50	
	5	26MAR96	36, .	0	130	78	108	135	67	100	103.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00237	SC	04NOV96	-7, .	0	124	58	66	114	64	75	149.50	68.0
	BL	11NOV96	1, .	0	113	63	96	111	51	103	146.60	
	1	18NOV96	8, .	0	115	57	84	107	64	98	148.80	
329.009.00238	SC	28OCT96	-15, .	0	115	60	83	106	55	100	112.20	66.5
	BL	12NOV96	1, .	0	107	53	88	106	52	97	113.60	
	1	19NOV96	8, .	0	106	48	74	112	62	95	114.80	
	2	26NOV96	15, .	0	108	47	74	99	57	86	115.00	
	3	03DEC96	22, .	0	99	42	78	105	47	88	115.80	
	4	10DEC96	29, .	0	107	49	72	105	54	78	114.50	
	5	17DEC96	36, .	0	112	51	82	115	59	100	112.80	
	6	23DEC96	42, .	0	97	45	76	108	47	88	114.40	
	7	31DEC96	50, .	0	111	54	77	109	58	86	115.00	
	8	07JAN97	57, .	0	104	56	72	110	52	87	112.50	
329.009.00276	SC	17JAN97	-4, .	0	123	39	77	116	64	101	127.40	66.6
	BL	21JAN97	1, .	0	115	59	85	.	.	.	128.60	
	1	28JAN97	8, .	0	116	58	78	109	54	90	125.10	
	2	04FEB97	15, .	0	115	56	85	114	64	93	127.00	
	3	11FEB97	22, .	0	112	43	73	119	49	100	126.50	
	4	18FEB97	29, .	0	122	64	91	115	59	97	129.00	
	5	25FEB97	36, .	0	123	61	80	121	49	95	128.10	
	6	04MAR97	43, .	0	121	62	91	107	70	111	128.10	
	7	13MAR97	52, .	0	125	67	82	112	68	101	123.70	
	8	18MAR97	57, .	0	105	49	76	107	57	98	121.50	
329.009.00302	SC	20MAR96	-7, .	0	145	51	56	147	50	77	157.10	68.0
	BL	27MAR96	1, .	0	138	59	85	130	44	85	158.20	
	1	03APR96	8, .	0	122	50	64	123	43	84	157.10	
	2	10APR96	15, .	0	123	50	66	115	50	60	158.60	
329.009.00306	SC	03JUN96	-8, .	0	106	60	57	99	53	89	115.40	64.0
	BL	11JUN96	1, .	0	115	49	70	117	70	98	120.30	
	1	18JUN96	8, .	0	94	53	99	98	58	96	118.50	
	2	25JUN96	15, .	0	140	90	90	131	76	87	116.20	
	3	02JUL96	22, .	0	117	59	79	118	72	93	118.40	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.009.00306	4	09JUL96	29, .	0	114	66	78	92	60	100	117.60	
	5	16JUL96	36, .	0	104	55	85	114	58	94	117.20	
	6	23JUL96	43, .	0	110	55	79	107	67	98	118.60	
	7	30JUL96	50, .	0	98	45	76	93	58	95	119.40	
	8	06AUG96	57, .	0	105	40	91	94	44 L	96	118.70	
329.009.00312	SC	30OCT96	-5, .	0	129	66	89	119	83	102	152.40	58.0
	BL	04NOV96	1, .	0	103	54	.	109	56	.	151.70	
	2	15NOV96	12, .	0	106	67	81	122	68	87	154.60	
	2	18NOV96	15, .	0	106	78	100	112	50	106	153.30	
	4	02DEC96	29, .	0	129	61	94	127	61	97	157.30	
	5	09DEC96	36, .	0	121	57	96	120	62	103	156.70	
	6	16DEC96	43, .	0	126	65	83	117	70	97	156.80	
	8	27DEC96	54, .	0	111	61	82	114	68	68	160.00	
	8	30DEC96	57, .	0	126	66	91	121	73	97	154.60	
	8	06JAN97	64, .	0	122	64	88	128	46	102	159.40	
329.009.00327	SC	09SEP96	-7, .	0	111	56	93	109	49	101	90.80	60.1
	BL	16SEP96	1, .	0	88	50	87	94	47	93	94.40	
	1	23SEP96	8, .	0	88	45	93	96	53	106	89.90	
	2	30SEP96	15, .	0	98	43	93	109	68	106	90.70	
	3	07OCT96	22, .	0	96	46	91	92	66	112	90.40	
	4	14OCT96	29, .	0	118	53	84	118	57	94	92.10	
	5	21OCT96	36, .	0	99	50	79	104	55	89	91.00	
329.009.00330	SC	15OCT96	-6, .	0	117	79	68	106	88	70	93.50	59.0
	BL	21OCT96	1, .	0	106	68	65	120	71	80	94.00	
	1	28OCT96	8, .	0	115	72	68	106	71	73	96.80	
	2	04NOV96	15, .	0	112	66	62	106	72	72	96.70	
329.010.00183	SC	21NOV95	-12, .	0	112	78	68	105	80	80	150.20	71.0
	BL	28NOV95	-5, .	0	100	60	65	100	50	72	155.50	
	1	05DEC95	3, .	0	125	75	68	110	70	82	154.00	
	1	12DEC95	10, .	0	115	70	72	98	65	92	153.50	
	2	19DEC95	17, .	0	122	78	68	108	68	92	158.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.010.00263	SC	24JUL96	-16, .	0	125	85	80	125	85	96	224.00	72.0
	BL	09AUG96	1, .	0	130	82	68	125	78	74	230.00	
	1	14AUG96	6, .	0	130	76	70	125	80	76	235.00	
	2	21AUG96	13, .	0	126	80	80	118	74	88	232.20	
	3	28AUG96	20, .	0	124	76	84	118	70	90	230.50	
	4	04SEP96	27, .	0	126	84	78	116	76	90	233.20	
	5	11SEP96	34, .	0	122	78	78	116	74	92	235.00	
	6	18SEP96	41, .	0	130	86	92	118	78	96	236.50	
	7	25SEP96	48, .	0	118	80	88	112	74	92	233.50	
	8	09OCT96	62, .	0	118	76	100	108	70	108	237.50	
329.010.00277	SC	23FEB96	-7, -63	0	130	90	88	115	70	92	203.00	64.0
	BL	01MAR96	1, -56	0	130	80	96	110	70	108	205.80	
	1	08MAR96	8, -49	0	130	90	96	125	75	110	206.50	
	3	22MAR96	22, -35	0	115	60	72	110	68	80	204.50	
	4	29MAR96	29, -28	0	122	88	80	112	80	82	201.50	
	6	15APR96	46, -11	0	105	90	87	134	78	87		
	7	19APR96	50, -7	0	130	70	80	130	85	90	198.00	
	8	26APR96	57, 1	0	129	78	77	136	78	92	198.00	
	12	24MAY96	85, 29	0	130	90	72	118	80	90	204.00	
	16	21JUN96	113, 57	0	132	90	90	135	96	95	208.50	
	24	07AUG96	160, 104#	0	125	75	84	118	70	96	219.00	
329.010.00282	SC	19JUL96	-7, .	0	115	68	70	110	65	74	158.00	66.0
	BL	26JUL96	1, .	0	118	78	78	100	72	92	157.80	
	1	02AUG96	8, .	0	118	70	62	110	68	74	159.00	
	2	09AUG96	15, .	0	118	74	64	110	70	78	161.00	
	3	16AUG96	22, .	0	122	74	64	114	68	76	162.00	
	4	26AUG96	32, .	0	116	74	70	112	70	86	160.20	
	6	03SEP96	40, .	0	118	74	68	112	68	76	161.00	
	7	13SEP96	50, .	0	114	78	68	110	70	76	161.00	
	8	19SEP96	56, .	0	116	76	64	120	80	64	160.50	
	8	27SEP96	64, .	0	118	72	72	110	68	78	161.00	
329.011.00164	SC	15DEC95	-7, .	0	130	90	60	130	80	68	136.50	71.0
	1	28DEC95	7, .	0	120	80	60	118	80	68	134.20	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.011.00164	2	04JAN96	14, .	0	120	80	60	118	78	68	136.70	
	3	11JAN96	21, .	0	118	70	64	118	70	64	137.20	
	4	18JAN96	28, .	0	118	70	64	118	70	68	138.00	
	5	25JAN96	35, .	0	120	80	58	118	78	64	140.50	
329.011.00210	SC	13SEP96	-15, -81	0	108	72	84	110	70	80	113.50	64.2
	BL	27SEP96	-1, -67	0	110	70	80	112	70	84	113.50	
	1	03OCT96	6, -61	0	110	60	70	110	60	70	114.20	
	2	09OCT96	12, -55	0	110	70	80	108	70	88	115.00	
	3	17OCT96	20, -47	0	100	70	72	102	70	76	112.00	
	4	24OCT96	27, -40	0	100	72	76	102	70	80	114.00	
	5	04NOV96	38, -29	0	100	70	80	100	74	86	113.00	
	6	12NOV96	46, -21	0	110	70	84	112	74	86	112.00	
	8	22NOV96	56, -11	0	102	74	80	106	76	86	113.50	
	8	02DEC96	66, -1	0	104	74	80	106	74	80	111.50	
329.011.00285	SC	08MAY96	-10, .	0	110	70	70	100	70	80	184.70	69.5
	BL	17MAY96	-1, .	0	110	70	70	106	70	80	184.70	
	1	27MAY96	10, .	0	110	60	80	110	60	80	185.20	
	2	03JUN96	17, .	0	108	70	80	108	70	84	185.20	
	3	10JUN96	24, .	0	108	68	80	110	70	80	185.00	
	5	21JUN96	35, .	0	104	72	84	110	76	88	184.50	
	6	28JUN96	42, .	0	110	60	80	110	60	84	182.70	
	7	08JUL96	52, .	0	120	60	80	120	60	84	185.50	
	8	18JUL96	62, .	0	118	60	80	114	64	84	184.50	
	8	24JUL96	68, .	0	120	70	88	120	74	88	186.50	
329.011.00287	SC	25JUN96	-8, .	0	104	70	60	104	72	64	121.70	61.0
	BL	02JUL96	-1, .	0	106	70	64	106	74	66	121.70	
	1	09JUL96	7, .	0	110	70	70	110	74	72	124.00	
	2	17JUL96	15, .	0	110	70	76	110	70	80	120.50	
	3	23JUL96	21, .	0	110	70	80	112	70	84	119.20	
	4	30JUL96	28, .	0	110	70	80	112	70	84	120.00	
	5	06AUG96	35, .	0	110	70	80	112	72	84	120.00	
	6	13AUG96	42, .	0	110	70	80	110	70	84	121.50	
	7	20AUG96	49, .	0	106	70	80	110	78	84	119.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.011.00287	8	27AUG96	56, .	0	110	70	80	108	72	84	120.20	
329.012.00027	SC	23NOV95	-13, .	0	110	64	68	104	72	80	154.13	71.7
	BL	06DEC95	1, .	0	110	76	88	120	78	92	158.76	
	1	12DEC95	7, .	0	126	72	96	120	86	70	158.32	
	2	19DEC95	14, .	0	110	70	60	110	80	62	156.33	
	3	27DEC95	22, .	0	100	62	72	110	70	100	159.64	
	4	02JAN96	28, .	0	122	66	60	110	52	64	159.64	
329.012.00217	SC	14MAY96	-7, .	0	92	70	76	100	70	80	110.03	61.4
	BL	21MAY96	1, .	0	100	66	60	96	64	84	108.93	
	1	31MAY96	11, .	0	110	70	80	108	74	70	110.69	
	2	07JUN96	18, .	0	110	70	74	100	76	80	111.35	
	3	14JUN96	25, .	0	120	80	70	110	80	76	110.03	
	4	19JUN96	30, .	0	100	60	64	100	70	72	108.49	
329.012.00218	SC	04JUN96	-12, -70	0	100	68	64	104	70	88	118.63	65.7
	BL	14JUN96	-2, -60	0	110	80	80	100	60	100	118.41	
	1	21JUN96	6, -53	0	120	80	80	100	70	88	119.95	
	2	28JUN96	13, -46	0	118	70	80	112	76	92	122.38	
	3	05JUL96	20, -39	0	110	70	76	118	74	80	121.05	
	4	12JUL96	27, -32	0	100	70	72	100	72	80	119.29	
	5	19JUL96	34, -25	0	110	70	72	120	80	72	119.73	
	6	29JUL96	44, -15	0	122	80	76	116	72	82	119.95	
	7	06AUG96	52, -7	0	112	70	80	110	70	76	121.05	
	8	13AUG96	59, 1	0	110	80	72	110	70	76	121.72	
	12	18SEP96	95, 37	0	110	70	72	110	80	80	124.36	
329.012.00224	SC	30AUG96	-17, -83	0	110	80	70	118	76	74	114.66	63.8
	BL	16SEP96	1, -66	0	130	84	86	126	80	82	113.78	
	1	24SEP96	9, -58	0	100	70	72	100	70	100	113.56	
	2	03OCT96	18, -49	0	120	72	80	108	60	90	114.88	
	3	10OCT96	25, -42	0	108	64	68	100	60	84	115.32	
	4	17OCT96	32, -35	0	112	68	74	110	70	86	116.42	
	6	25OCT96	40, -27	0	100	80	80	100	70	82	117.31	
	7	04NOV96	50, -17	0	110	60	72	112	80	72	115.98	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.1

Listing of Vital Sign Values by Treatment Group and Patient
Intent-to-Treat Population

Treatment Group=PLACEBO

Patient ID	Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
329.012.00224	8	12NOV96	58, -9	0	100	70	68	100	70	88	116.42	
	8	20NOV96	66, -1	0	117	78	80	120	76	100	116.42	
	12	19DEC96	95, 29	0	120	80	80	116	78	84	115.10	
	16	20JAN97	127, 61	0	110	70	88	120	70	92	119.07	
	24	18FEB97	156, 90	0	108	70	78	100	70	86	119.95	
329.012.00225	SC	19NOV96	-7, -71	0	130	78	74	124	76	72	133.40	68.1
	BL	26NOV96	1, -64	0	126	60	72	118	70	92	132.30	
	1	03DEC96	8, -57	0	120	80	80	118	80	90	133.40	
	2	10DEC96	15, -50	0	120	68	64	118	72	68	131.20	
	3	20DEC96	25, -40	0	117	68	72	120	68	80	132.30	
	4	27DEC96	32, -33	0	120	80	86	117	78	90	134.51	
	6	06JAN97	42, -23	0	110	60	80	110	70	76	133.40	
	7	13JAN97	49, -16	0	112	70	76	120	70	92	133.40	
	8	21JAN97	57, -8	0	110	70	64	120	70	72	136.71	
	8	29JAN97	65, 1	0	120	70	64	112	76	96	134.51	
	12	24FEB97	91, 27	0	110	70	68	110	68	78	135.61	
	16	20MAR97	115, 51	0	120	70	82	110	60	88	132.30	
	20	21APR97	147, 83	0	110	64	87	105	62	120	135.61	
	24	26MAY97	182, 118	0	106	64	72	114	64	98	137.37	
	32	30JUN97	217, 153	0	100	70	80	94	70	100	134.51	
	32	30JUL97	247, 183	0	100	62	60	110	64	76	134.95	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.2

Listing of Clinically Significant Abnormal Vital Signs by Treatment Group and Parameter
Acute Phase
Intent-to-Treat Population

Treatment	Parameter	Flag	Patient ID	Relative Days *	Value	Baseline Value
PAROXETINE	Diastolic B.P. - Sitting (mmHg)	L	329.005.00299	45	48.00	80.00
	Diastolic B.P. - Standing (mmHg)	L	329.005.00299	45	42.00	80.00
	Pulse - Standing (bpm)	H	329.001.00068	50	124.00	80.00
		L	329.003.00292	15	45.00	80.00
	Systolic B.P. - Standing (mmHg)	L	329.005.00300	43	58.00	88.00
			329.009.00304	43	68.00	121.00
			329.009.00324	29	77.00	131.00
	Weight (lbs)	H	329.005.00004	53	152.90	141.50
			329.009.00201	57	163.80	150.80
		L	329.004.00015	7	107.16	116.87
				14	106.06	116.87
				21	104.96	116.87
				28	102.53	116.87
				35	102.97	116.87
				42	105.18	116.87
				49	105.18	116.87
				58	105.84	116.87
			329.010.00182	32	130.00	140.50
IMIPRAMINE	Diastolic B.P. - Standing (mmHg)	L	329.009.00172	45	47.00	73.00
				58	33.00	73.00
	Pulse - Sitting (bpm)	H	329.002.00056	22	132.00	100.00
			329.006.00040	14	132.00	72.00
			329.009.00172	8	129.00	84.00
			329.009.00264	46	137.00	102.00
	Pulse - Standing (bpm)	H	329.001.00061	14	124.00	72.00
			329.001.00066	14	124.00	80.00
			329.002.00056	29	140.00	102.00
			329.002.00057	15	140.00	89.00
				57	140.00	89.00
			329.002.00322	8	130.00	86.00
				36	132.00	86.00
			329.003.00073	20	132.00	87.00
				35	130.00	87.00

* Days Relative to Start of Acute Phase
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.2

Listing of Clinically Significant Abnormal Vital Signs by Treatment Group and Parameter
Acute Phase
Intent-to-Treat Population

Treatment	Parameter	Flag	Patient ID	Relative Days *	Value	Baseline Value
IMIPRAMINE	Pulse - Standing (bpm)	H	329.003.00073	42	128.00	87.00
				49	140.00	87.00
			329.006.00040	14	140.00	84.00
			329.008.00159	49	122.00	80.00
			329.008.00273	8	136.00	102.00
			329.009.00195	19	129.00	77.00
				25	125.00	77.00
			329.009.00236	8	121.00	86.00
				22	133.00	86.00
			329.009.00239	35	121.00	74.00
				49	131.00	74.00
			329.009.00262	29	129.00	84.00
				50	121.00	84.00
			329.009.00264	11	140.00	82.00
				18	133.00	82.00
				25	145.00	82.00
				32	137.00	82.00
				41	150.00	82.00
				46	140.00	82.00
				53	148.00	82.00
			329.009.00301	36	126.00	75.00
			329.009.00305	29	132.00	89.00
				50	135.00	89.00
				58	140.00	89.00
			329.009.00325	28	131.00	97.00
	Systolic B.P. - Standing (mmHg)	L	329.002.00322	22	88.00	120.00
			329.009.00172	58	85.00	124.00
	Weight (lbs)	L	329.003.00073	49	128.11	140.00
			329.008.00273	46	140.00	153.00
				56	138.00	153.00
				64	140.00	153.00
			329.009.00262	50	134.50	145.90
PLACEBO	Diastolic B.P. - Sitting (mmHg)	L	329.003.00080	33	48.00	70.00
			329.009.00136	15	48.00	76.00
	Diastolic B.P. - Standing (mmHg)	L	329.009.00306	57	44.00	70.00

* Days Relative to Start of Acute Phase
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix E.2

Listing of Clinically Significant Abnormal Vital Signs by Treatment Group and Parameter
Acute Phase
Intent-to-Treat Population

Treatment	Parameter	Flag	Patient ID	Relative Days *	Value	Baseline Value
PLACEBO	Pulse - Standing (bpm)	H	329.005.00005	8	136.00	88.00
	Systolic B.P. - Standing (mmHg)	L	329.002.00060	36	70.00	112.00
			329.009.00136	8	84.00	124.00
			329.009.00197	40	86.00	124.00
	Weight (lbs)	H	329.002.00107	41	179.00	167.00
				51	179.50	167.00
			329.005.00114	22	155.89	145.00
				29	157.00	145.00
				38	157.00	145.00
			329.005.00120	51	164.71	152.15
				58	166.04	152.15
		L	329.002.00323	15	109.00	118.00

* Days Relative to Start of Acute Phase
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix F: Patient Data Listings of Laboratory Values

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00063

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.6	.	.	.	30 - 70	%
				Lymphocytes	42.3	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	9.7	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	216	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00063

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00065

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.4	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	209	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00065

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00068

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.6	.	.	.	30 - 70	%
				Lymphocytes	39	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Platelets	291000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00068

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	43	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	3.3	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	329000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00068

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00072

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.1	.	.	.	30 - 70	%
				Lymphocytes	48.1	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	252	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00072

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00121

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	180000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	187	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00121

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	183000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	29	White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.2	L	.	-	41 - 50	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	147000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	170	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00121

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.9	.	.	.	30 - 70	%
				Lymphocytes	42.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	170000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	157	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00121

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	140		Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	87	.	.	.	70 - 115	MG/DL
					Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
		VISIT 17/DOWN TITRATION	155	(1)	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	37.5	L	.	.	41 - 50	%
					Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	50.5	.	.	.	30 - 70	%
					Lymphocytes	41.3	.	.	.	21 - 51	%
					Monocytes	4.6	.	.	.	0 - 10	%
					Eosinophils	2	.	.	.	0 - 5	%
					Basophils	1.5	.	.	.	0 - 2	%
					Platelets	195000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.8	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	93	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00205

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	33.6	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	349	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	60 - 110	MG/DL
				Globulin	2.5	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00205

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00206

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.1	.	.	.	30 - 70	%
				Lymphocytes	33.7	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	187000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	129	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	116	H	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00206

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	33.4	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	130	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	35	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.001.00206

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00055

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.6	.	.	.	12 - 16	G/DL
				Hematocrit	39.4	.	.	.	36 - 49	%
				Red Blood Cell Count	4.87	.	.	.	4 - 5.2	10^12/L
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	10^9/L
				Neutrophil Bands	56	.	.	+	30 - 70	%
				Segmented Neutrophils	56	.	.	.	30 - 70	%
				Lymphocytes	31	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	3640000	H	.	+	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 33	PG
				Mean Corpuscle Volume	81	.	.	.	77 - 95	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	12	H	.	+	0.7 - 1.4	MG/DL
				Uric Acid	6.6	.	.	.	4 - 8.5	MG/DL
				Alkaline Phosphatase	328	.	.	.	60 - 500	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 42	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 45	U/L
				Total Bilirubin	1	.	.	.	0 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6 - 8.5	GM/DL
				Albumin	4.2	.	.	.	3.2 - 5	GM/DL
				Glucose - Random	108	.	.	.	70 - 113	MG/DL
				Globulin	2.3	.	.	.	2.2 - 4.2	GM/DL
				Urine Blood - Random	NEG	.	.	.		
				Urine Bilirubin	NEG	.	.	.		
				Urine Ketones (Acetone)	NEG	.	.	.		
				Urine PH	5.0	.	.	.		
				Total Protein in Urine	TRACE	.	.	.		
				Urine Specific Gravity	1.030	.	.	.		
				Urine Appearance	CLEAR	.	.	.		
				Urine Color	YELLOW	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00055

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	33.3	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	6.6	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	295	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00055

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	27	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	284	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00058

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	25.7	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	197000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00058

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	4	.	.	.	4 - 12	%
				Segmented Neutrophils	85	H	.	.	30 - 70	%
				Lymphocytes	5	L	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	183000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00058

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59		Urine White Blood Cells/HPF	5	.	.	+		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	130	(11)	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
					Hematocrit	40.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	62.4	.	.	.	30 - 70	%
					Lymphocytes	26.4	.	.	.	21 - 51	%
					Monocytes	8.4	.	.	.	0 - 10	%
					Eosinophils	2.2	.	.	.	0 - 5	%
					Basophils	0.6	.	.	.	0 - 2	%
					Platelets	193000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	89	.	.	.	70 - 115	MG/DL
					Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00058

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	130 (11)	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00099

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.8	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	30.5	.	.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	80	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1.4	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00099

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1	.	.	.	30 - 70	%
				Lymphocytes	33.9	.	.	.	21 - 51	%
				Monocytes	9.9	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00099

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	16	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6	.	.	.	30 - 70	%
				Lymphocytes	32.1	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00099

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	153	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	239	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	1	L	.	.	4 - 12	%
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	22	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00099

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 16/CONTINUATION-WEEK 32	239	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00102

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	389000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00102

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37.9	.	.	.	30 - 70	%
				Lymphocytes	44.1	.	.	.	21 - 51	%
				Monocytes	10.7	H	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	323000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00102

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.3	.	.	.	30 - 70	%
				Lymphocytes	31.7	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	7.1	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	380000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00102

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	237	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5	.	.	.	30 - 70	%
				Lymphocytes	32.9	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	361000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00105

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	19	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	93	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00106

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.4	.	.	.	30 - 70	%
				Lymphocytes	26.9	.	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00106

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00242

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	389000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00242

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.8	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	391000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
		VISIT 17/DOWN TITRATION	155 (35)	Hemoglobin	14.6	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00242

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 17/DOWN TITRATION	155	(35)	Hematocrit	42.8	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	60	.	.	.	30 - 70	%
					Lymphocytes	26.6	.	.	.	21 - 51	%
					Monocytes	8.1	.	.	.	0 - 10	%
					Eosinophils	4.7	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	316000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	113	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	57	L	.	.	70 - 115	MG/DL
					Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00245

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	220000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	159	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	118	H	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00245

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00319

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.8	H	.	.	30 - 70	%
				Lymphocytes	19.5	L	.	.	21 - 51	%
				Monocytes	2.7	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	251000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00319

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.4	. . .	12 - 15.6	G/DL
				Hematocrit	39	. . .	35 - 46	%
				Red Blood Cell Count	4.5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.4	. . .	30 - 70	%
				Lymphocytes	27.5	. . .	21 - 51	%
				Monocytes	5.2	. . .	0 - 10	%
				Eosinophils	1.8	. . .	0 - 5	%
				Basophils	0.1	. . .	0 - 2	%
				Platelets	184000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	. . .	25 - 35	PG
				Mean Corpuscle Volume	87	. . .	80 - 100	FL
				Blood Urea Nitrogen	12	. . .	7 - 25	MG/DL
				Creatinine	0.8	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4.2	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	. . .	22 - 130	U/L
				Aspartate Aminotransferase	13	. . .	0 - 41	U/L
				Alanine Aminotransferase	7	. . .	0 - 48	U/L
				Total Bilirubin	0.9	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.4	. . .	6.2 - 8.8	G/DL
				Albumin	4.2	. . .	3.1 - 5.3	G/DL
				Glucose - Random	90	. . .	70 - 115	MG/DL
				Globulin	3.2	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00319

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.5	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	3.4	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.002.00319

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	148	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	232	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	171000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00075

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00075

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35.8	.	.	.	30 - 70	%
				Lymphocytes	54.7	H	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	304000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00075

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	141	Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.8	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	232	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00075

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 16/CONTINUATION-WEEK 32	232	Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	41.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	0.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	335000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	140	H	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00081

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
				Hematocrit	35.8	.	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	188	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00081

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7		Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	(1)	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	35.2	.	.	.	35 - 46	%
					Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	53.6	.	.	.	30 - 70	%
					Lymphocytes	33.8	.	.	.	21 - 51	%
					Monocytes	7.9	.	.	.	0 - 10	%
					Eosinophils	3.4	.	.	.	0 - 5	%
					Basophils	1.3	.	.	.	0 - 2	%
					Platelets	229000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
					Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	156	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7	.	.	.	5.7 - 8.2	G/DL
					Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	113	H	.	.	60 - 110	MG/DL
					Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
					Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00081

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	59 (1)	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00087

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	24.9	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	10.8	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00087

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00089

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-63	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	42	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	188	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00089

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-63	Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3	.	.	.	30 - 70	%
				Lymphocytes	23.9	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	319000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00089

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00091

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	7.8	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	103	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00091

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00091

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.5	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	9.9	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00091

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	229	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.5	.	.	.	30 - 70	%
				Lymphocytes	20	L	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	250000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00248

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.5	.	.	.	30 - 70	%
				Lymphocytes	37.6	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	210000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	156	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00248

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	11.9	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.4	L	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2	.	.	.	30 - 70	%
				Lymphocytes	39.9	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	7.3	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	228000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	137	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00250

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	3	L	.	.	4 - 12	%
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	340000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	25.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	77	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00250

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	6	Serum BHCG pregnancy test	NEGATIVE	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00292

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	4.3	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	134	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00292

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-5		Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70	(12)	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	45.2	.	.	.	41 - 50	%
					Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	76.1	H	.	.	30 - 70	%
					Lymphocytes	18.9	L	.	.	21 - 51	%
					Monocytes	2.4	.	.	.	0 - 10	%
					Eosinophils	2	.	.	.	0 - 5	%
					Basophils	0.6	.	.	.	0 - 2	%
					Platelets	325000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	6.1	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	101	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	82	.	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	+		
					Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00292

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	70 (12)	Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00313

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	57.9	.	.	.	40 - 75	%
				Lymphocytes	32.5	.	.	.	16 - 46	%
				Monocytes	6.5	.	.	.	0 - 12	%
				Eosinophils	2.7	.	.	.	0 - 7	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	205000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	69	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.003.00313

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00015

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.3	.	.	.	30 - 70	%
				Lymphocytes	27	.	.	.	21 - 51	%
				Monocytes	2.6	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	206000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00015

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	28.1	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEC	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00015

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	-1	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.2	H	.	.	30 - 70	%
				Lymphocytes	19.7	L	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	258000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	35	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.6	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00015

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 7/ACUTE PHASE-WEEK 5	35	Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	21.8	.	.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	222000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00015

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	82	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	16.8	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.9	H	.	.	30 - 70	%
				Lymphocytes	15.6	L	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	344000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	133	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.4	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00015

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	133	Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	215000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 14/UNSCHEDULED LAB 1	182	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.6	.	.	.	30 - 70	%
				Lymphocytes	21	.	.	.	21 - 51	%
				Monocytes	9.2	.	.	.	0 - 10	%

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00015

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 14/UNSCHEDULED LAB 1	182	Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00017

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00017

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.7	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	30	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	32.3	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.8	.	.	.	35 - 46	%

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00017

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	277000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	24	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00017

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	142	White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	42	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	169	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00017

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 14/CONTINUATION-WEEK 24	169	White Blood Cell Count	11.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	313000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
		VISIT 16/CONTINUATION-WEEK 32	225	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	28.3	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	290000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00017

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	225	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00019

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.1	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	5.9	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	209000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	2.2	L	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00019

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00212

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00212

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-10		Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	26	(3)	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.2	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	46.1	.	.	.	30 - 70	%
					Lymphocytes	43.1	.	.	.	21 - 51	%
					Monocytes	6.6	.	.	.	0 - 10	%
					Eosinophils	3.9	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	211000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
					Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	19	L	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00212

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 5/ACUTE PHASE-WEEK 3	26	(3)	Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF		3	.	.		
					Urine Bacteria		3	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		
					Urine Squamous Epithelial Cells		4	.	.		
					Serum BHCG pregnancy test	NEGATIVE	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00214

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	318000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	4.3	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00214

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.8	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00214

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	88	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	27.4	.	.	.	21 - 51	%
				Monocytes	11.3	H	.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	266000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.004.00214

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	88	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00002

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.4	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00002

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 3/ACUTE PHASE-WEEK 1	8	Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	31	L	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids POS		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	22	Glucose - Random	87	.	.	.	70 - 115	MG/DL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.3	H	.	.	30 - 70	%
				Lymphocytes	13.4	L	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00002

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57		Creatinine	1	. . .	0.8 - 1.5	MG/DL
					Uric Acid	4.9	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	88	. . .	44 - 280	U/L
					Aspartate Aminotransferase	16	. . .	0 - 41	U/L
					Alanine Aminotransferase	8	. . .	0 - 48	U/L
					Total Bilirubin	0.8	. . .	0.3 - 1.3	MG/DL
					Total Protein	8	. . .	6.2 - 8.8	G/DL
					Albumin	4.5	. . .	3.1 - 5.3	G/DL
					Glucose - Random	109	. . .	70 - 115	MG/DL
					Globulin	3.5	. . .	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	(1)	Hemoglobin	13.4	. . .	12 - 15.6	G/DL
					Hematocrit	38.9	. . .	35 - 46	%
					Red Blood Cell Count	4.3	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.1	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	58.2	. . .	30 - 70	%
					Lymphocytes	33.2	. . .	21 - 51	%
					Monocytes	6.2	. . .	0 - 10	%
					Eosinophils	1.9	. . .	0 - 5	%
					Basophils	0.5	. . .	0 - 2	%
					Platelets	271000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.4	. . .	25 - 35	PG
					Mean Corpuscle Volume	91	. . .	80 - 100	FL
					Blood Urea Nitrogen	13	. . .	7 - 25	MG/DL
					Creatinine	1.2	. . .	0.8 - 1.5	MG/DL
					Uric Acid	5.8	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	96	. . .	44 - 280	U/L
					Aspartate Aminotransferase	12	. . .	0 - 41	U/L
					Alanine Aminotransferase	5	. . .	0 - 48	U/L
					Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.5	. . .	6.2 - 8.8	G/DL
					Albumin	4.3	. . .	3.1 - 5.3	G/DL
					Glucose - Random	86	. . .	70 - 115	MG/DL
					Globulin	3.2	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00002

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	147 (1)	Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF		4	.	.	.	
				Urine Bacteria		4	.	.	.	
				Urine Protein - Dipstick		2	.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	POS		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
				Urine Squamous Epithelial Cells		4	.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00004

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.5	.	.	.	30 - 70	%
				Lymphocytes	24.1	.	.	.	21 - 51	%
				Monocytes	10.5	H	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	2.1	H	.	+	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00004

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-4	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.2	.	.	.	30 - 70	%
				Lymphocytes	22.3	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	1.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	148	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00004

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	60	Lymphocytes	37.5	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	264000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	122	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00008

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	38.6	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	222000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	281	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	32	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00008

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6		Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56		Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	37.9	L	.	.	41 - 50	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	44.4	.	.	.	30 - 70	%
					Lymphocytes	41.8	.	.	.	21 - 51	%
					Monocytes	10.3	H	.	.	0 - 10	%
					Eosinophils	2.8	.	.	.	0 - 5	%
					Basophils	0.7	.	.	.	0 - 2	%
					Platelets	207000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	16	.	.	.	8 - 21	MG/DL
					Creatinine	1.1	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.4	.	.	.	2.6 - 7	MG/DL
					Alkaline Phosphatase	244	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	23	.	.	.	0 - 39	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	103	.	.	.	60 - 110	MG/DL
					Globulin	2.7	.	.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	176	(34)	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	37.4	L	.	.	41 - 50	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	44.2	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00008

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	176	(34)	Lymphocytes	44.4	.	.	.	21 - 51	%
					Monocytes	7.8	.	.	.	0 - 10	%
					Eosinophils	3.2	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	211000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	19	.	.	.	8 - 21	MG/DL
					Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
					Alkaline Phosphatase	320	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	30	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.8	.	.	.	5.7 - 8.2	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	103	.	.	.	60 - 110	MG/DL
					Globulin	2.4	.	.	.	2.1 - 3.8	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	NEG		.	.	.	
					Urine Red Blood Cells/HPF	NEG		.	.	.	
					Urine White Blood Cells/HPF	NEG		.	.	.	
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00011

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	24.7	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	235000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00011

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	35	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	56.6	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	51000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00011

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Segmented Neutrophils	64	.	.	.	30 - 70	%
				Lymphocytes	26	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00109

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.5	.	.	.	30 - 70	%
				Lymphocytes	47.5	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	1.2	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	304000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.5	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	23	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.2	L	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	41	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00109

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	54		Monocytes	7	. . .	0 - 10	%
					Eosinophils	3	. . .	0 - 5	%
					Basophils	1	. . .	0 - 2	%
					Blood Urea Nitrogen	13	. . .	7 - 25	MG/DL
					Creatinine	1	. . .	0.8 - 1.5	MG/DL
					Uric Acid	2.2	L . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	39	. . .	22 - 130	U/L
					Aspartate Aminotransferase	16	. . .	0 - 41	U/L
					Alanine Aminotransferase	12	. . .	0 - 48	U/L
					Total Bilirubin	0.4	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.6	. . .	6.2 - 8.8	G/DL
					Albumin	4.2	. . .	3.1 - 5.3	G/DL
					Glucose - Random	100	. . .	70 - 115	MG/DL
					Globulin	3.4	. . .	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	(9)	Hemoglobin	13.4	. . .	12 - 15.6	G/DL
					Hematocrit	38.8	. . .	35 - 46	%
					Red Blood Cell Count	4.1	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.8	. . .	30 - 70	%
					Lymphocytes	38.3	. . .	21 - 51	%
					Monocytes	7.1	. . .	0 - 10	%
					Eosinophils	1.1	. . .	0 - 5	%
					Basophils	0.8	. . .	0 - 2	%
					Platelets	319000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.3	. . .	25 - 35	PG
					Mean Corpuscle Volume	94	. . .	80 - 100	FL
					Blood Urea Nitrogen	15	. . .	7 - 25	MG/DL
					Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
					Uric Acid	3.3	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	32	. . .	22 - 130	U/L
					Aspartate Aminotransferase	20	. . .	0 - 41	U/L
					Alanine Aminotransferase	16	. . .	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00109

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	147 (9)	Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids POS		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00112

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32	.	.	.	30 - 70	%
				Lymphocytes	60	H	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	300	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	32	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	31	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00112

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	34.3	.	.	.	30 - 70	%
				Lymphocytes	55.2	H	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	10000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	280	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	37	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	40	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00112

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	56		Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
		VISIT 17/DOWN TITRATION	147	(54)	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	43.2	.	.	.	41 - 50	%
					Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	30.5	.	.	.	30 - 70	%
					Lymphocytes	58.7	H	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	4.3	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	270000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.7	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	326	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	32	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
					Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	130	H	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00116

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	34.9	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00116

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	52	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.4	.	.	.	30 - 70	%
				Lymphocytes	33.7	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	71000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00116

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59		Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	93	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	NEG		.	.	.	
					Urine Red Blood Cells/HPF	NEG		.	.	.	
					Urine White Blood Cells/HPF	NEG		.	.	.	
					Urine Protein - Dipstick	NEG		.	.	.	
		VISIT 17/DOWN TITRATION	170	(15)	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.6	.	.	.	35 - 46	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	57.6	.	.	.	30 - 70	%
					Lymphocytes	32.1	.	.	.	21 - 51	%
					Monocytes	6.9	.	.	.	0 - 10	%
					Eosinophils	2.5	.	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	218000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	7	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	95	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00116

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 17/DOWN TITRATION	170 (15)	Globulin	2.7	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00119

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.5	.	.	.	30 - 70	%
				Lymphocytes	38.3	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	249000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00119

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.8	.	.	.	30 - 70	%
				Lymphocytes	39.7	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00119

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	60		Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	80	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	(1)	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	37.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	46.9	.	.	.	30 - 70	%
					Lymphocytes	38.4	.	.	.	21 - 51	%
					Monocytes	9.1	.	.	.	0 - 10	%
					Eosinophils	4.7	.	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	300000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	106	.	.	.	44 - 280	U/L

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00119

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	141	(1)	Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	93	.	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	NEG		.	.	.	
					Urine Red Blood Cells/HPF	NEG		.	.	.	
					Urine White Blood Cells/HPF	NEG		.	.	.	
					Urine Protein - Dipstick	NEG		.	.	.	
					Urine Amphetamines	NEG		.	.	.	
					Urine Barbiturates	NEG		.	.	.	
					Urine Benzodiazepines	NEG		.	.	.	
					Urine Cannabinoids	NEG		.	.	.	
					Urine Cocaine	NEG		.	.	.	
					Urine Methadone	NEG		.	.	.	
					Urine Methaqualone	NEG		.	.	.	
					Urine Opiates	NEG		.	.	.	
					Urine Phencyclidine	NEG		.	.	.	
					Urine Propoxyphene	NEG		.	.	.	
					Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00151

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.9	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	11.5	H	.	+	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	131000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	89	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00151

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.3	.	.	.	30 - 70	%
				Lymphocytes	44.3	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00151

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00151

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	148		Urine Red Blood Cells/HPF	NEG	. . .		
					Urine White Blood Cells/HPF	3	. . .		
					Urine Bacteria	4	. . .		
					Urine Protein - Dipstick	6	. . .		
		VISIT 14/CONTINUATION-WEEK 24	175		Urine Glucose - Dipstick	NEG	. . .		
					Urine Blood - Dipstick	NEG	. . .		
					Urine Red Blood Cells/HPF	NEG	. . .		
					Urine White Blood Cells/HPF	3	. . .		
					Urine Bacteria	3	. . .		
					Urine Protein - Dipstick	6	. . .		
					Urine Squamous Epithelial Cells	4	. . .		
		VISIT 16/CONTINUATION-WEEK 32	239	(1)	Hemoglobin	14.4	. . .	12 - 15.6	G/DL
					Hematocrit	42	. . .	35 - 46	%
					Red Blood Cell Count	4.6	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	40.1	. . .	30 - 70	%
					Lymphocytes	46.6	. . .	21 - 51	%
					Monocytes	8.4	. . .	0 - 10	%
					Eosinophils	4.1	. . .	0 - 5	%
					Basophils	0.8	. . .	0 - 2	%
					Platelets	252000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.6	. . .	25 - 35	PG
					Mean Corpuscle Volume	92	. . .	80 - 100	FL
					Blood Urea Nitrogen	14	. . .	7 - 25	MG/DL
					Creatinine	0.8	. . .	0.8 - 1.5	MG/DL
					Uric Acid	3.4	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	76	. . .	44 - 280	U/L
					Aspartate Aminotransferase	20	. . .	0 - 41	U/L

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00151

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	239 (1)	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00152

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.8	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	308000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	-3	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00152

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-3	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00257

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.8	.	.	.	30 - 70	%
				Lymphocytes	22.3	.	.	.	21 - 51	%
				Monocytes	9.5	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	136000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	60 - 110	MG/DL
				Globulin	2.7	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00257

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Hemoglobin	24.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	72.4	H	.	.	35 - 46	%
				Red Blood Cell Count	8.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	19.1	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.7	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	17000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.6	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	3.3	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00257

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	129	H	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG			.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	150	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00257

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	150	Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	225	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	30.4	.	.	.	21 - 51	%
				Monocytes	3.6	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00257

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 16/CONTINUATION-WEEK 32	225	Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00258

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-21	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	35.8	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00258

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-21		Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/UNSCHEDULED LAB 1	-14		Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	4	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	2	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
					Hematocrit	35.9	.	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	47.6	.	.	.	30 - 70	%
					Lymphocytes	37.2	.	.	.	21 - 51	%
					Monocytes	7.7	.	.	.	0 - 10	%
					Eosinophils	6.6	H	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	275000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	19	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00258

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	95	.	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	+		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	6	.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00299

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	22.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	67.3	H	.	.	35 - 46	%
				Red Blood Cell Count	7.9	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	14	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	25.1	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	10000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	266	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00299

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-11	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-4	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70	.	.	.	30 - 70	%
				Lymphocytes	18.5	L	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	232000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.4	.	.	.	30 - 70	%
				Lymphocytes	23.4	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00299

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	226	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	144	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.5	H	.	.	30 - 70	%
				Lymphocytes	15.1	L	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00299

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	144	Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	131	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEC		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00299

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	144	Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00300

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.8	.	.	.	30 - 70	%
				Lymphocytes	46.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	327000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.3	L	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	306	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00300

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	38	L	.	.	41 - 50	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	44.4	.	.	.	30 - 70	%
					Lymphocytes	43.1	.	.	.	21 - 51	%
					Monocytes	8.9	.	.	.	0 - 10	%
					Eosinophils	3.1	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	290000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
					Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	2	L	.	.	2.6 - 7	MG/DL
					Alkaline Phosphatase	259	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	102	.	.	.	60 - 110	MG/DL
					Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
					Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00300

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00333

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	384000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00333

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00336

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	7.9	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.5	.	.	.	30 - 70	%
				Lymphocytes	46.4	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.005.00336

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00038

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	286000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00038

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00039

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	234000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00039

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.3	H	.	.	30 - 70	%
				Lymphocytes	13.2	L	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	200000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00260

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.2	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	70	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
		VISIT 6/ACUTE PHASE-WEEK 4	28	Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00260

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 6/ACUTE PHASE-WEEK 4	28	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	81.8	H	.	.	30 - 70	%
				Lymphocytes	9.8	L	.	.	21 - 51	%
				Monocytes	0.4	.	.	.	0 - 10	%
				Eosinophils	8	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	103000	L	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	99	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00260

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/UNSCHEDULED LAB 1	98	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	40 - 75	%
				Lymphocytes	38.3	.	.	.	16 - 46	%
				Monocytes	3.3	.	.	.	0 - 12	%
				Eosinophils	3.3	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	112	Urine Glucose - Dipstick NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00260

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 12/CONTINUATION-WEEK 16	112	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	40 - 75	%
				Lymphocytes	28.4	.	.	.	16 - 46	%
				Monocytes	3.6	.	.	.	0 - 12	%
				Eosinophils	6.5	.	.	.	0 - 7	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00260

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	141	Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00261

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-4	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.1	.	.	.	30 - 70	%
				Lymphocytes	24.8	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	6.8	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	278000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00261

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.3	.	.	.	30 - 70	%
				Lymphocytes	26	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	89	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	74	H	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.006.00261

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00140

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4 - 5.2	10^12/L
				White Blood Cell Count	8.6	.	.	.	4.5 - 13.5	10^9/L
				Segmented Neutrophils	48.9	.	.	.	30 - 60	%
				Lymphocytes	36.1	.	.	.	25 - 55	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	222000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 33	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	226	.	.	.	44 - 330	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	60 - 110	MG/DL
				Globulin	2.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00140

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 1/SCREENING (WEEK -1)	-8		Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56		Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	36.7	L	.	-	41 - 50	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.8	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.3	.	.	.	30 - 70	%
					Lymphocytes	33.2	.	.	.	21 - 51	%
					Monocytes	6.6	.	.	.	0 - 10	%
					Eosinophils	6.7	H	.	.	0 - 5	%
					Basophils	1.1	.	.	.	0 - 2	%
					Platelets	246000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	18	.	.	.	8 - 21	MG/DL
					Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.7	.	.	.	2.6 - 7	MG/DL
					Alkaline Phosphatase	175	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
					Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.2	.	.	.	5.7 - 8.2	G/DL
					Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	122	H	.	.	60 - 110	MG/DL
					Globulin	2.1	.	.	.	2.1 - 3.8	G/DL
		VISIT 11/CONTINUATION-WEEK 12	69	(1)	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	38.3	L	.	.	41 - 50	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	11.9	.	.	.	4.5 - 13	THOU/MCL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00140

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 11/CONTINUATION-WEEK 12	69	(1)	Segmented Neutrophils	63.9	.	.	.	30 - 70	%
					Lymphocytes	24	.	.	.	21 - 51	%
					Monocytes	7.1	.	.	.	0 - 10	%
					Eosinophils	3.9	.	.	.	0 - 5	%
					Basophils	1.2	.	.	.	0 - 2	%
					Platelets	249000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEC	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
					Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00142

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.9	.	.	.	30 - 70	%
				Lymphocytes	41.6	.	.	.	21 - 51	%
				Monocytes	9.3	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	179	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	123	H	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00142

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6		Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	65	(17)	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	43.6	.	.	.	41 - 50	%
					Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	46	.	.	.	30 - 70	%
					Lymphocytes	45	.	.	.	21 - 51	%
					Monocytes	4	.	.	.	0 - 10	%
					Eosinophils	3	.	.	.	0 - 5	%
					Basophils	2	.	.	.	0 - 2	%
					Platelets	239000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.7	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	159	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	35	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	97	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00142

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 9/ACUTE PHASE-WEEK 7	65	(17)	Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00145

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.5	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	22.5	.	.	.	21 - 51	%
				Monocytes	16.5	H	.	+	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	115	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00145

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.4	L	.	-	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	280000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEC	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	15	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00145

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 4/ACUTE PHASE-WEEK 2	15	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.1	.	.	.	30 - 70	%
				Lymphocytes	42.1	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00145

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	47	.	.	.	21 - 51	%
				Monocytes	1	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	107000	L	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00145

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 14/CONTINUATION-WEEK 24	169		Platelets	235000	.	.	.	130000 - 400000	PER CUMM
		VISIT 16/CONTINUATION-WEEK 32	226	(1)	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	41.9	.	.	.	41 - 50	%
					Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	48.5	.	.	.	30 - 70	%
					Lymphocytes	37.3	.	.	.	21 - 51	%
					Monocytes	9.3	.	.	.	0 - 10	%
					Eosinophils	4	.	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	239000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.5	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	106	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	59	H	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	93	.	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	NEG		.	.	.	
					Urine Red Blood Cells/HPF	NEG		.	.	.	
					Urine White Blood Cells/HPF	NEG		.	.	.	
					Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00265

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	10.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	32.7	L	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	221000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	21.7	L	.	.	25 - 35	PG
				Mean Corpuscle Volume	67	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00265

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	10	L	.	.	12 - 15.6	G/DL
				Hematocrit	30.9	L	.	-	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	68.5	.	.	.	30 - 70	%
				Lymphocytes	21.9	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	21.4	L	.	.	25 - 35	PG
				Mean Corpuscle Volume	66	L	.	.	80 - 100	FL
		VISIT 3/ACUTE PHASE-WEEK 1	15 (1)	Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00268

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	351000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	186	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00268

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-11	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.6	L	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.2	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	165	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00268

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	60	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	38	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	150	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	116	H	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00268

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 14/CONTINUATION-WEEK 24	183		Hemoglobin	12	.	.	.	12 - 15.6	G/DL
					Hematocrit	35.5	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	13	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	53.3	.	.	.	30 - 70	%
					Lymphocytes	38.4	.	.	.	21 - 51	%
					Monocytes	4.8	.	.	.	0 - 10	%
					Eosinophils	3.3	.	.	.	0 - 5	%
					Basophils	0.2	.	.	.	0 - 2	%
					Platelets	382000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
		VISIT 17/DOWN TITRATION	277	(15)	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
					Hematocrit	34.9	L	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	12	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	51.2	.	.	.	30 - 70	%
					Lymphocytes	37	.	.	.	21 - 51	%
					Monocytes	6.8	.	.	.	0 - 10	%
					Eosinophils	5	.	.	.	0 - 5	%
					Basophils	0	.	.	.	0 - 2	%
					Platelets	324000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	123	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	80	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00268

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 17/DOWN TITRATION	277	(15)	Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00294

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	90	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00309

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-4	Segmented Neutrophils	57	.	.	.	40 - 75	%
				Lymphocytes	33	.	.	.	16 - 46	%
				Monocytes	9	.	.	.	0 - 12	%
				Eosinophils	1	.	.	.	0 - 7	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00309

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	65.4	.	.	.	40 - 75	%
				Lymphocytes	23.9	.	.	.	16 - 46	%
				Monocytes	5.5	.	.	.	0 - 12	%
				Eosinophils	4.5	.	.	.	0 - 7	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	289000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	53	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	40 - 75	%
				Lymphocytes	25.8	.	.	.	16 - 46	%
				Monocytes	9	.	.	.	0 - 12	%
				Eosinophils	4.4	.	.	.	0 - 7	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	256000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00309

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	53	Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	2.6	L	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	4.7	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	55.1	.	.	.	40 - 75	%
				Lymphocytes	28.8	.	.	.	16 - 46	%
				Monocytes	7.6	.	.	.	0 - 12	%
				Eosinophils	7.4	H	.	.	0 - 7	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00309

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 13/CONTINUATION-WEEK 20	152	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	242	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	40 - 75	%
				Lymphocytes	32.8	.	.	.	16 - 46	%
				Monocytes	6.1	.	.	.	0 - 12	%
				Eosinophils	9.8	H	.	.	0 - 7	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	216000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00309

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 16/CONTINUATION-WEEK 32	242	Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00310

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.5	H	.	.	30 - 70	%
				Lymphocytes	20.3	L	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	254000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00310

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	32.2	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	286000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00310

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	169	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	298000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00310

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	169	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	260	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	95	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00310

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	260	Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00318

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)		Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	31.7	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	254000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	231	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.007.00318

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)		Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00157

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7	.	.	.	30 - 70	%
				Lymphocytes	41	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	7.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	348000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	173	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-1	Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00157

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-1	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	4.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	338000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	162	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00157

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	108	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	388000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	128	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00157

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 12/CONTINUATION-WEEK 16	108	Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.3	.	.	.	30 - 70	%
				Lymphocytes	31.7	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	130	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00157

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	147	Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00160

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2	.	.	.	30 - 70	%
				Lymphocytes	34.5	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	9.4	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	110	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00160

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	9.5	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	205000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	107	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00160

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	161	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	30.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	12.4	H	.	+	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	217000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00160

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	161	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	266	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.8	H	.	.	30 - 70	%
				Lymphocytes	16.8	L	.	.	21 - 51	%
				Monocytes	1.2	.	.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00160

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	266	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00188

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.5	.	.	.	30 - 70	%
				Lymphocytes	39	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00188

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.1	.	.	.	30 - 70	%
				Lymphocytes	28.8	.	.	.	21 - 51	%
				Monocytes	3.4	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00188

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		4	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00271

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-46	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.5	L	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.9	.	.	.	30 - 70	%
				Lymphocytes	35.3	.	.	.	21 - 51	%
				Monocytes	3.8	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00271

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	34.5	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.2	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37	.	.	.	30 - 70	%
				Lymphocytes	49	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00271

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	65	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	180	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.8	.	.	.	30 - 70	%
				Lymphocytes	37.8	.	.	.	21 - 51	%
				Monocytes	3.8	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00271

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 14/CONTINUATION-WEEK 24	180	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	240	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.8	.	.	.	30 - 70	%
				Lymphocytes	21	.	.	.	21 - 51	%
				Monocytes	2.6	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	110	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00271

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	240	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00275

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	231	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00275

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.1	.	.	.	30 - 70	%
				Lymphocytes	22.1	.	.	.	21 - 51	%
				Monocytes	12.4	H	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	266000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	216	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00275

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	132	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67	.	.	.	30 - 70	%
				Lymphocytes	23.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	219	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	53	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.008.00275

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	223	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4	.	.	.	30 - 70	%
				Lymphocytes	35.9	.	.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	240	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00130

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	223	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00130

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	22	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.8	.	.	.	30 - 70	%
				Lymphocytes	27.9	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 400	U/L

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00130

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	155	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	28000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	207	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00130

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	155	Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	

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F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00131

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.4	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	374000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	103	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	120	H	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00131

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39.4	.	.	.	30 - 70	%
				Lymphocytes	46.2	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	410000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	100	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00131

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	85	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.9	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	381000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 13/CONTINUATION-WEEK 20	148 (30)	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	33.8	.	.	.	30 - 70	%
				Lymphocytes	54.5	H	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	315000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00131

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	148	(30)	Alkaline Phosphatase	102	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
					Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	94	.	.	.	70 - 115	MG/DL
					Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	NEG		.	.	.	
					Urine Red Blood Cells/HPF	NEG		.	.	.	
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.	.	
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00133

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	33.3	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	233000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	109	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00133

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00138

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	4.8	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	296000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	149	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00170

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	301000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	141	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	114	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
			-5	Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00170

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	26.4	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	2.9	H	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	6	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00170

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.4	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	122	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00170

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	147	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	231	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.9	.	.	.	30 - 70	%
				Lymphocytes	48.3	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	125	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	45	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	61	H	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00170

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	231		Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 17/DOWN TITRATION	247	(2)	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	55.3	.	.	.	30 - 70	%
					Lymphocytes	38.6	.	.	.	21 - 51	%
					Monocytes	3.5	.	.	.	0 - 10	%
					Eosinophils	1.7	.	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	216000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	115	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	62	L	.	.	70 - 115	MG/DL
					Globulin	3.6	.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00173

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-12	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	33	.	.	.	30 - 70	%
				Lymphocytes	46	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	8	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	382	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00173

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	36	.	.	.	30 - 70	%
				Lymphocytes	57	H	.	.	21 - 51	%
				Monocytes	0	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	293000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	289	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	5.7 - 8.2	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00173

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00193

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	14	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H	.	.	30 - 70	%
				Lymphocytes	16.7	L	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	324000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	173	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00193

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	162	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00193

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00196

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	10.9	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.1	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.1	.	.	.	30 - 70	%
				Lymphocytes	22.9	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	1.4	.	.	.	0 - 2	%
				Platelets	386000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	130	H	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2		.	.		
				Urine Red Blood Cells/HPF	3		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	4		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00196

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	11.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.1	L	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	16.7	H	.	+	3.8 - 10.8	THOU/MCL
				Neutrophil Bands	5	.	.	.	0 - 8	%
				Segmented Neutrophils	89	H	.	.	40 - 75	%
				Lymphocytes	5	L	.	.	16 - 46	%
				Monocytes	1	.	.	.	0 - 12	%
				Eosinophils	0	.	.	.	0 - 7	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	417000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.1	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.1	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	123	H	.	.	70 - 115	MG/DL
				Globulin	4.9	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	6	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00196

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00201

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.1	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	9.9	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	180000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	208	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00201

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.2	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	10.2	H	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	163000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	214	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	4.3	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00201

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00204

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	31	.	.	.	30 - 70	%
				Lymphocytes	53	H	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	339	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 39	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00204

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	36.4	.	.	.	30 - 70	%
				Lymphocytes	51.7	H	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	293000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.1	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	319	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	122	H	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00204

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	34	.	.	.	30 - 70	%
				Lymphocytes	51	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL
				Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	329	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00204

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	148	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00235

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	30 - 70	%
				Lymphocytes	33.9	.	.	.	21 - 51	%
				Monocytes	9.9	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	103	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	1.9	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	59	L	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00235

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-1	Glucose - Random	83	.	.	.	60 - 110	MG/DL
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.2	H	.	.	30 - 70	%
				Lymphocytes	14.6	L	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00235

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00240

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	298000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	193	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00240

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-11	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00303

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.3	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	11.8	H	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	167000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00303

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.1	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	35.5	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	177000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00303

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.6	.	.	.	30 - 70	%
				Lymphocytes	40.6	.	.	.	21 - 51	%
				Monocytes	10.7	H	.	.	0 - 10	%
				Eosinophils	5.6	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	177000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00303

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	148	Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	253	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	30000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	56	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00303

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 16/UNSCHEDULED LAB 1	256	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL

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F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00304

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.8	.	.	.	30 - 70	%
				Lymphocytes	39.8	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	217000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	143	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	24	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00304

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	17.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.6	.	.	.	30 - 70	%
				Lymphocytes	31	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	230000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	165	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00304

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	16.6		.	.	13.8 - 17.2	G/DL
				Hematocrit	47.9		.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68		.	.	30 - 70	%
				Lymphocytes	23.8		.	.	21 - 51	%
				Monocytes	4.1		.	.	0 - 10	%
				Eosinophils	3.6		.	.	0 - 5	%
				Basophils	0.5		.	.	0 - 2	%
				Platelets	270000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3		.	.	25 - 35	PG
				Mean Corpuscle Volume	88		.	.	80 - 100	FL
				Blood Urea Nitrogen	13		.	.	7 - 25	MG/DL
				Creatinine	1		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4		.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153		.	.	22 - 180	U/L
				Aspartate Aminotransferase	25		.	.	0 - 41	U/L
				Alanine Aminotransferase	30		.	.	0 - 48	U/L
				Total Bilirubin	0.5		.	.	0.3 - 1.3	MG/DL
				Total Protein	8		.	.	6.2 - 8.8	G/DL
				Albumin	4.5		.	.	3.1 - 5.3	G/DL
				Glucose - Random	88		.	.	70 - 115	MG/DL
				Globulin	3.5		.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3		.	.		
				Urine Bacteria	3		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00304

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	141	Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00324

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9	.	.	.	30 - 70	%
				Lymphocytes	29.1	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	328000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria		3	.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells		4	.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00324

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	65	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00324

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00328

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)		Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35	.	.	.	30 - 70	%
				Lymphocytes	56	H	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	197000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	398	.	.	+	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00328

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)		Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00329

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	16.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	34.5	.	.	.	21 - 51	%
				Monocytes	3.5	.	.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	346	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	118	H	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00329

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.8	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	298	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.009.00329

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00182

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	73.5	.	.	.	40 - 75	%
				Lymphocytes	16	.	.	.	16 - 46	%
				Monocytes	6.7	.	.	.	0 - 12	%
				Eosinophils	2.7	.	.	.	0 - 7	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00182

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	25	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEC	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00278

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	33.4	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	1.4	.	.	.	0 - 2	%
				Platelets	257000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	31	L	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00278

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3	.	.	.	30 - 70	%
				Lymphocytes	22.3	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00278

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alkaline Phosphatase	73	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	24.6	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00278

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	140	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	224	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.6	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	82	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	48	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00278

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 16/CONTINUATION-WEEK 32	224	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00280

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	314000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00280

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	48	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00280

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56		Alkaline Phosphatase	102	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	80	.	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	61		Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	2	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	4	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		3100.ZZ2	71		Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	97	(23)	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
					Hematocrit	37.9	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	10.4	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	73	H	.	.	30 - 70	%
					Lymphocytes	20	L	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.010.00280

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 11/CONTINUATION-WEEK 12	97	(23)	Monocytes	3.8	.	.	.	0 - 10	%
					Eosinophils	3	.	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	298000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	109	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	76	.	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	2	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	5	.	.	+		
					Urine Protein - Dipstick	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.011.00283

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7	.	.	.	30 - 70	%
				Lymphocytes	24.9	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	228000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.011.00283

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.6	H	.	.	30 - 70	%
				Lymphocytes	17.9	L	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	264000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	127	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.011.00283

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.011.00288

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-7	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.7	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.1	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	0.6	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	230	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	67	L	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	2		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.011.00288

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-7	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00025

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	34.7	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	287000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00025

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3	.	.	.	30 - 70	%
				Lymphocytes	40.3	.	.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00025

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 10/UNSCHEDULED LAB 1	65	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00220

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	194000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	168	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00220

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	36.3	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	159	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	134	H	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00220

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	89	Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	145	Hemoglobin	16.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39.4	.	.	.	30 - 70	%
				Lymphocytes	44.4	.	.	.	21 - 51	%
				Monocytes	9.5	.	.	.	0 - 10	%
				Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	216000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	135	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00220

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	145		Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	110	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	173	(15)	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	44.5	.	.	.	41 - 50	%
					Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	40.1	.	.	.	30 - 70	%
					Lymphocytes	42.4	.	.	.	21 - 51	%
					Monocytes	6.7	.	.	.	0 - 10	%
					Eosinophils	9.1	H	.	.	0 - 5	%
					Basophils	1.8	.	.	.	0 - 2	%
					Platelets	202000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
					Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.5	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	123	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	23	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00220

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 14/CONTINUATION-WEEK 24	173	(15)	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	99	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00222

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	296000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.5	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00222

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	72	H	.	.	30 - 70	%
				Lymphocytes	21	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	70	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00222

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 10/UNSCHEDULED LAB 1	76	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00222

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	92 (6)	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.6	.	.	.	30 - 70	%
				Lymphocytes	34.6	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	365000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00226

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.1	.	.	.	30 - 70	%
				Lymphocytes	34.8	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	203000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	136	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00226

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00228

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.5	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00228

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00231

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	45.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	35.4	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	243000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00231

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00231

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	4.3	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	100	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	116	H	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 17/DOWN TITRATION	166 (1)	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PAROXETINE PID: 329.012.00231

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 17/DOWN TITRATION	166	(1)	Hematocrit	43.5	.	.	.	35 - 46	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	63	.	.	.	30 - 70	%
					Lymphocytes	29.1	.	.	.	21 - 51	%
					Monocytes	5.9	.	.	.	0 - 10	%
					Eosinophils	1.6	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	232000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	49	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	82	.	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	+		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00061

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	90	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00061

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00066

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	.	.	.	30 - 70	%
				Lymphocytes	48.2	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	311000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00066

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00067

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.7	L	.	-	41 - 50	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	229	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	+		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00067

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00070

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.5	L	.	-	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3	.	.	.	30 - 70	%
				Lymphocytes	48.2	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	331000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	245	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00070

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00122

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.1	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.8	.	.	.	30 - 70	%
				Lymphocytes	43.2	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	1.6	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00122

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.4	.	.	.	30 - 70	%
				Lymphocytes	46.8	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00122

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	45	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	200000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	104	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.1	L	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.001.00122

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	141	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00050

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4	.	.	.	30 - 70	%
				Lymphocytes	25.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	275000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	186	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	46	L	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00050

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 1/UNSCHEDULED LAB 1	-6	Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4.6	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	203	H . .	22 - 180	U/L
				Aspartate Aminotransferase	16	. . .	0 - 41	U/L
				Alanine Aminotransferase	8	. . .	0 - 48	U/L
				Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
				Total Protein	8	. . .	6.2 - 8.8	G/DL
				Albumin	4.7	. . .	3.1 - 5.3	G/DL
				Glucose - Random	80	. . .	70 - 115	MG/DL
				Globulin	3.3	. . .	2.3 - 4.1	G/DL
		VISIT 6/ACUTE PHASE-WEEK 4	37 (2)	Hemoglobin	13.4	L . .	13.8 - 17.2	G/DL
				Hematocrit	39	L . .	41 - 50	%
				Red Blood Cell Count	4.9	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.8	. . .	30 - 70	%
				Lymphocytes	35.3	. . .	21 - 51	%
				Monocytes	5.9	. . .	0 - 10	%
				Eosinophils	2	. . .	0 - 5	%
				Basophils	0	. . .	0 - 2	%
				Platelets	244000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	. . .	25 - 35	PG
				Mean Corpuscle Volume	80	. . .	80 - 100	FL
				Blood Urea Nitrogen	9	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4	. . .	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00050

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 6/ACUTE PHASE-WEEK 4	37	(2)	Alkaline Phosphatase	199	H	.	.	22 - 180	U/L
					Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	41	L	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00056

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	11.8	L	.	.	12 - 15.6	G/DL
				Hematocrit	35.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	62	.	.	.	40 - 75	%
				Lymphocytes	27.9	.	.	.	16 - 46	%
				Monocytes	7.2	.	.	.	0 - 12	%
				Eosinophils	2.2	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	406000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	25.6	L	.	.	27 - 33	PG
				Mean Corpuscle Volume	77	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00056

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00057

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-28	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	28.8	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	321000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00057

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-28	Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-21	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		1010.ZZ2	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEC	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00057

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	48	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	23.6	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	347000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00057

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	100	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	POS		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
		VISIT 11/CONTINUATION-WEEK 12	85	Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00057

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	85	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	113	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	29.2	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	375000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	75	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00057

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 12/CONTINUATION-WEEK 16	113	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00098

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	27.9	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00098

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.2	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00098

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	NEG	. . .		
				Urine Protein - Dipstick	NEG	. . .		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00100

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.5	.	.	.	30 - 70	%
				Lymphocytes	23.3	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	156000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	115	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00100

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	16.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.1	.	.	.	30 - 70	%
				Lymphocytes	23.9	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	175000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00100

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00103

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.6	.	.	.	30 - 70	%
				Lymphocytes	22.2	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	319000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00103

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	82	H	.	.	30 - 70	%
				Lymphocytes	15	L	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	331000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00103

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00104

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	29.4	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	329000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	401	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00104

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.6	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	348	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00104

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	153	White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.5	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	334000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	272	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	244	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	15.1	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	82.2	H	.	.	30 - 70	%
				Lymphocytes	10.8	L	.	.	21 - 51	%

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00104

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 16/CONTINUATION-WEEK 32	244	Monocytes	3.6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	476000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	24	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00243

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5	.	.	.	30 - 70	%
				Lymphocytes	36.1	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00243

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00244

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.2	.	.	.	30 - 70	%
				Lymphocytes	32.8	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00244

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.8	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	70	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00244

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00321

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.2	.	.	.	30 - 70	%
				Lymphocytes	39.6	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	249000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	100	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00321

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00322

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	9.2	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	294	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.002.00322

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-3	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00073

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.2	.	.	.	30 - 70	%
				Lymphocytes	31.6	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00073

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00076

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	317000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00076

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	44	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	0.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00076

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	15.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	38	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	286000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	51	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00076

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	149		Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	254	(14)	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	42.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54.5	.	.	.	30 - 70	%
					Lymphocytes	37.3	.	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	1.8	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	300000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	67	H	.	.	0 - 48	U/L
					Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	119	H	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00076

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	254	(14)	Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00079

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	38.2	.	.	.	30 - 70	%
				Lymphocytes	49	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00079

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00082

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	10.5	H	.	+	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00082

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00088

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-22	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	58.5	.	.	.	30 - 70	%
				Lymphocytes	29.2	.	.	.	21 - 51	%
				Monocytes	11.2	H	.	.	0 - 10	%
				Eosinophils	0.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	45000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00088

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-22	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00090

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.9	.	.	.	30 - 70	%
				Lymphocytes	42.3	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	275000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	128	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00090

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	45	. . .	30 - 70	%
				Lymphocytes	40	. . .	21 - 51	%
				Monocytes	8	. . .	0 - 10	%
				Eosinophils	2	. . .	0 - 5	%
				Basophils	0	. . .	0 - 2	%
				Blood Urea Nitrogen	11	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.3	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	. . .	44 - 280	U/L
				Aspartate Aminotransferase	16	. . .	0 - 41	U/L
				Alanine Aminotransferase	20	. . .	0 - 48	U/L
				Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.7	. . .	6.2 - 8.8	G/DL
				Albumin	4.7	. . .	3.1 - 5.3	G/DL
				Glucose - Random	86	. . .	70 - 115	MG/DL
				Globulin	3	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	4	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	4	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00090

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/UNSCHEDULED LAB 1	78	(9)	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
					Hematocrit	40.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.9	.	.	.	30 - 70	%
					Lymphocytes	39.7	.	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	0.8	.	.	.	0 - 5	%
					Basophils	0.6	.	.	.	0 - 2	%
					Platelets	310000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00092

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-20	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.2	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.3	.	.	.	30 - 70	%
				Lymphocytes	46.2	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	192000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	320	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	60 - 110	MG/DL
				Globulin	2.8	.	.	.	2.1 - 3.8	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-5	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00092

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/UNSCHEDULED LAB 1	-5	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	40	.	.	.	30 - 70	%
				Lymphocytes	52	H	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	245	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	42.4	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00092

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	147	Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	223	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	60	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.9	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	7000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00092

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 16/CONTINUATION-WEEK 32	245	Alkaline Phosphatase	225	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	2.8	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/UNSCHEDULED LAB 1	259	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	27.6	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	187000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00093

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	27	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
		VISIT 1/UNSCHEDULED LAB 1	-8	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.5	.	.	.	30 - 70	%
				Lymphocytes	36.2	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	361000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00093

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/UNSCHEDULED LAB 1	-8	Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	30	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	108	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00093

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	63		Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/UNSCHEDULED LAB 1	72		Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.7	.	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
					Platelets	344000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
		VISIT 11/CONTINUATION-WEEK 12	105	(25)	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	59.6	.	.	.	30 - 70	%
					Lymphocytes	29.7	.	.	.	21 - 51	%
					Monocytes	5	.	.	.	0 - 10	%
					Eosinophils	5.3	H	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	370000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	109	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00093

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/CONTINUATION-WEEK 12	105	(25)	Glucose - Random	102	.	.	.	70 - 115	MG/DL
					Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	+		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	2	.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00247

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.2	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	139	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00247

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	14.6	. . .	13.8 - 17.2	G/DL
				Hematocrit	41.8	. . .	41 - 50	%
				Red Blood Cell Count	4.9	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	. . .	30 - 70	%
				Lymphocytes	30.2	. . .	21 - 51	%
				Monocytes	5.8	. . .	0 - 10	%
				Eosinophils	4.2	. . .	0 - 5	%
				Basophils	0.9	. . .	0 - 2	%
				Platelets	238000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	. . .	25 - 35	PG
				Mean Corpuscle Volume	85	. . .	80 - 100	FL
				Blood Urea Nitrogen	8	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	117	. . .	22 - 180	U/L
				Aspartate Aminotransferase	15	. . .	0 - 41	U/L
				Alanine Aminotransferase	12	. . .	0 - 48	U/L
				Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.7	. . .	6.2 - 8.8	G/DL
				Albumin	4.5	. . .	3.1 - 5.3	G/DL
				Glucose - Random	102	. . .	70 - 115	MG/DL
				Globulin	3.2	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00247

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00249

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	320000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00249

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.3	.	.	.	30 - 70	%
				Lymphocytes	37.5	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	376000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00249

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00289

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.9	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	2.6	.	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00289

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	10.3	L	.	.	12 - 15.6	G/DL
				Hematocrit	30.4	L	.	-	35 - 46	%
				Red Blood Cell Count	3.4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.4	.	.	.	30 - 70	%
				Lymphocytes	33.1	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.6	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00289

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	143	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	36	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40.6	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00289

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	143	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	227	Hemoglobin	10.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	30.5	L	.	-	35 - 46	%
				Red Blood Cell Count	3.4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.4	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	19	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	47	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00289

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	227	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00290

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	38.9	.	.	.	30 - 70	%
				Lymphocytes	44.3	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	68	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00290

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00314

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.8	.	.	.	30 - 70	%
				Lymphocytes	23.2	.	.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	301000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00314

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	50	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEC	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.3	.	.	.	30 - 70	%
				Lymphocytes	21.1	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00314

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Monocytes	11.7	H	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00317

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	34.6	L	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60	.	.	.	30 - 70	%
				Lymphocytes	24.3	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	2.6	H	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
				Urine Amphetamines	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00317

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.3	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66	.	.	.	30 - 70	%
				Lymphocytes	24.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.003.00317

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00013

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.5	.	.	.	30 - 70	%
				Lymphocytes	31.1	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	118	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00013

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.3	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	85	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00013

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 11/CONTINUATION-WEEK 12	85	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.1	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	172000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00013

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	141	Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	176	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	26.9	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	9.8	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	177000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 15/CONTINUATION-WEEK 28	204	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9	.	.	.	30 - 70	%
				Lymphocytes	25.9	.	.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00013

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 15/CONTINUATION-WEEK 28	204	Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	235	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.7	.	.	.	30 - 70	%
				Lymphocytes	31.3	.	.	.	21 - 51	%
				Monocytes	12.1	H	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00013

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 16/CONTINUATION-WEEK 32	235	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	64	L	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00014

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	174	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00014

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.9	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.6	.	.	.	30 - 70	%
				Lymphocytes	36.4	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	8.5	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	163000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
		VISIT 4/ACUTE PHASE-WEEK 2	15	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	32.5	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	174000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	179	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00014

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 4/ACUTE PHASE-WEEK 2	15	Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEC		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00211

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	37.3	L	.	.	40 - 75	%
				Lymphocytes	48.4	H	.	.	16 - 46	%
				Monocytes	10.4	.	.	.	0 - 12	%
				Eosinophils	3.1	.	.	.	0 - 7	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00211

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-9		Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	53	(4)	Hemoglobin	15.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	44.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.9	.	.	.	3.9 - 5.2	MILL/MCL
					White Blood Cell Count	5.1	.	.	.	3.8 - 10.8	THOU/MCL
					Segmented Neutrophils	72.4	.	.	.	40 - 75	%
					Lymphocytes	14.1	L	.	.	16 - 46	%
					Monocytes	9.4	.	.	.	0 - 12	%
					Eosinophils	2.4	.	.	.	0 - 7	%
					Basophils	1.8	.	.	.	0 - 2	%
					Platelets	244000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.1	.	.	.	27 - 33	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	96	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	67	H	.	.	0 - 41	U/L
					Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	91	.	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00215

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	30.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	9.4	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	97	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.004.00215

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8		Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	41	(1)	Segmented Neutrophils	54	.	.	.	30 - 70	%
					Lymphocytes	39	.	.	.	21 - 51	%
					Monocytes	4	.	.	.	0 - 10	%
					Eosinophils	1	.	.	.	0 - 5	%
					Basophils	2	.	.	.	0 - 2	%
					Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00003

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.8	.	.	.	30 - 70	%
				Lymphocytes	37.7	.	.	.	21 - 51	%
				Monocytes	3.6	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	108	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	116	H	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00003

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00006

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Blood Urea Nitrogen	15	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5.2	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	73	. . .	22 - 180	U/L
				Aspartate Aminotransferase	12	. . .	0 - 41	U/L
				Alanine Aminotransferase	7	. . .	0 - 48	U/L
				Total Bilirubin	1	. . .	0.3 - 1.3	MG/DL
				Total Protein	6.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.1	. . .	3.1 - 5.3	G/DL
				Glucose - Random	99	. . .	70 - 115	MG/DL
				Globulin	2.7	. . .	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.5	. . .	13.8 - 17.2	G/DL
				Hematocrit	42.4	. . .	41 - 50	%
				Red Blood Cell Count	4.9	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	. . .	30 - 70	%
				Lymphocytes	33.2	. . .	21 - 51	%
				Monocytes	9.7	. . .	0 - 10	%
				Eosinophils	1.7	. . .	0 - 5	%
				Basophils	0.5	. . .	0 - 2	%
				Platelets	306000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	. . .	25 - 35	PG
				Mean Corpuscle Volume	87	. . .	80 - 100	FL
				Blood Urea Nitrogen	17	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4.8	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	73	. . .	22 - 180	U/L
				Aspartate Aminotransferase	13	. . .	0 - 41	U/L
				Alanine Aminotransferase	9	. . .	0 - 48	U/L
				Total Bilirubin	0.9	. . .	0.3 - 1.3	MG/DL
				Total Protein	6.9	. . .	6.2 - 8.8	G/DL
				Albumin	4.1	. . .	3.1 - 5.3	G/DL
				Glucose - Random	90	. . .	70 - 115	MG/DL
				Globulin	2.8	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00006

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	3	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	15.7	. . .	13.8 - 17.2	G/DL
				Hematocrit	44.8	. . .	41 - 50	%
				Red Blood Cell Count	5.2	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55	. . .	30 - 70	%
				Lymphocytes	36	. . .	21 - 51	%
				Monocytes	6	. . .	0 - 10	%
				Eosinophils	3	. . .	0 - 5	%
				Basophils	0	. . .	0 - 2	%
				Platelets	114000 L	. .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	. . .	25 - 35	PG
				Mean Corpuscle Volume	86	. . .	80 - 100	FL
				Blood Urea Nitrogen	13	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4.7	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	76	. . .	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00006

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	61		Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	93	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
		VISIT 17/DOWN TITRATION	176	(1)	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	48.4	.	.	.	41 - 50	%
					Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.3	.	.	.	30 - 70	%
					Lymphocytes	34	.	.	.	21 - 51	%
					Monocytes	9.3	.	.	.	0 - 10	%
					Eosinophils	4.1	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	292000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	20	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	6	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
					Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	92	.	.	.	70 - 115	MG/DL
					Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00006

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 17/DOWN TITRATION	176	(1)	Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00007

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.1	.	.	.	30 - 70	%
				Lymphocytes	27.4	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	307000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00007

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.3	.	.	.	30 - 70	%
				Lymphocytes	22.7	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	0.6	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	44000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	107	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00007

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	99	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	17.4	H	.	.	12 - 15.6	G/DL
				Hematocrit	51.5	H	.	.	35 - 46	%
				Red Blood Cell Count	6.1	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	28.4	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	0.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	28000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00007

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	162		Urine Red Blood Cells/HPF	NEG		.	.	.	
					Urine White Blood Cells/HPF	3		.	.	.	
					Urine Bacteria	4		.	.	.	
					Urine Protein - Dipstick	NEG		.	.	.	
					Urine Squamous Epithelial Cells	4		.	.	.	
		VISIT 15/CONTINUATION-WEEK 28	274	(82)	Hemoglobin	13.6		.	.	.	12 - 15.6	G/DL
					Hematocrit	41.1		.	.	.	35 - 46	%
					Red Blood Cell Count	4.9		.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.8		.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	63		.	.	.	30 - 70	%
					Lymphocytes	28.3		.	.	.	21 - 51	%
					Monocytes	6		.	.	.	0 - 10	%
					Eosinophils	1.2		.	.	.	0 - 5	%
					Basophils	1.6		.	.	.	0 - 2	%
					Platelets	238000		.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.8		.	.	.	25 - 35	PG
					Mean Corpuscle Volume	84		.	.	.	80 - 100	FL
					Blood Urea Nitrogen	8		.	.	.	7 - 25	MG/DL
					Creatinine	1.1		.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.9		.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	71		.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	16		.	.	.	0 - 41	U/L
					Alanine Aminotransferase	7		.	.	.	0 - 48	U/L
					Total Bilirubin	0.5		.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7		.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2		.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	82		.	.	.	70 - 115	MG/DL
					Globulin	2.8		.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00009

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.5	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.5	H	.	.	30 - 70	%
				Lymphocytes	20.3	L	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00009

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	45.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.4	H	.	.	30 - 70	%
				Lymphocytes	20.5	L	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	54000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	45	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	49	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00009

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria		5	.	.		
				Urine Protein - Dipstick		2	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00110

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	22.5	.	.	.	21 - 51	%
				Monocytes	16.2	H	.	+	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEC	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00110

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	46	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	42	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test BORDERLINE		.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	10 (1)	Serum BHCG pregnancy test POSITIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00113

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	33	.	.	.	30 - 70	%
				Lymphocytes	58	H	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	54000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00113

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00117

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	28.9	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	364000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00117

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	119	H	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00118

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	35.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00118

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	35	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEC	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00153

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	32	L	.	.	40 - 75	%
				Lymphocytes	58	H	.	.	16 - 46	%
				Monocytes	9	.	.	.	0 - 12	%
				Eosinophils	1	.	.	.	0 - 7	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	228000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	53	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00153

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-3	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	9.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.4	.	.	.	40 - 75	%
				Lymphocytes	31.2	.	.	.	16 - 46	%
				Monocytes	4.1	.	.	.	0 - 12	%
				Eosinophils	7.6	H	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.8	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00153

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	15.8	H	.	.	12 - 15.6	G/DL
				Hematocrit	45.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	60.3	.	.	.	40 - 75	%
				Lymphocytes	27.9	.	.	.	16 - 46	%
				Monocytes	6	.	.	.	0 - 12	%
				Eosinophils	4.8	.	.	.	0 - 7	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00153

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 13/CONTINUATION-WEEK 20	142	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	224	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	40 - 75	%
				Lymphocytes	31.4	.	.	.	16 - 46	%
				Monocytes	4.3	.	.	.	0 - 12	%
				Eosinophils	6.4	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	282000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00255

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2	.	.	.	30 - 70	%
				Lymphocytes	30.5	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	17.7	H	.	+	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	299000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00255

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	53	.	.	.	30 - 70	%
				Lymphocytes	34	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	299000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00255

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Serum BHCG pregnancy test	NEGATIVE	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00256

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.6	.	.	.	30 - 70	%
				Lymphocytes	20.9	L	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	98	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00256

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	32.4	.	.	.	21 - 51	%
				Monocytes	8.7	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	23.7	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	218000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00256

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
		VISIT 12/CONTINUATION-WEEK 16	120	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	28	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	206000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00256

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 12/CONTINUATION-WEEK 16	120	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00295

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62	.	.	.	30 - 70	%
				Lymphocytes	34	.	.	.	21 - 51	%
				Monocytes	2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	29	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00295

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	.	.	.	30 - 70	%
				Lymphocytes	22.7	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	277000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00295

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		4	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00297

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-22	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	40 - 75	%
				Lymphocytes	31.3	.	.	.	16 - 46	%
				Monocytes	8.6	.	.	.	0 - 12	%
				Eosinophils	3.8	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	146000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.4	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00297

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-22	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-16	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00332

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	UNSATISFACTO	U	.	U	22 - 180	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEC		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.6	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00332

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	1	Eosinophils	8.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	46.4	.	.	.	40 - 75	%
				Lymphocytes	37.4	.	.	.	16 - 46	%
				Monocytes	7.3	.	.	.	0 - 12	%
				Eosinophils	8.1	H	.	.	0 - 7	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	183	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00335

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.3	.	.	.	30 - 70	%
				Lymphocytes	36.8	.	.	.	21 - 51	%
				Monocytes	3.5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	359000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00335

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.9	. . .	12 - 15.6	G/DL
				Hematocrit	41	. . .	35 - 46	%
				Red Blood Cell Count	5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	. . .	30 - 70	%
				Lymphocytes	32.3	. . .	21 - 51	%
				Monocytes	7	. . .	0 - 10	%
				Eosinophils	2.1	. . .	0 - 5	%
				Basophils	0.2	. . .	0 - 2	%
				Platelets	309000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	. . .	25 - 35	PG
				Mean Corpuscle Volume	82	. . .	80 - 100	FL
				Blood Urea Nitrogen	8	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.8	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	. . .	44 - 280	U/L
				Aspartate Aminotransferase	21	. . .	0 - 41	U/L
				Alanine Aminotransferase	16	. . .	0 - 48	U/L
				Total Bilirubin	0.5	. . .	0.3 - 1.3	MG/DL
				Total Protein	8.4	. . .	6.2 - 8.8	G/DL
				Albumin	4.3	. . .	3.1 - 5.3	G/DL
				Glucose - Random	105	. . .	70 - 115	MG/DL
				Globulin	4.1	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.005.00335

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.006.00040

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.6	.	.	.	40 - 75	%
				Lymphocytes	34	.	.	.	16 - 46	%
				Monocytes	6.7	.	.	.	0 - 12	%
				Eosinophils	1.4	.	.	.	0 - 7	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	310000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	48	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.006.00040

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.006.00041

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	40 - 75	%
				Lymphocytes	37.5	.	.	.	16 - 46	%
				Monocytes	7.3	.	.	.	0 - 12	%
				Eosinophils	3.3	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	98	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.006.00041

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	53	.	.	.	40 - 75	%
				Lymphocytes	35.5	.	.	.	16 - 46	%
				Monocytes	8	.	.	.	0 - 12	%
				Eosinophils	3.1	.	.	.	0 - 7	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	98	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	39	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	92	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.006.00041

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 11/CONTINUATION-WEEK 12	92	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	44.4	.	.	.	40 - 75	%
				Lymphocytes	28.2	.	.	.	16 - 46	%
				Monocytes	12	.	.	.	0 - 12	%
				Eosinophils	14.4	H	.	+	0 - 7	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	201000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	107	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	48	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
		VISIT 15/CONTINUATION-WEEK 28	203	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.006.00041

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 15/CONTINUATION-WEEK 28	203	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	231	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	58.1	.	.	.	40 - 75	%
				Lymphocytes	31.3	.	.	.	16 - 46	%
				Monocytes	7.6	.	.	.	0 - 12	%
				Eosinophils	2.5	.	.	.	0 - 7	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00139

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.1	.	.	.	30 - 70	%
				Lymphocytes	45.9	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	270	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	63	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00139

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-3		Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	43	(25)	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.8	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	49.7	.	.	.	30 - 70	%
					Lymphocytes	39.7	.	.	.	21 - 51	%
					Monocytes	7.1	.	.	.	0 - 10	%
					Eosinophils	2.7	.	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	296000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
					Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	227	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
					Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	86	.	.	.	60 - 110	MG/DL
					Globulin	3.1	.	.	.	2.1 - 3.8	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00143

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.2	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00143

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	14	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.3	.	.	.	35 - 46	%
				White Blood Cell Count	10	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00146

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	25.7	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	2.4	H	.	.	0 - 2	%
				Platelets	233000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	89	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00146

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	24.7	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	209000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00146

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	134	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	82	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	34	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00146

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	134	Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	229	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/UNSCHEDULED LAB 1	232	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00146

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/UNSCHEDULED LAB 1	232	Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00269

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	259	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00269

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Cannabinoids	NEG	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Opiates	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	22	(7)	Hemoglobin	14.3	. . .	13.8 - 17.2	G/DL
					Hematocrit	41	. . .	41 - 50	%
					Red Blood Cell Count	4.6	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.9	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	42.9	. . .	30 - 70	%
					Lymphocytes	45.4	. . .	21 - 51	%
					Monocytes	9	. . .	0 - 10	%
					Eosinophils	1.8	. . .	0 - 5	%
					Basophils	1	. . .	0 - 2	%
					Platelets	272000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9	. . .	25 - 35	PG
					Mean Corpuscle Volume	89	. . .	80 - 100	FL
					Blood Urea Nitrogen	6	L . .	7 - 25	MG/DL
					Creatinine	1	. . .	0.8 - 1.5	MG/DL
					Uric Acid	5.5	. . .	4 - 8	MG/DL
					Alkaline Phosphatase	239	. . .	44 - 400	U/L
					Aspartate Aminotransferase	21	. . .	0 - 41	U/L
					Alanine Aminotransferase	26	. . .	0 - 48	U/L
					Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.8	. . .	6.2 - 8.8	G/DL
					Albumin	4.3	. . .	3.1 - 5.3	G/DL
					Glucose - Random	108	. . .	70 - 115	MG/DL
					Globulin	3.5	. . .	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	. . .		
					Urine Blood - Dipstick	NEG	. . .		
					Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00269

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	22 (7)	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00270

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.5	.	.	.	30 - 70	%
				Lymphocytes	41.6	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	318	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00270

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	50 (7)	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	38.3	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	343	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00270

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	50 (7)	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00307

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.4	.	.	.	30 - 70	%
				Lymphocytes	32.9	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	328000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00307

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	20.6	L	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00308

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	256000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	221	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.007.00308

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00159

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.8	.	.	.	30 - 70	%
				Lymphocytes	19.2	L	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	333000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00159

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	29.2	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	344000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	43	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00159

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00161

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	26.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	327000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00161

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-16		Urine Benzodiazepines	NEG	. . .		
					Urine Cannabinoids	NEG	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Opiates	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	56	(1)	Hemoglobin	14.7	. . .	13.8 - 17.2	G/DL
					Hematocrit	41.7	. . .	41 - 50	%
					Red Blood Cell Count	4.8	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.1	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	67.4	. . .	30 - 70	%
					Lymphocytes	23.2	. . .	21 - 51	%
					Monocytes	7	. . .	0 - 10	%
					Eosinophils	1.5	. . .	0 - 5	%
					Basophils	1	. . .	0 - 2	%
					Platelets	312000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9	. . .	25 - 35	PG
					Mean Corpuscle Volume	87	. . .	80 - 100	FL
					Blood Urea Nitrogen	9	. . .	7 - 25	MG/DL
					Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
					Uric Acid	5.2	. . .	4 - 8	MG/DL
					Alkaline Phosphatase	73	. . .	22 - 180	U/L
					Aspartate Aminotransferase	9	. . .	0 - 41	U/L
					Alanine Aminotransferase	8	. . .	0 - 48	U/L
					Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.1	. . .	6.2 - 8.8	G/DL
					Albumin	4.2	. . .	3.1 - 5.3	G/DL
					Glucose - Random	88	. . .	70 - 115	MG/DL
					Globulin	2.9	. . .	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	. . .		
					Urine Blood - Dipstick	NEG	. . .		
					Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00161

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	56 (1)	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00187

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.6	.	.	.	30 - 70	%
				Lymphocytes	45.5	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	267000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00187

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 4/ACUTE PHASE-WEEK 2	16	Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	0.8	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.1	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	. . .	22 - 130	U/L
				Aspartate Aminotransferase	12	. . .	0 - 41	U/L
				Alanine Aminotransferase	8	. . .	0 - 48	U/L
				Total Bilirubin	1.5	H . .	0.3 - 1.3	MG/DL
				Total Protein	7.1	. . .	6.2 - 8.8	G/DL
				Albumin	4.3	. . .	3.1 - 5.3	G/DL
				Glucose - Random	76	. . .	70 - 115	MG/DL
				Globulin	2.8	. . .	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.4	. . .	12 - 15.6	G/DL
				Hematocrit	41.6	. . .	35 - 46	%
				Red Blood Cell Count	4.7	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.3	. . .	30 - 70	%
				Lymphocytes	38.3	. . .	21 - 51	%
				Monocytes	8.1	. . .	0 - 10	%
				Eosinophils	3	. . .	0 - 5	%
				Basophils	0.4	. . .	0 - 2	%
				Platelets	302000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	11	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.3	. . .	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00187

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00192

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-20	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.5	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35	.	.	.	30 - 70	%
				Lymphocytes	54	H	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	357	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00192

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-20	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00272

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	.	.	.	30 - 70	%
				Lymphocytes	48.9	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	451000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.2	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	305	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	64	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00272

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-15	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.4	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	320000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	274	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00272

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37	L	.	-	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	31.9	.	.	.	30 - 70	%
				Lymphocytes	44.8	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	15.9	H	.	+	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	285	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00272

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	141	Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00273

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-28	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.1	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	427000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	263	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00273

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-28	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-10	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	341000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	251	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.008.00273

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	60 - 110	MG/DL
				Globulin	3.9	H	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00127

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	338000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	8 - 21	MG/DL
				Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 39	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	60 - 110	MG/DL
				Globulin	2.8	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00127

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00132

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1	.	.	.	30 - 70	%
				Lymphocytes	40.1	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	234	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00132

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.5	.	.	.	30 - 70	%
				Lymphocytes	35.5	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	7.2	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	255	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	155	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00132

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	155	White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	41.7	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	267	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEC		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00134

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	325000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00134

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	34.9	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	363000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00134

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00137

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	2.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	310000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	426	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00137

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.7	L	.	-	41 - 50	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.7	.	.	.	30 - 70	%
				Lymphocytes	24.5	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	367	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00137

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00171

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1	.	.	.	30 - 70	%
				Lymphocytes	22.1	.	.	.	21 - 51	%
				Monocytes	2.7	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	404000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	128	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00171

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00172

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7	.	.	.	30 - 70	%
				Lymphocytes	36.6	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00172

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00172

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.7	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.1	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	127	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00172

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	141	Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	239	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.3	.	.	.	30 - 70	%
				Lymphocytes	42.9	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	267000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00172

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	239	Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00194

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36	L	.	-	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.3	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	316000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	244	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	125	H	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00194

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.9	L	.	-	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.1	.	.	.	30 - 70	%
				Lymphocytes	32.7	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	78	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.1	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	259	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00194

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	12.8	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	28.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	289000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	239	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00194

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	148	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00195

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	38.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	220000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	96	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	61	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00195

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	13	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00199

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.3	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	28.6	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	148000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00199

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.7	.	.	.	30 - 70	%
				Lymphocytes	30	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	0.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00199

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		4	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00203

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.6	.	.	.	30 - 70	%
				Lymphocytes	39.8	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	227	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	60 - 110	MG/DL
				Globulin	2.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00203

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00236

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	183	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00236

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00239

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	31	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	67000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	43	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00239

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.3	.	.	.	30 - 70	%
				Lymphocytes	28.5	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	42	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Amphetamines	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00239

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58		Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	(1)	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.2	.	.	.	35 - 46	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	70.7	H	.	.	30 - 70	%
					Lymphocytes	22.2	.	.	.	21 - 51	%
					Monocytes	5.2	.	.	.	0 - 10	%
					Eosinophils	1	.	.	.	0 - 5	%
					Basophils	1	.	.	.	0 - 2	%
					Platelets	191000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	37	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	54	L	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00239

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	147 (1)	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00262

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	399	.	.	+	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00262

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	3.9	.	.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	285	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00264

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.7	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	354000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00264

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	25	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.3	.	.	.	30 - 70	%
				Lymphocytes	42	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	287000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	53	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.2	.	.	.	30 - 70	%
				Lymphocytes	26	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	314000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00264

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	53	Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	96	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00301

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-6	Neutrophil Bands	1	L	.	.	4 - 12	%
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	229	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00301

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.4	.	.	.	30 - 70	%
				Lymphocytes	32.5	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	8.7	H	.	.	0 - 5	%
				Basophils	2.5	H	.	.	0 - 2	%
				Platelets	272000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6	.	.	.	30 - 70	%
				Lymphocytes	34	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	171	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00301

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00305

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.5	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	200	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00305

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.3	.	.	.	30 - 70	%
				Lymphocytes	30	.	.	.	21 - 51	%
				Monocytes	12.2	H	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	154000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	225	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00305

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	9	. . .	0 - 48	U/L
				Total Bilirubin	1.3	. . .	0.3 - 1.3	MG/DL
				Total Protein	6.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.2	. . .	3.1 - 5.3	G/DL
				Glucose - Random	99	. . .	70 - 115	MG/DL
				Globulin	2.6	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	NEG	. . .		
				Urine Bacteria	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	14.7	. . .	13.8 - 17.2	G/DL
				Hematocrit	42.6	. . .	41 - 50	%
				Red Blood Cell Count	4.8	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4	. . .	30 - 70	%
				Lymphocytes	39	. . .	21 - 51	%
				Monocytes	6.6	. . .	0 - 10	%
				Eosinophils	2.6	. . .	0 - 5	%
				Basophils	0.4	. . .	0 - 2	%
				Platelets	164000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	. . .	25 - 35	PG
				Mean Corpuscle Volume	88	. . .	80 - 100	FL
				Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	200	. . .	44 - 400	U/L
				Aspartate Aminotransferase	18	. . .	0 - 41	U/L
				Alanine Aminotransferase	12	. . .	0 - 48	U/L
				Total Bilirubin	1.4	H . .	0.3 - 1.3	MG/DL
				Total Protein	6.5	. . .	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00305

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	141	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	249	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	33.6	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	195	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00305

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	249	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	70	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00325

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.2	.	.	.	30 - 70	%
				Lymphocytes	40.1	.	.	.	21 - 51	%
				Monocytes	9.3	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00325

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	32.2	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	0.5	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	313000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00325

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	112	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	44.2	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	0.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	340000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00326

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	35.7	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	181	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	78	H	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00326

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	27.7	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	234000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	34	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	120	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 12/CONTINUATION-WEEK 16	103	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.009.00326

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 12/CONTINUATION-WEEK 16	103	White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	134	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00279

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	34.8	.	.	.	21 - 51	%
				Monocytes	13.5	H	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	168000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	164	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00279

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	68	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	163000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00279

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	140	Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	132	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	67	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	230	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	178000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00279

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	230	Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.8	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00281

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.8	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	256000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	252	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00281

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	0.9	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	250000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	235	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00281

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	62	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.4	H	.	.	30 - 70	%
				Lymphocytes	18.2	L	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	0.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	215	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00281

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	148	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	162	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.1	.	.	.	30 - 70	%
				Lymphocytes	42.5	.	.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	0.2	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	275000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.010.00281

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 14/CONTINUATION-WEEK 24	162	Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00163

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Segmented Neutrophils	SMEARS RECEI	U	.	U	30 - 70	%
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.3	H	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	4.3	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3		.	.	.	
				Urine Bacteria	3		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4		.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00163

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 3/ACUTE PHASE-WEEK 1	7	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.2	H	.	.	30 - 70	%
				Lymphocytes	19.7	L	.	.	21 - 51	%
				Monocytes	1.9	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	251000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00208

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.5	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	182000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	208	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00208

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	-1	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.5	.	.	.	30 - 70	%
				Lymphocytes	36.9	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	171000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	174	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00209

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	293	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00209

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 2/ELIGIBILITY	-1	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	41	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	311000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	230	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	107	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00284

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	41	.	.	.	30 - 70	%
				Lymphocytes	49	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	180000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00284

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	2	L	.	.	4 - 12	%
				Segmented Neutrophils	43	.	.	.	30 - 70	%
				Lymphocytes	47	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	216000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00284

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	137	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	2.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	21	L	.	.	30 - 70	%
				Lymphocytes	72	H	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	165000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	97	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	85	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	4.7	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00284

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	137	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00286

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	8.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	RESULT INVAL	U	.	U	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00286

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	69	Hemoglobin	15.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3	.	.	.	30 - 70	%
				Lymphocytes	19.9	L	.	.	21 - 51	%
				Monocytes	10.9	H	.	.	0 - 10	%
				Eosinophils	0.8	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00286

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	69	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	173	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.2	.	.	.	30 - 70	%
				Lymphocytes	23.2	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.011.00286

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	173	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00026

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-19	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.3	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	203000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	256	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00026

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-19	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00219

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	173000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	176	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	1.8	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00219

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	181	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.9	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1	.	.	.	30 - 70	%
				Lymphocytes	37.7	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	166	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00219

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	92	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	172000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	187	.	.	.	44 - 400	U/L

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00219

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	148		Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	97	.	.	.	70 - 115	MG/DL
					Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 14/CONTINUATION-WEEK 24	176		Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	2	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	239	(6)	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	44.6	.	.	.	41 - 50	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	51	.	.	.	30 - 70	%
					Lymphocytes	34.9	.	.	.	21 - 51	%
					Monocytes	11	H	.	.	0 - 10	%
					Eosinophils	2.7	.	.	.	0 - 5	%
					Basophils	0.3	.	.	.	0 - 2	%
					Platelets	163000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.6	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	172	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00219

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	239 (6)	Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00221

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	26.6	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	235000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	114	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00221

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	1	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	27.9	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00221

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	64	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00223

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.1	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	359000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	154	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	44	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	67	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00223

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00227

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00227

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.6	H	.	.	30 - 70	%
				Lymphocytes	15.4	L	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00227

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	70	Urine Bacteria	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	3	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	POS	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 13/CONTINUATION-WEEK 20	160	Hemoglobin	15.5	. . .	13.8 - 17.2	G/DL
				Hematocrit	45.8	. . .	41 - 50	%
				Red Blood Cell Count	5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.9	. . .	30 - 70	%
				Lymphocytes	33.5	. . .	21 - 51	%
				Monocytes	9.5	. . .	0 - 10	%
				Eosinophils	5.8	H . .	0 - 5	%
				Basophils	0.3	. . .	0 - 2	%
				Platelets	246000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	. . .	25 - 35	PG
				Mean Corpuscle Volume	92	. . .	80 - 100	FL
				Blood Urea Nitrogen	12	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4.1	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	100	. . .	22 - 180	U/L
				Aspartate Aminotransferase	13	. . .	0 - 41	U/L
				Alanine Aminotransferase	18	. . .	0 - 48	U/L
				Total Bilirubin	0.5	. . .	0.3 - 1.3	MG/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00227

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	160	Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60	.	.	.	30 - 70	%
				Lymphocytes	24.3	.	.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00227

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 16/CONTINUATION-WEEK 32	245	Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00230

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	48.9	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	186	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	1	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.2	.	.	.	30 - 70	%
				Lymphocytes	35.5	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: IMIPRAMINE PID: 329.012.00230

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	356000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	158	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00062

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66	.	.	.	30 - 70	%
				Lymphocytes	25.4	.	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	2.7	H	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00062

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00064

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.5	.	.	.	30 - 70	%
				Lymphocytes	44.1	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	7.6	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	195000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	265	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00064

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.8	.	.	.	30 - 70	%
				Lymphocytes	32.4	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	195000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	200	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00064

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	139	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	2.4	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	197000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	189	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
			145	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00064

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	145	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00069

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.9	.	.	.	30 - 70	%
				Lymphocytes	21.3	.	.	.	21 - 51	%
				Monocytes	2.7	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	104	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00069

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.7	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	2	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00069

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00071

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.4	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	181	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00071

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00071

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		4	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00123

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	30.7	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	297000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00123

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00207

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	238	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	42	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00207

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37.3	.	.	.	30 - 70	%
				Lymphocytes	50.7	.	.	.	21 - 51	%
				Monocytes	9.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	225	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	122	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.001.00207

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00049

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	1000.PRE	-13	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.7	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	27.5	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	123	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	68	L	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		
		VISIT 1/SCREENING (WEEK -1)	-6	Urine Glucose - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00049

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3	.	.	.	30 - 70	%
				Lymphocytes	33	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00049

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	58		Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
					Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	25	L	.	.	70 - 115	MG/DL
					Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	91	(17)	Glucose - Random	96	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00059

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6	. . .	13.8 - 17.2	G/DL
				Hematocrit	45	. . .	41 - 50	%
				Red Blood Cell Count	5.2	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.7	. . .	30 - 70	%
				Lymphocytes	40.9	. . .	21 - 51	%
				Monocytes	9.4	. . .	0 - 10	%
				Eosinophils	2.9	. . .	0 - 5	%
				Basophils	0.1	. . .	0 - 2	%
				Platelets	162000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	. . .	25 - 35	PG
				Mean Corpuscle Volume	87	. . .	80 - 100	FL
				Blood Urea Nitrogen	8	. . .	7 - 25	MG/DL
				Creatinine	1.2	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5.6	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	121	. . .	22 - 180	U/L
				Aspartate Aminotransferase	17	. . .	0 - 41	U/L
				Alanine Aminotransferase	7	. . .	0 - 48	U/L
				Total Bilirubin	1	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.7	. . .	3.1 - 5.3	G/DL
				Glucose - Random	87	. . .	70 - 115	MG/DL
				Globulin	3.1	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	NEG	. . .		
				Urine Bacteria	5	. . .		
				Urine Protein - Dipstick	6	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00059

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	16.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	50.1	H	.	.	41 - 50	%
				Red Blood Cell Count	5.8	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.7	.	.	.	30 - 70	%
				Lymphocytes	32.7	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	112	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00059

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00060

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	32.7	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	141	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00060

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	127	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00060

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00097

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12	. . .	12 - 15.6	G/DL
				Hematocrit	35.4	. . .	35 - 46	%
				Red Blood Cell Count	4.3	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.7	. . .	30 - 70	%
				Lymphocytes	32.9	. . .	21 - 51	%
				Monocytes	6.9	. . .	0 - 10	%
				Eosinophils	3.8	. . .	0 - 5	%
				Basophils	0.8	. . .	0 - 2	%
				Platelets	277000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	. . .	25 - 35	PG
				Mean Corpuscle Volume	82	. . .	80 - 100	FL
				Blood Urea Nitrogen	11	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.2	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	. . .	44 - 280	U/L
				Aspartate Aminotransferase	16	. . .	0 - 41	U/L
				Alanine Aminotransferase	8	. . .	0 - 48	U/L
				Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.6	. . .	6.2 - 8.8	G/DL
				Albumin	4.5	. . .	3.1 - 5.3	G/DL
				Glucose - Random	79	. . .	70 - 115	MG/DL
				Globulin	3.1	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	4	. . .		
				Serum BHCG pregnancy test	NEGATIVE	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00097

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	11.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5	.	.	.	30 - 70	%
				Lymphocytes	33.6	.	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	1.8	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00097

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	178	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.7	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	304000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	109	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00097

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 14/CONTINUATION-WEEK 24	178	Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	NEG	. . .		
				Urine Bacteria	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		
		VISIT 16/CONTINUATION-WEEK 32	246	Hemoglobin	13.1	. . .	12 - 15.6	G/DL
				Hematocrit	38.5	. . .	35 - 46	%
				Red Blood Cell Count	4.5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	. . .	30 - 70	%
				Lymphocytes	34.6	. . .	21 - 51	%
				Monocytes	6	. . .	0 - 10	%
				Eosinophils	2.2	. . .	0 - 5	%
				Basophils	0.5	. . .	0 - 2	%
				Platelets	250000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	. . .	25 - 35	PG
				Mean Corpuscle Volume	85	. . .	80 - 100	FL
				Blood Urea Nitrogen	12	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.8	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	. . .	44 - 280	U/L
				Aspartate Aminotransferase	12	. . .	0 - 41	U/L
				Alanine Aminotransferase	6	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.4	. . .	6.2 - 8.8	G/DL
				Albumin	4.5	. . .	3.1 - 5.3	G/DL
				Glucose - Random	107	. . .	70 - 115	MG/DL
				Globulin	2.9	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00097

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	246	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00101

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	15.4	. . .	13.8 - 17.2	G/DL
				Hematocrit	46	. . .	41 - 50	%
				Red Blood Cell Count	5.2	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.4	. . .	30 - 70	%
				Lymphocytes	44.7	. . .	21 - 51	%
				Monocytes	4.6	. . .	0 - 10	%
				Eosinophils	2.2	. . .	0 - 5	%
				Basophils	1.1	. . .	0 - 2	%
				Platelets	258000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	9	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	6	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	108	. . .	22 - 180	U/L
				Aspartate Aminotransferase	14	. . .	0 - 41	U/L
				Alanine Aminotransferase	11	. . .	0 - 48	U/L
				Total Bilirubin	0.8	. . .	0.3 - 1.3	MG/DL
				Total Protein	8.1	. . .	6.2 - 8.8	G/DL
				Albumin	4.9	. . .	3.1 - 5.3	G/DL
				Glucose - Random	81	. . .	70 - 115	MG/DL
				Globulin	3.2	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	4	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	4	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00101

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 6/ACUTE PHASE-WEEK 4	31	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.9	. . .	13.8 - 17.2	G/DL
				Hematocrit	43.2	. . .	41 - 50	%
				Red Blood Cell Count	4.9	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.9	. . .	30 - 70	%
				Lymphocytes	41.3	. . .	21 - 51	%
				Monocytes	7.6	. . .	0 - 10	%
				Eosinophils	2.7	. . .	0 - 5	%
				Basophils	0.5	. . .	0 - 2	%
				Platelets	203000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	16	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5.6	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	96	. . .	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00101

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEC		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
		VISIT 11/CONTINUATION-WEEK 12	87	Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	POS		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00101

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 11/CONTINUATION-WEEK 12	87	Urine Propoxyphene	NEG	. . .		
		VISIT 12/CONTINUATION-WEEK 16	92	Hemoglobin	14.8	. . .	13.8 - 17.2	G/DL
				Hematocrit	43	. . .	41 - 50	%
				Red Blood Cell Count	4.8	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H . .	30 - 70	%
				Lymphocytes	15.5	L . .	21 - 51	%
				Monocytes	7.7	. . .	0 - 10	%
				Eosinophils	3.1	. . .	0 - 5	%
				Basophils	0.1	. . .	0 - 2	%
				Platelets	188000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	13	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5.5	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	91	. . .	22 - 180	U/L
				Aspartate Aminotransferase	10	. . .	0 - 41	U/L
				Alanine Aminotransferase	5	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.5	. . .	6.2 - 8.8	G/DL
				Albumin	4.5	. . .	3.1 - 5.3	G/DL
				Glucose - Random	93	. . .	70 - 115	MG/DL
				Globulin	3	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	NEG	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	3	. . .		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00107

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00107

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5	. . .	12 - 15.6	G/DL
				Hematocrit	42.2	. . .	35 - 46	%
				Red Blood Cell Count	4.9	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67	. . .	30 - 70	%
				Lymphocytes	24.9	. . .	21 - 51	%
				Monocytes	5.7	. . .	0 - 10	%
				Eosinophils	1.7	. . .	0 - 5	%
				Basophils	0.7	. . .	0 - 2	%
				Platelets	207000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	. . .	25 - 35	PG
				Mean Corpuscle Volume	86	. . .	80 - 100	FL
				Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5.7	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	. . .	44 - 280	U/L
				Aspartate Aminotransferase	19	. . .	0 - 41	U/L
				Alanine Aminotransferase	25	. . .	0 - 48	U/L
				Total Bilirubin	0.9	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.6	. . .	6.2 - 8.8	G/DL
				Albumin	4.4	. . .	3.1 - 5.3	G/DL
				Glucose - Random	92	. . .	70 - 115	MG/DL
				Globulin	3.2	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00107

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.6	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.6	.	.	.	30 - 70	%
				Lymphocytes	35.6	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00107

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	148	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	246	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	167	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	58	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	101	H	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00107

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/CONTINUATION-WEEK 32	246	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00241

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	6.6	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00241

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.5	. . .	13.8 - 17.2	G/DL
				Hematocrit	44.3	. . .	41 - 50	%
				Red Blood Cell Count	5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.1	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.5	. . .	30 - 70	%
				Lymphocytes	27.6	. . .	21 - 51	%
				Monocytes	7.6	. . .	0 - 10	%
				Eosinophils	5.4	H . .	0 - 5	%
				Basophils	0.8	. . .	0 - 2	%
				Platelets	288000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	. . .	25 - 35	PG
				Mean Corpuscle Volume	88	. . .	80 - 100	FL
				Blood Urea Nitrogen	11	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5.7	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	115	. . .	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00241

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	30	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00246

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-17	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	25.4	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00246

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-17	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.5	. . .	12 - 15.6	G/DL
				Hematocrit	39	. . .	35 - 46	%
				Red Blood Cell Count	4.6	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	. . .	30 - 70	%
				Lymphocytes	30.6	. . .	21 - 51	%
				Monocytes	6.8	. . .	0 - 10	%
				Eosinophils	1.5	. . .	0 - 5	%
				Basophils	0.7	. . .	0 - 2	%
				Platelets	322000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	. . .	25 - 35	PG
				Mean Corpuscle Volume	86	. . .	80 - 100	FL
				Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5.6	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	90	. . .	22 - 130	U/L
				Aspartate Aminotransferase	34	. . .	0 - 41	U/L
				Alanine Aminotransferase	45	. . .	0 - 48	U/L
				Total Bilirubin	0.8	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.7	. . .	6.2 - 8.8	G/DL
				Albumin	4	. . .	3.1 - 5.3	G/DL
				Glucose - Random	114	. . .	70 - 115	MG/DL
				Globulin	3.7	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00246

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00320

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.6	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	7.5	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	198	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00320

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	30.1	.	.	.	21 - 51	%
				Monocytes	11.2	H	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	175	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00320

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00323

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.7	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	198000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.9	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	56	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

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F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00323

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.6	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00323

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	143	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	30 - 70	%
				Lymphocytes	27.2	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	53	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.002.00323

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	143	Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	4	. . .		
		VISIT 16/CONTINUATION-WEEK 32	213	Blood Urea Nitrogen	12	. . .	7 - 25	MG/DL
				Creatinine	0.8	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	. . .	22 - 130	U/L
				Aspartate Aminotransferase	15	. . .	0 - 41	U/L
				Alanine Aminotransferase	18	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.4	. . .	6.2 - 8.8	G/DL
				Albumin	4.2	. . .	3.1 - 5.3	G/DL
				Glucose - Random	72	. . .	70 - 115	MG/DL
				Globulin	3.2	. . .	2.3 - 4.1	G/DL

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00074

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	2	L	.	.	4 - 12	%
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	152000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	344	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	106	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00074

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1	.	.	.	30 - 70	%
				Lymphocytes	25.4	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	2.9	H	.	.	0 - 2	%
				Platelets	185000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	406	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00074

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	146	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.2	.	.	.	30 - 70	%
				Lymphocytes	45.1	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	148000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	359	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00074

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	146	Urine Protein - Dipstick	NEG	. . .		
		VISIT 16/CONTINUATION-WEEK 32	260	Hemoglobin	14.4	. . .	13.8 - 17.2	G/DL
				Hematocrit	41.8	. . .	41 - 50	%
				Red Blood Cell Count	4.2	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.4	. . .	30 - 70	%
				Lymphocytes	29.6	. . .	21 - 51	%
				Monocytes	6.3	. . .	0 - 10	%
				Eosinophils	2.2	. . .	0 - 5	%
				Basophils	0.6	. . .	0 - 2	%
				Platelets	188000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	34	. . .	25 - 35	PG
				Mean Corpuscle Volume	99	. . .	80 - 100	FL
				Blood Urea Nitrogen	14	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4.2	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	316	. . .	44 - 400	U/L
				Aspartate Aminotransferase	20	. . .	0 - 41	U/L
				Alanine Aminotransferase	9	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.3	. . .	6.2 - 8.8	G/DL
				Albumin	4.5	. . .	3.1 - 5.3	G/DL
				Glucose - Random	97	. . .	70 - 115	MG/DL
				Globulin	2.8	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00074

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 16/CONTINUATION-WEEK 32	260	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00078

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.4	H	.	.	30 - 70	%
				Lymphocytes	19.9	L	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00078

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7		Urine Benzodiazepines	NEG	. . .		
					Urine Cannabinoids	NEG	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Opiates	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	58		Blood Urea Nitrogen	12	. . .	7 - 25	MG/DL
					Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
					Uric Acid	4.9	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	83	. . .	22 - 130	U/L
					Aspartate Aminotransferase	12	. . .	0 - 41	U/L
					Alanine Aminotransferase	9	. . .	0 - 48	U/L
					Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.2	. . .	6.2 - 8.8	G/DL
					Albumin	4.4	. . .	3.1 - 5.3	G/DL
					Glucose - Random	93	. . .	70 - 115	MG/DL
					Globulin	2.8	. . .	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	. . .		
					Urine Blood - Dipstick	NEG	. . .		
					Urine Red Blood Cells/HPF	NEG	. . .		
					Urine White Blood Cells/HPF	NEC	. . .		
					Urine Bacteria	3	. . .		
					Urine Protein - Dipstick	NEG	. . .		
		VISIT 10/UNSCHEDULED LAB 1	78	(14)	Hemoglobin	13.6	. . .	12 - 15.6	G/DL
					Hematocrit	38.1	. . .	35 - 46	%
					Red Blood Cell Count	4.4	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.2	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	66.7	. . .	30 - 70	%
					Lymphocytes	23.8	. . .	21 - 51	%
					Monocytes	7.3	. . .	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00078

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/UNSCHEDULED LAB 1	78	(14)	Eosinophils	1.5	.	.	.	0 - 5	%
					Basophils	0.7	.	.	.	0 - 2	%
					Platelets	198000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	87	.	.	.	80 - 100	FL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00080

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	205000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	RESULT IS AN	U	.	U	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00080

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	34.5	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	106	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00080

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00085

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	25.7	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00085

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-13	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	3	L	.	.	4 - 12	%
				Segmented Neutrophils	70	.	.	.	30 - 70	%
				Lymphocytes	13	L	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	4.6	H	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	63	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	.	.	.	30 - 70	%
				Lymphocytes	23.6	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00085

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/UNSCHEDULED LAB 1	63	Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	276000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00086

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-19	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	20000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	178	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00086

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-19	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	17.1	H	.	.	12 - 15.6	G/DL
				Hematocrit	52.3	H	.	.	35 - 46	%
				Red Blood Cell Count	5.9	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	215000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	173	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00086

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	144	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00086

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	263	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.9	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	199000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	124	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00094

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73	H	.	.	30 - 70	%
				Lymphocytes	19.4	L	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00094

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	71	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H	.	.	30 - 70	%
				Lymphocytes	19.3	L	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	206000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	115	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00094

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	71	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00251

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.5	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00251

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00252

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
				Hematocrit	34	L	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.4	H	.	.	30 - 70	%
				Lymphocytes	22	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	103	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00252

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	30.7	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00291

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-2	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	290000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00291

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-2	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	65	. . .	30 - 70	%
				Lymphocytes	25	. . .	21 - 51	%
				Monocytes	7	. . .	0 - 10	%
				Eosinophils	3	. . .	0 - 5	%
				Basophils	0	. . .	0 - 2	%
				Blood Urea Nitrogen	9	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.9	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	. . .	22 - 130	U/L
				Aspartate Aminotransferase	18	. . .	0 - 41	U/L
				Alanine Aminotransferase	7	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.3	. . .	6.2 - 8.8	G/DL
				Albumin	4.2	. . .	3.1 - 5.3	G/DL
				Glucose - Random	84	. . .	70 - 115	MG/DL
				Globulin	3.1	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	4	. . .		
				Urine Protein - Dipstick	2	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00291

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00315

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.6	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	7.1	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00315

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.8	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	1.8	.	.	.	0 - 2	%
				Platelets	320000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00315

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00316

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.5	H	.	.	30 - 70	%
				Lymphocytes	17.3	L	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	606000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	142	H	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00316

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.6	. . .	12 - 15.6	G/DL
				Hematocrit	40.6	. . .	35 - 46	%
				Red Blood Cell Count	4.5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.2	. . .	30 - 70	%
				Lymphocytes	21.1	. . .	21 - 51	%
				Monocytes	6.2	. . .	0 - 10	%
				Eosinophils	2.6	. . .	0 - 5	%
				Basophils	0.8	. . .	0 - 2	%
				Platelets	771000	H . +	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	14	. . .	7 - 25	MG/DL
				Creatinine	0.7	L . .	0.8 - 1.5	MG/DL
				Uric Acid	3.8	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	115	. . .	22 - 130	U/L
				Aspartate Aminotransferase	15	. . .	0 - 41	U/L
				Alanine Aminotransferase	13	. . .	0 - 48	U/L
				Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.5	. . .	6.2 - 8.8	G/DL
				Albumin	4.3	. . .	3.1 - 5.3	G/DL
				Glucose - Random	79	. . .	70 - 115	MG/DL
				Globulin	3.2	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.003.00316

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00016

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	33.1	.	.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	131	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00016

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-3	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEC	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	31	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.6	.	.	.	30 - 70	%
				Lymphocytes	36.1	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00016

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 6/ACUTE PHASE-WEEK 4	31	Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
		VISIT 7/ACUTE PHASE-WEEK 5	38	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.9	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.9	.	.	.	0 - 2	%
				Platelets	315000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00016

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 7/ACUTE PHASE-WEEK 5	38	Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00018

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	POS		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00018

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 1/UNSCHEDULED LAB 1	-7	Hemoglobin	13.6	. . .	12 - 15.6	G/DL
				Hematocrit	39.2	. . .	35 - 46	%
				Red Blood Cell Count	4.2	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	. . .	30 - 70	%
				Lymphocytes	36.8	. . .	21 - 51	%
				Monocytes	6	. . .	0 - 10	%
				Eosinophils	1.6	. . .	0 - 5	%
				Basophils	0.4	. . .	0 - 2	%
				Platelets	278000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	. . .	25 - 35	PG
				Mean Corpuscle Volume	93	. . .	80 - 100	FL
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEC	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		1010.ZZ2	-2	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00018

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	1010.ZZ2	-2	Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	POS	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.5	. . .	12 - 15.6	G/DL
				Hematocrit	40	. . .	35 - 46	%
				Red Blood Cell Count	4.2	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	. . .	30 - 70	%
				Lymphocytes	28.4	. . .	21 - 51	%
				Monocytes	3	. . .	0 - 10	%
				Eosinophils	4.3	. . .	0 - 5	%
				Basophils	0.6	. . .	0 - 2	%
				Platelets	204000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4	. . .	25 - 35	PG
				Mean Corpuscle Volume	96	. . .	80 - 100	FL
				Blood Urea Nitrogen	9	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	2.8	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	. . .	22 - 130	U/L
				Aspartate Aminotransferase	15	. . .	0 - 41	U/L
				Alanine Aminotransferase	12	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	6.8	. . .	6.2 - 8.8	G/DL
				Albumin	4	. . .	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00018

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Glucose - Random	119	H	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		ACUTE PHASE/DOWN TITRATION	72	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00020

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.5	.	.	.	30 - 70	%
				Lymphocytes	35.3	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	199000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00020

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	16	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.8	.	.	.	30 - 70	%
				Lymphocytes	37.9	.	.	.	21 - 51	%
				Monocytes	2.5	.	.	.	0 - 10	%
				Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	219000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00020

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 4/ACUTE PHASE-WEEK 2	16	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00213

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74.3	H	.	.	30 - 70	%
				Lymphocytes	17.4	L	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	308000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00213

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.7	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	318000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	43	.	.	.	35 - 46	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.8	H	.	.	30 - 70	%
				Lymphocytes	21.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00213

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.5	.	.	.	30 - 70	%
				Lymphocytes	21.2	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	319000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	8	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00213

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	174	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74.9	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	79	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00213

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 14/CONTINUATION-WEEK 24	174	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	230	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.7	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.2	L	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.004.00213

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/CONTINUATION-WEEK 32	230	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00001

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14	. . .	12 - 15.6	G/DL
				Hematocrit	41.3	. . .	35 - 46	%
				Red Blood Cell Count	4.5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.6	. . .	30 - 70	%
				Lymphocytes	26.2	. . .	21 - 51	%
				Monocytes	4.3	. . .	0 - 10	%
				Eosinophils	0.4	. . .	0 - 5	%
				Basophils	1.5	. . .	0 - 2	%
				Platelets	265000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	. . .	25 - 35	PG
				Mean Corpuscle Volume	92	. . .	80 - 100	FL
				Blood Urea Nitrogen	12	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.1	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	. . .	22 - 130	U/L
				Aspartate Aminotransferase	20	. . .	0 - 41	U/L
				Alanine Aminotransferase	6	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	8.6	. . .	6.2 - 8.8	G/DL
				Albumin	4.8	. . .	3.1 - 5.3	G/DL
				Glucose - Random	98	. . .	70 - 115	MG/DL
				Globulin	3.8	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	4	. . .		
				Serum BHCG pregnancy test	NEGATIVE	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00001

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/UNSCHEDULED LAB 1	-2	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	67	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		ACUTE PHASE/DOWN TITRATION	70	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00001

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	ACUTE PHASE/DOWN TITRATION	70	Monocytes	7	. . .	0 - 10	%
				Eosinophils	1.1	. . .	0 - 5	%
				Basophils	0.8	. . .	0 - 2	%
				Platelets	268000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	. . .	25 - 35	PG
				Mean Corpuscle Volume	94	. . .	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00005

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	34.2	.	.	.	21 - 51	%
				Monocytes	3.3	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	340	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00005

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Serum BHCG pregnancy test	NEGATIVE	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00010

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.8	.	.	.	30 - 70	%
				Lymphocytes	24.4	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	208000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00010

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.2	H	.	.	30 - 70	%
				Lymphocytes	15.8	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	1.2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00010

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.9	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	24000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00010

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	149	Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	240	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00010

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	240	Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00012

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.2	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.6	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	32	L	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00012

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.7	.	.	.	30 - 70	%
				Lymphocytes	46.5	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	2.1	H	.	.	0 - 2	%
				Platelets	298000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	36	L	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00012

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	60	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	164	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5	.	.	.	30 - 70	%
				Lymphocytes	43.9	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	36	L	.	.	44 - 280	U/L
				Aspartate Aminotransferase	8	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00111

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.6	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	323000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00111

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	99	Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00114

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.6	.	.	.	30 - 70	%
				Lymphocytes	21.1	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	99	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00114

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	58		White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	39	.	.	.	30 - 70	%
					Lymphocytes	49	.	.	.	21 - 51	%
					Monocytes	10	.	.	.	0 - 10	%
					Eosinophils	2	.	.	.	0 - 5	%
					Basophils	0	.	.	.	0 - 2	%
					Platelets	103000	L	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	1.4	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	6.8	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	91	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	101	.	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 17/DOWN TITRATION	107	(9)	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	46	.	.	.	41 - 50	%
					Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	60	.	.	.	30 - 70	%

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00114

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 17/DOWN TITRATION	107 (9)	Lymphocytes	35	. . .	21 - 51	%
				Monocytes	1	. . .	0 - 10	%
				Eosinophils	4	. . .	0 - 5	%
				Basophils	0	. . .	0 - 2	%
				Platelets	225000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	. . .	25 - 35	PG
				Mean Corpuscle Volume	91	. . .	80 - 100	FL
				Blood Urea Nitrogen	13	. . .	7 - 25	MG/DL
				Creatinine	1.3	. . .	0.8 - 1.5	MG/DL
				Uric Acid	6.3	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	89	. . .	22 - 180	U/L
				Aspartate Aminotransferase	15	. . .	0 - 41	U/L
				Alanine Aminotransferase	14	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7	. . .	6.2 - 8.8	G/DL
				Albumin	4.3	. . .	3.1 - 5.3	G/DL
				Glucose - Random	89	. . .	70 - 115	MG/DL
				Globulin	2.7	. . .	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00115

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	53.7	.	.	.	40 - 75	%
				Lymphocytes	41.6	.	.	.	16 - 46	%
				Monocytes	3.5	.	.	.	0 - 12	%
				Eosinophils	1	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00115

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	72	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7	.	.	.	3.8 - 10.8	THOU/MCL
				Neutrophil Bands	0	.	.	.	0 - 8	%
				Segmented Neutrophils	44	.	.	.	40 - 75	%
				Lymphocytes	35	.	.	.	16 - 46	%
				Monocytes	3	.	.	.	0 - 12	%
				Eosinophils	0	.	.	.	0 - 7	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	221000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	118	H	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00115

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	72		Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	5	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	81	(6)	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	3.9 - 5.2	MILL/MCL
					White Blood Cell Count	5.7	.	.	.	3.8 - 10.8	THOU/MCL
					Segmented Neutrophils	51.8	.	.	.	40 - 75	%
					Lymphocytes	40.7	.	.	.	16 - 46	%
					Monocytes	5.8	.	.	.	0 - 12	%
					Eosinophils	1.5	.	.	.	0 - 7	%
					Basophils	0.3	.	.	.	0 - 2	%
					Platelets	215000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.4	.	.	.	27 - 33	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00120

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.7	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	9.1	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	340	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00120

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	270	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	145	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00120

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00253

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.4	.	.	.	30 - 70	%
				Lymphocytes	45.9	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00253

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8		Urine Benzodiazepines	NEG	. . .		
					Urine Cannabinoids	NEG	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	56	(1)	Hemoglobin	14.6	. . .	12 - 15.6	G/DL
					Hematocrit	42.9	. . .	35 - 46	%
					Red Blood Cell Count	4.8	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	56.1	. . .	30 - 70	%
					Lymphocytes	35.2	. . .	21 - 51	%
					Monocytes	6.1	. . .	0 - 10	%
					Eosinophils	1.9	. . .	0 - 5	%
					Basophils	0.7	. . .	0 - 2	%
					Platelets	249000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.7	. . .	25 - 35	PG
					Mean Corpuscle Volume	90	. . .	80 - 100	FL
					Blood Urea Nitrogen	14	. . .	7 - 25	MG/DL
					Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
					Uric Acid	2.9	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	61	. . .	22 - 130	U/L
					Aspartate Aminotransferase	12	. . .	0 - 41	U/L
					Alanine Aminotransferase	8	. . .	0 - 48	U/L
					Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
					Total Protein	6.9	. . .	6.2 - 8.8	G/DL
					Albumin	4.4	. . .	3.1 - 5.3	G/DL
					Glucose - Random	91	. . .	70 - 115	MG/DL
					Globulin	2.5	. . .	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	. . .		
					Urine Blood - Dipstick	NEG	. . .		
					Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00253

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56	(1)	Urine White Blood Cells/HPF	NEG	.	.	.		
					Urine Bacteria		4	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		
					Urine Squamous Epithelial Cells		4	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00254

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.4	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	243000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00254

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	209000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00254

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	15.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	45	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.2	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00254

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Hematocrit	42.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00254

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00293

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.7	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32.3	.	.	.	30 - 70	%
				Lymphocytes	45	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	12.3	H	.	+	0 - 5	%
				Basophils	2.5	H	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	39	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	68	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00293

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	30	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	33.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00293

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00298

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00298

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	227000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	144	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00298

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	41	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/CONTINUATION-WEEK 32	237	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00298

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	237	Hematocrit	36.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.1	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	112	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00331

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	24	H	.	.	12 - 15.6	G/DL
				Hematocrit	69.9	H	.	.	35 - 46	%
				Red Blood Cell Count	7.3	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	19.1	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74	H	.	.	30 - 70	%
				Lymphocytes	17	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	12000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00331

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	7	Hemoglobin	14.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	28.6	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00331

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 3/ACUTE PHASE-WEEK 1	7	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	25.6	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	266000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00331

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	11	. . .	0 - 48	U/L
				Total Bilirubin	0.8	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.9	. . .	3.1 - 5.3	G/DL
				Glucose - Random	87	. . .	70 - 115	MG/DL
				Globulin	2.9	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	4	. . .		
				Urine Protein - Dipstick	2	. . .		
				Urine Squamous Epithelial Cells	4	. . .		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00334

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	45.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	201000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.005.00334

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	16.1	H	.	.	12 - 15.6	G/DL
				Hematocrit	48.2	H	.	.	35 - 46	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7	.	.	.	30 - 70	%
				Lymphocytes	30.9	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00037

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7	.	.	.	30 - 70	%
				Lymphocytes	26.1	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	360000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	56	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00037

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00042

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	16.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.8	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	40 - 75	%
				Lymphocytes	26.8	.	.	.	16 - 46	%
				Monocytes	8.7	.	.	.	0 - 12	%
				Eosinophils	2	.	.	.	0 - 7	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	46	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
		VISIT 2/ELIGIBILITY	-1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00042

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 2/ELIGIBILITY	-1	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	50.8	.	.	.	40 - 75	%
				Lymphocytes	33.3	.	.	.	16 - 46	%
				Monocytes	13.2	H	.	.	0 - 12	%
				Eosinophils	1.7	.	.	.	0 - 7	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	113	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	38	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00042

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 13/CONTINUATION-WEEK 20	139	Hemoglobin	16.3	. . .	13.8 - 17.2	G/DL
				Hematocrit	48.2	. . .	41 - 50	%
				Red Blood Cell Count	5.7	. . .	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	10.9	H . .	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	63.1	. . .	40 - 75	%
				Lymphocytes	26.2	. . .	16 - 46	%
				Monocytes	7.6	. . .	0 - 12	%
				Eosinophils	2.3	. . .	0 - 7	%
				Basophils	0.8	. . .	0 - 2	%
				Platelets	241000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	. . .	27 - 33	PG
				Mean Corpuscle Volume	85	. . .	80 - 100	FL
				Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	6.2	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	116	. . .	22 - 180	U/L
				Aspartate Aminotransferase	17	. . .	0 - 41	U/L
				Alanine Aminotransferase	35	. . .	0 - 48	U/L
				Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.2	. . .	3.1 - 5.3	G/DL
				Glucose - Random	87	. . .	70 - 115	MG/DL
				Globulin	3.6	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		. . .		
				Urine Blood - Dipstick NEG		. . .		
				Urine Red Blood Cells/HPF NEG		. . .		
				Urine White Blood Cells/HPF NEG		. . .		
				Urine Bacteria	3	. . .		
				Urine Protein - Dipstick NEG		. . .		
		VISIT 16/CONTINUATION-WEEK 32	223	Hemoglobin	15.7	. . .	13.8 - 17.2	G/DL
				Hematocrit	46.5	. . .	41 - 50	%

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00042

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 16/CONTINUATION-WEEK 32	223	Red Blood Cell Count	5.5	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.8	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	45.7	.	.	.	40 - 75	%
				Lymphocytes	35.3	.	.	.	16 - 46	%
				Monocytes	10.7	.	.	.	0 - 12	%
				Eosinophils	7.8	H	.	.	0 - 7	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	46	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00259

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-32	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	11.2	H	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	280000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	120	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-28	Urine Amphetamines	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00259

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/UNSCHEDULED LAB 1	-28	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	14.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	249000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	99	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.006.00259

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00141

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	403000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	333	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00141

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00144

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.3	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	179	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00144

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7		Urine Benzodiazepines	NEG	. . .		
					Urine Cannabinoids	NEG	. . .		
					Urine Cocaine	NEG	. . .		
					Urine Methadone	NEG	. . .		
					Urine Methaqualone	NEG	. . .		
					Urine Opiates	NEG	. . .		
					Urine Phencyclidine	NEG	. . .		
					Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	12.8	. . .	12 - 15.6	G/DL
					Hematocrit	37.7	. . .	35 - 46	%
					Red Blood Cell Count	4.4	. . .	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.9	. . .	4.5 - 13	THOU/MCL
					Segmented Neutrophils	56.1	. . .	30 - 70	%
					Lymphocytes	32.2	. . .	21 - 51	%
					Monocytes	7.5	. . .	0 - 10	%
					Eosinophils	2.2	. . .	0 - 5	%
					Basophils	2	. . .	0 - 2	%
					Platelets	301000	. . .	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.1	. . .	25 - 35	PG
					Mean Corpuscle Volume	85	. . .	80 - 100	FL
					Blood Urea Nitrogen	15	. . .	8 - 21	MG/DL
					Creatinine	0.6	. . .	0.4 - 1.1	MG/DL
					Uric Acid	3.2	. . .	2.3 - 7	MG/DL
					Alkaline Phosphatase	169	. . .	44 - 280	U/L
					Aspartate Aminotransferase	12	. . .	0 - 41	U/L
					Alanine Aminotransferase	12	. . .	0 - 39	U/L
					Total Bilirubin	0.4	. . .	0.3 - 1.3	MG/DL
					Total Protein	7.2	. . .	5.7 - 8.2	G/DL
					Albumin	4.3	. . .	3.1 - 5.3	G/DL
					Glucose - Random	81	. . .	60 - 110	MG/DL
					Globulin	2.9	. . .	2.1 - 3.8	G/DL
					Urine Glucose - Dipstick	NEG	. . .		
					Urine Blood - Dipstick	NEG	. . .		
					Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00144

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00266

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.8	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	35.9	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	253	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	63	.	.	.	60 - 110	MG/DL
				Globulin	2.5	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00266

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	44	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	251000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	190	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00266

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00267

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.8	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	50	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00267

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 9/ACUTE PHASE-WEEK 7	50		Urine Cannabinoids	POS	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	43.2	.	.	.	41 - 50	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	51.8	.	.	.	30 - 70	%
					Lymphocytes	41.6	.	.	.	21 - 51	%
					Monocytes	4.5	.	.	.	0 - 10	%
					Eosinophils	1.6	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	245000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	8	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	73	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	128	H	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00267

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00311

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.3	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	9.7	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	256	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	+		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00311

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	24	.	.	.	21 - 51	%
				Monocytes	13	H	.	.	0 - 10	%
				Eosinophils	11	H	.	+	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00311

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	232	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9	.	.	.	30 - 70	%
				Lymphocytes	20.9	L	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	11.2	H	.	+	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00311

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	162		Platelets	183000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.7	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	220	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	105	.	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	6	.	.	.		
					Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 17/DOWN TITRATION	219	(15)	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	44.5	.	.	.	41 - 50	%
					Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54.7	.	.	.	30 - 70	%
					Lymphocytes	32.5	.	.	.	21 - 51	%
					Monocytes	3.8	.	.	.	0 - 10	%
					Eosinophils	8.6	H	.	.	0 - 5	%
					Basophils	0.3	.	.	.	0 - 2	%
					Platelets	206000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.007.00311

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 17/DOWN TITRATION	219	(15)	Mean Corpuscle Hemoglobin	31.2	. . .	25 - 35	PG
					Mean Corpuscle Volume	91	. . .	80 - 100	FL
					Blood Urea Nitrogen	15	. . .	7 - 25	MG/DL
					Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
					Uric Acid	5.2	. . .	4 - 8	MG/DL
					Alkaline Phosphatase	229	. . .	44 - 400	U/L
					Aspartate Aminotransferase	15	. . .	0 - 41	U/L
					Alanine Aminotransferase	10	. . .	0 - 48	U/L
					Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
					Total Protein	8	. . .	6.2 - 8.8	G/DL
					Albumin	4.7	. . .	3.1 - 5.3	G/DL
					Glucose - Random	103	. . .	70 - 115	MG/DL
					Globulin	3.3	. . .	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	. . .		
					Urine Blood - Dipstick	NEG	. . .		
					Urine Red Blood Cells/HPF	NEG	. . .		
					Urine White Blood Cells/HPF	3	. . .		
					Urine Protein - Dipstick	6	. . .		
					Urine Squamous Epithelial Cells	3	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00158

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.9	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.9	.	.	.	30 - 70	%
				Lymphocytes	35.7	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	2.1	H	.	.	0 - 2	%
				Platelets	355000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00158

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.1	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	7.3	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	335000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00162

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	2.9	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	415000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	50	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00162

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	37	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEC	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00162

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Basophils	0.6	. . .	0 - 2	%
				Platelets	387000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	9	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	2.7	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	. . .	22 - 130	U/L
				Aspartate Aminotransferase	16	. . .	0 - 41	U/L
				Alanine Aminotransferase	12	. . .	0 - 48	U/L
				Total Bilirubin	0.6	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.9	. . .	6.2 - 8.8	G/DL
				Albumin	4.5	. . .	3.1 - 5.3	G/DL
				Glucose - Random	101	. . .	70 - 115	MG/DL
				Globulin	3.4	. . .	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	13.1	. . .	12 - 15.6	G/DL
				Hematocrit	37.1	. . .	35 - 46	%
				Red Blood Cell Count	4.1	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.2	. . .	30 - 70	%
				Lymphocytes	31.4	. . .	21 - 51	%
				Monocytes	2.5	. . .	0 - 10	%
				Eosinophils	2.5	. . .	0 - 5	%
				Basophils	0.4	. . .	0 - 2	%
				Platelets	414000	H . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	. . .	25 - 35	PG
				Mean Corpuscle Volume	90	. . .	80 - 100	FL
				Blood Urea Nitrogen	12	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.3	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	44	. . .	22 - 130	U/L
				Aspartate Aminotransferase	21	. . .	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00162

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	162	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.8	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	362000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00162

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	62	L	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00191

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7	.	.	.	30 - 70	%
				Lymphocytes	46.5	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00191

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	41	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	234000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.008.00191

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00128

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.3	L	.	-	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3	.	.	.	30 - 70	%
				Lymphocytes	45.8	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	232000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	216	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00128

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00129

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	33.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	141000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	127	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00129

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00135

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.9	. . .	12 - 15.6	G/DL
				Hematocrit	40.2	. . .	35 - 46	%
				Red Blood Cell Count	4.5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	. . .	30 - 70	%
				Lymphocytes	23.4	. . .	21 - 51	%
				Monocytes	4.5	. . .	0 - 10	%
				Eosinophils	3.9	. . .	0 - 5	%
				Basophils	0.4	. . .	0 - 2	%
				Platelets	259000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	8	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	2.7	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	. . .	22 - 130	U/L
				Aspartate Aminotransferase	13	. . .	0 - 41	U/L
				Alanine Aminotransferase	14	. . .	0 - 48	U/L
				Total Bilirubin	0.5	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.4	. . .	6.2 - 8.8	G/DL
				Albumin	4.2	. . .	3.1 - 5.3	G/DL
				Glucose - Random	110	. . .	70 - 115	MG/DL
				Globulin	3.2	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	3	. . .		
				Urine Protein - Dipstick	NEG	. . .		
				Urine Squamous Epithelial Cells	4	. . .		
				Serum BHCG pregnancy test	NEGATIVE	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00135

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00136

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61	.	.	.	30 - 70	%
				Lymphocytes	25.1	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	346000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	130	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00136

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	34.7	L	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.1	H	.	.	30 - 70	%
				Lymphocytes	19	L	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	119	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00136

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00169

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.4	.	.	.	30 - 70	%
				Lymphocytes	32.2	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	203	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00169

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	267000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	210	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00169

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine White Blood Cells/HPF	NEG	. . .		
				Urine Protein - Dipstick	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00174

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	56	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00174

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14	. . .	12 - 15.6	G/DL
				Hematocrit	40.3	. . .	35 - 46	%
				Red Blood Cell Count	4.6	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	. . .	30 - 70	%
				Lymphocytes	34	. . .	21 - 51	%
				Monocytes	3.8	. . .	0 - 10	%
				Eosinophils	1.4	. . .	0 - 5	%
				Basophils	0.4	. . .	0 - 2	%
				Platelets	304000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	. . .	25 - 35	PG
				Mean Corpuscle Volume	88	. . .	80 - 100	FL
				Blood Urea Nitrogen	15	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	6.3	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	. . .	44 - 280	U/L
				Aspartate Aminotransferase	12	. . .	0 - 41	U/L
				Alanine Aminotransferase	10	. . .	0 - 48	U/L
				Total Bilirubin	0.9	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.3	. . .	3.1 - 5.3	G/DL
				Glucose - Random	102	. . .	70 - 115	MG/DL
				Globulin	3.5	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00174

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00197

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	155	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00197

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	38.4	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	134	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	145	Hemoglobin	13	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00197

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	145	Segmented Neutrophils	43.6	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	7.2	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	123	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	236	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5	.	.	.	30 - 70	%
				Lymphocytes	43.8	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00197

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 16/CONTINUATION-WEEK 32	236	Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	4.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	147	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00198

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	44	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00198

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.9	. . .	12 - 15.6	G/DL
				Hematocrit	40	. . .	35 - 46	%
				Red Blood Cell Count	4.6	. . .	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.7	. . .	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	52.2	. . .	40 - 75	%
				Lymphocytes	35.1	. . .	16 - 46	%
				Monocytes	6	. . .	0 - 12	%
				Eosinophils	5.1	. . .	0 - 7	%
				Basophils	1.5	. . .	0 - 2	%
				Platelets	183000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	. . .	27 - 33	PG
				Mean Corpuscle Volume	88	. . .	80 - 100	FL
				Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	0.7	L . .	0.8 - 1.5	MG/DL
				Uric Acid	2.6	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	44	. . .	22 - 130	U/L
				Aspartate Aminotransferase	20	. . .	0 - 41	U/L
				Alanine Aminotransferase	23	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.1	. . .	6.2 - 8.8	G/DL
				Albumin	4.2	. . .	3.1 - 5.3	G/DL
				Glucose - Random	87	. . .	70 - 115	MG/DL
				Globulin	2.9	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00198

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00200

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	11.4	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72	H	.	.	30 - 70	%
				Lymphocytes	19.4	L	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	313000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	23.5	L	.	.	25 - 35	PG
				Mean Corpuscle Volume	72	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	37	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00200

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00202

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	273000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00202

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	36	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00237

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.6	.	.	.	30 - 70	%
				Lymphocytes	46.1	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	213	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00237

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00238

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	31.3	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00238

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	88	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00276

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	1	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.6	.	.	.	30 - 70	%
				Lymphocytes	44.4	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00276

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	1	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	1.2	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	210000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	140	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	58	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	36	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00302

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7	.	.	.	30 - 70	%
				Lymphocytes	35.4	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	11.4	H	.	+	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	108	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00302

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00306

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	36	.	.	.	30 - 70	%
				Lymphocytes	60	H	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00306

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-5	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.6	.	.	.	30 - 70	%
				Lymphocytes	30.3	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	11.8	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5	.	.	.	30 - 70	%
				Lymphocytes	30.3	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	114	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00306

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00312

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.2	.	.	.	30 - 70	%
				Lymphocytes	31.3	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	6.8	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	421000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00312

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	419000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00327

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	27.6	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00327

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.6	.	.	.	30 - 70	%
				Lymphocytes	28.5	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00327

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 7/ACUTE PHASE-WEEK 5	36	Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00330

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1	.	.	.	30 - 70	%
				Lymphocytes	26.3	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	340000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	3.7	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.009.00330

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00183

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.8	L	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37	.	.	.	30 - 70	%
				Lymphocytes	51	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	107	H	.	+	7 - 25	MG/DL
				Creatinine	13.2	H	.	+	0.8 - 1.5	MG/DL
				Uric Acid	8.8	H	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	285	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00183

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-5	Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	322	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 3/ACUTE PHASE-WEEK 1	3	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	335	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00263

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	16	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.6	.	.	.	40 - 75	%
				Lymphocytes	35.4	.	.	.	16 - 46	%
				Monocytes	5.9	.	.	.	0 - 12	%
				Eosinophils	1.3	.	.	.	0 - 7	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00263

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-16	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	58	.	.	.	40 - 75	%
				Lymphocytes	34.9	.	.	.	16 - 46	%
				Monocytes	5.4	.	.	.	0 - 12	%
				Eosinophils	1.7	.	.	.	0 - 7	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00263

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 10/ACUTE PHASE-WEEK 8	62	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		3	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00277

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.4	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	332000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00277

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	6	. . .		
				Urine Red Blood Cells/HPF	5	. . .		
				Urine White Blood Cells/HPF	3	. . .		
				Urine Bacteria	4	. . .		
				Urine Protein - Dipstick	6	. . .		
				Urine Squamous Epithelial Cells	4	. . .		
		VISIT 4/ACUTE PHASE-WEEK 2	18	Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		
				Urine White Blood Cells/HPF	NEG	. . .		
				Urine Protein - Dipstick	6	. . .		
				Urine Squamous Epithelial Cells	4	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.2	. . .	12 - 15.6	G/DL
				Hematocrit	35.4	. . .	35 - 46	%
				Red Blood Cell Count	4	L . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.7	. . .	30 - 70	%
				Lymphocytes	40.8	. . .	21 - 51	%
				Monocytes	11.1	H . .	0 - 10	%
				Eosinophils	2.1	. . .	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00277

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57		Basophils	0.3	.	.	.	0 - 2	%
					Platelets	312000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
					Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	96	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	2	.	.	.		
					Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16	165	(52)	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
					Hematocrit	33.9	L	.	.	35 - 46	%
					Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54	.	.	.	30 - 70	%
					Lymphocytes	31.4	.	.	.	21 - 51	%
					Monocytes	11	H	.	.	0 - 10	%
					Eosinophils	2.9	.	.	.	0 - 5	%
					Basophils	0.6	.	.	.	0 - 2	%
					Platelets	317000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00277

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16	165 (52)	Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	70	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00282

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.1	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	339000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	4	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.010.00282

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	326000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	68	L	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00164

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.7	.	.	.	30 - 70	%
				Lymphocytes	29.4	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	1028	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	59	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00164

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-1	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00210

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	194000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	137	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00210

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1	.	.	.	30 - 70	%
				Lymphocytes	24.8	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	155000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	133	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00210

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00285

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4	.	.	.	30 - 70	%
				Lymphocytes	36.9	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00285

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	68	Hemoglobin	15	. . .	13.8 - 17.2	G/DL
				Hematocrit	44	. . .	41 - 50	%
				Red Blood Cell Count	4.7	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	. . .	30 - 70	%
				Lymphocytes	33.9	. . .	21 - 51	%
				Monocytes	8.4	. . .	0 - 10	%
				Eosinophils	3.9	. . .	0 - 5	%
				Basophils	0.7	. . .	0 - 2	%
				Platelets	281000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	. . .	25 - 35	PG
				Mean Corpuscle Volume	93	. . .	80 - 100	FL
				Blood Urea Nitrogen	10	. . .	7 - 25	MG/DL
				Creatinine	1.1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	5	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	80	. . .	22 - 180	U/L
				Aspartate Aminotransferase	15	. . .	0 - 41	U/L
				Alanine Aminotransferase	16	. . .	0 - 48	U/L
				Total Bilirubin	0.8	. . .	0.3 - 1.3	MG/DL
				Total Protein	7.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.5	. . .	3.1 - 5.3	G/DL
				Glucose - Random	84	. . .	70 - 115	MG/DL
				Globulin	3.3	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00285

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	68	Urine White Blood Cells/HPF		3	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00287

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.2	.	.	.	30 - 70	%
				Lymphocytes	26.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00287

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.1	. . .	12 - 15.6	G/DL
				Hematocrit	37.7	. . .	35 - 46	%
				Red Blood Cell Count	4.3	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.5	. . .	30 - 70	%
				Lymphocytes	26.5	. . .	21 - 51	%
				Monocytes	4.1	. . .	0 - 10	%
				Eosinophils	2.6	. . .	0 - 5	%
				Basophils	1.3	. . .	0 - 2	%
				Platelets	218000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	. . .	25 - 35	PG
				Mean Corpuscle Volume	87	. . .	80 - 100	FL
				Blood Urea Nitrogen	14	. . .	7 - 25	MG/DL
				Creatinine	0.9	. . .	0.8 - 1.5	MG/DL
				Uric Acid	3.5	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	. . .	44 - 280	U/L
				Aspartate Aminotransferase	10	. . .	0 - 41	U/L
				Alanine Aminotransferase	7	. . .	0 - 48	U/L
				Total Bilirubin	0.7	. . .	0.3 - 1.3	MG/DL
				Total Protein	6.8	. . .	6.2 - 8.8	G/DL
				Albumin	4.3	. . .	3.1 - 5.3	G/DL
				Glucose - Random	95	. . .	70 - 115	MG/DL
				Globulin	2.5	. . .	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	. . .		
				Urine Blood - Dipstick	NEG	. . .		
				Urine Red Blood Cells/HPF	NEG	. . .		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.011.00287

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00027

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35	.	.	.	30 - 70	%
				Lymphocytes	48.3	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00027

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.1	.	.	.	30 - 70	%
				Lymphocytes	42.2	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	9.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	314000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	20	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00027

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	1	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	14	L	.	-	30 - 70	%
				Lymphocytes	67	H	.	.	21 - 51	%
				Monocytes	14	H	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	116	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00027

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 6/ACUTE PHASE-WEEK 4	28	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00217

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4	.	.	.	30 - 70	%
				Lymphocytes	22.7	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00217

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7		Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	30	(5)	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.5	.	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	58.6	.	.	.	30 - 70	%
					Lymphocytes	26.2	.	.	.	21 - 51	%
					Monocytes	12.1	H	.	.	0 - 10	%
					Eosinophils	2.8	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	233000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	65	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
					Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	98	.	.	.	70 - 115	MG/DL
					Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00217

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 6/ACUTE PHASE-WEEK 4	30	(5)	Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF	NEG	.	.	.		
					Urine Bacteria		3	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		
					Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00218

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	377000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	99	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00218

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-2	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.5	.	.	.	30 - 70	%
				Lymphocytes	28.8	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	12.6	H	.	+	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	82	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00218

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	95	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	11	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	366000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00218

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/CONTINUATION-WEEK 12	95	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00224

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-19	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	14	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	370000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	248	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 1/SCREENING (WEEK -1)	-17	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00224

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/UNSCHEDULED LAB 1	-10	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.5	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.9	.	.	.	30 - 70	%
				Lymphocytes	22	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	9.2	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	32	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	27.2	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	12.9	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	367000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00224

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	205	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	156	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	15	L	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	12	H	.	+	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00224

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	156	Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	167	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00225

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	157	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00225

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	36	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	194000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	138	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00225

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75	H	.	.	30 - 70	%
				Lymphocytes	20.8	L	.	.	21 - 51	%
				Monocytes	3.1	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	247	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix F.1

Listing of Laboratory Values by Treatment Group and Patient
Intent-to-Treat Population

TREATMENT GROUP: PLACEBO PID: 329.012.00225

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	247	White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	113	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix F.2

Listing of Clinically Significant Abnormal Laboratory Values by Patient and Treatment Group
Acute Phase
Intent-to-Treat Population

Treatment	Parameter	Flag	Patient ID	Relative Days *	Value	Baseline Value	Comments
PAROXETINE	Hematocrit	L	329.001.00121	57	36.2	40.2	
			329.007.00140	56	36.7	37.5	
	Platelets	L	329.005.00011	57	51000.0	235000.0	
			329.005.00112	56	10000.0	245000.0	THE PLATELET COUNT IS LOW DUE TO IN VITRO CLUMPING OF PLATELETS.
			329.005.00116	59	71000.0	284000.0	THE PLATELET COUNT IS LOW DUE TO IN VITRO CLUMPING OF PLATELETS.
			329.005.00257	29	17000.0	136000.0	PLATELET HISTOGRAM APPEARS CLUMPED; PLATELET COUNT RESULT MAY BE IN QUESTION.
	Urine Red Blood Cells/HPF	H	329.003.00292	70	5-10		5-10
			329.004.00015	28	INNUMERABLE		INNUMERABLE
			329.005.00258	57	15-25	5-10	15-25
			329.008.00160	66	10-15	25-50	10-15
			329.009.00196	57	10-15	1-3	10-15
	Urine White Blood Cells/HPF	H	329.002.00058	59	15-25		15-25
	White Blood Cell Count	H	329.005.00257	29	19.1	7.0	
			329.009.00196	57	16.7	10.3	
IMIPRAMINE	Hematocrit	L	329.003.00289	57	30.4	35.3	
			329.009.00137	57	35.7	38.6	
			329.009.00194	57	35.9	36.0	

* Days Relative to Start of Acute Phase
Lab Abnormality Criteria: Blood Chemistry: AlkPhos: H = >=390; BUN: H = >=30.0; Creatinine: H = >=2.0; AST/SGOT: H = >=150;
ALT/SGPT: H = >=165; T.Bilirubin: H = >=2.0;
Hematology: HGB: (M) L = <=11.5 (F) L = <=9.5; HCT: (M) L = <=37.0 (F) L = <=32.0; WBC: L = <=2.8 H = >=16.0; Neut(Segs): L= <=15;
Neut(Bands): H = >10; Lymph: H = >=75; Monos: H = >=15; Eosins: H = >=10; Basos: H = >=10; Platelets: L = <=75000 H = >=700000.
Urinalysis: Protein: H = 4+; Glucose: H = 4+; RBC: (M) H = >8 (F) H = >10; WBC: H = >10.

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PAROXETINE - PROTOCOL 329

Appendix F.2

Listing of Clinically Significant Abnormal Laboratory Values by Patient and Treatment Group
Acute Phase
Intent-to-Treat Population

Treatment	Parameter	Flag	Patient ID	Relative Days *	Value	Baseline Value	Comments
IMIPRAMINE	Platelets	L	329.005.00007	64	44000.0	307000.0	THE PLATELET COUNT IS LOW DUE TO IN VITRO CLUMPING OF PLATELETS.
			329.005.00009	58	54000.0	211000.0	PLATELET HISTOGRAM APPEARS CLUMPED; PLATELET COUNT RESULT MAY BE IN QUESTION.
	Urine Red Blood Cells/HPF	H	329.009.00134	55	50-100		50-100
	Urine White Blood Cells/HPF	H	329.008.00159	63	25-50	10-15	25-50
PLACEBO	Alkaline Phosphatase	H	329.003.00074	57	406.0	344.0	
	Eosinophils	H	329.007.00311	61	11.0	9.7	
			329.012.00218	59	12.6	7.0	
			329.012.00224	66	12.9	9.2	
	Platelets	H	329.003.00316	57	771000.0	606000.0	
	Segmented Neutrophils	L	329.012.00027	28	14.0	41.1	
	Urine Red Blood Cells/HPF	H	329.009.00327	36	10-15		10-15
			329.012.00218	59	50-100	5-10	50-100

* Days Relative to Start of Acute Phase
Lab Abnormality Criteria: Blood Chemistry: AlkPhos: H = >=390; BUN: H = >=30.0; Creatinine: H = >=2.0; AST/SGOT: H = >=150;
ALT/SGPT: H = >=165; T.Bilirubin: H = >=2.0;
Hematology: HGB: (M) L = <=11.5 (F) L = <=9.5; HCT: (M) L = <=37.0 (F) L = <=32.0; WBC: L = <=2.8 H = >=16.0; Neut(Segs): L= <=15;
Neut(Bands): H = >10; Lymph: H = >=75; Monos: H = >=15; Eosins: H = >=10; Basos: H = >=10; Platelets: L = <=75000 H = >=700000.
Urinalysis: Protein: H = 4+; Glucose: H = 4+; RBC: (M) H = >8 (F) H = >10; WBC: H = >10.

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Appendix G: CRF Tabulations by Patient

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Appendix H CRFs for All Patients with Adverse Experiences Leading to Withdrawal, Serious Adverse Experiences and Deaths

Adverse Experiences Leading to Withdrawal

PID
329.001.00061
329.001.00063
329.001.00065
329.001.00066
329.001.00067
329.001.00070
329.002.00050
329.002.00056
329.001.00205
329.003.00073
329.003.00088
329.004.00014
329.002.00243
329.002.00245
329.005.00003
329.005.00005
329.002.00321
329.002.00322
329.003.00290
329.005.00110
329.004.00211
329.003.00313
329.005.00113
329.004.00215
329.006.00038
329.006.00040
329.005.00152
329.007.00139
329.007.00141
329.007.00143
329.007.00269
329.007.00270
329.007.00307
329.009.00127
329.009.00128
329.009.00171
329.009.00195

329.009.00203
329.009.00236
329.009.00240
329.009.00302
329.009.00330
329.011.00163
329.012.00217
329.012.00226

Serious Adverse Experiences

PID
329.001.00065
329.001.00123
329.002.00106
329.003.00089
329.002.00245
329.002.00321
329.003.00248
329.003.00250
329.003.00313
329.004.00215
329.006.00038
329.005.00333
329.007.00270
329.007.00307
329.009.00201
329.009.00240
329.012.00217
329.012.00223

Paroxetine - Protocol 329
Table 13.37
Number (%) of Patient Having CGI Global Improvement of 1 or 2
Acute Phase
Intent to Treat Population

	PAROXETINE		IMIPRAMINE		PLACEBO		-- Pairwise Comparisons ---		
	n/N	%	n/N	%	n/N	%	Par vs Pla		Imp vs Pla
Week 1	6 /88	(6.8)	3 /90	(3.3)	3 /84	(3.6)	0.481		0.892
Week 2	17 /80	(21.3)	16 /89	(18.0)	17 /79	(21.5)	0.992		0.677
Week 3	33 /76	(43.4)	22 /78	(28.2)	23 /75	(30.7)	0.095		0.986
Week 4	39 /76	(51.3)	25 /69	(36.2)	32 /73	(43.8)	0.314		0.496
Week 5	33 /72	(45.8)	35 /68	(51.5)	31 /70	(44.3)	0.853		0.202
Week 6	44 /73	(60.3)	37 /61	(60.7)	41 /66	(62.1)	0.825		0.980
Week 7	43 /66	(65.2)	34 /53	(64.2)	38 /63	(60.3)	0.602		0.710
Week 8	53 /67	(79.1)	38 /56	(67.9)	40 /66	(60.6)	0.020	*	0.506
Endpoint	59 /90	(65.6)	49 /94	(52.1)	42 /87	(48.3)	0.020	*	0.642

Only patients with one or more on-therapy evaluations are included.
* - significantly different from placebo for alpha = 0.05
Treatment p-value obtained from categorical analysis using a model with effects for treatment and investigator.

Appendix H:
CRF for all Patient with Adverse Experiences Leading to Withdrawal, Serious Adverse Experiences and Deaths

sent under separate cover

PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	29JUL94	1	03AUG94	6	6
00061	Oral	2	100 MG	04AUG94	7	10AUG94	13	7
00061	Oral	3	150 MG	11AUG94	14	17AUG94	20	7
00061	Oral	4	200 MG	18AUG94	21	24AUG94	27	7
00061	Oral	4	200 MG	25AUG94	28	31AUG94	34	7
	Oral	4	200 MG	01SEP94	35	14SEP94	48	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	48	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
REPEATED SINUS INFECTIONS ABOUT ONE TIME PER MONTH	SINUSITIS, OTHER	RESPIRATORY SYST DIS	CUR	1989
FOOT CASTED	THERAPY, REHAB	PROCEDURES	PRV	1977
FOOT TURNED AT BIRTH	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1977
REPEATED STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	PRV	1978
RESPIRATORY DIFFICULTIES AT BIRTH	CONDITIONS, PERINATAL	PERINATAL COND	PRV	1977
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Diphenhydramine Citrate	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
	Paracetamol	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
DERMATOLOGICALS	Diphenhydramine Citrate	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
	Paracetamol	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-15, .	14JUL94	14JUL94#	200MG	HEADACHE
RESPIRATORY	Diphenhydramine Citrate	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA
	Paracetamol	Excedrin Pm	-28, .	01JUL94	28JUL94#	1TABLET	INSOMNIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Qt Interval Prolonged	WIDENED CORRECTED QT {INTERVAL} QRS	35, .	Not Stated	200	CON	MIL	STP	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	14, .	Not Stated	150	CON	MIL	NO	REL	No	No
	Dysphagia	DIFFICULTY SWALLOWING 1 HOUR DURATION AFTER AWAKENING	31, .	Not Stated	200	3	MIL	NO	PSR	No	No
Nervous System	Concentration Impaired	DECREASE CONCENTRATION	2, .	27 Days	50	CON	MOD	NO	REL	No	No
			35, .	Not Stated	200	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS UPON GETTING UP SUDDENLY	9, .	20 Days	100	CON	MIL	NO	REL	No	No
	Insomnia	INSOMNIA MIDDLE	21, .	Not Stated	200	7	MIL	NO	REL	No	No
	Tremor	HAND TREMORS	28, .	Not Stated	200	4	MIL	NO	REL	No	No
Respiratory System	Pharyngitis	SORE THROAT 1 HOUR DURATION AFTER AWAKENING	31, .	Not Stated	200	3	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19JUL94	-10, .	0	104	60	76	106	64	76	145.00	61.0
BL	29JUL94	1, .	0	102	58	72	108	64	72	146.00	
1	04AUG94	7, .	100	94	62	92	100	70	104	143.00	
2	11AUG94	14, .	150	104	64	102	96	64	124 H	145.80	
3	18AUG94	21, .	200	100	62	102	102	64	108	147.80	
4	25AUG94	28, .	200	108	74	96	102	70	102	147.80	
5	01SEP94	35, .	200	100	68	100	98	62	112	149.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	90	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00061 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	20OCT94	1	26OCT94	7	7
00062	Oral	2	0 MG	27OCT94	8	02NOV94	14	7
00062	Oral	3	0 MG	03NOV94	15	09NOV94	21	7
00062	Oral	4	0 MG	10NOV94	22	15NOV94	27	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	27	0	Protocol violation, including non-compliance	PATIENT REFUSED FURTHER MEDICATION.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1979
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1988

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Mylanta	-2240, .	01SEP88	01SEP93#	2TSP	STOMACH ACHE
	Dimeticone, Activated	Mylanta	-2240, .	01SEP88	01SEP93#	2TSP	STOMACH ACHE
	Magnesium Hydroxide	Mylanta	-2240, .	01SEP88	01SEP93#	2TSP	STOMACH ACHE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-5437, .	01DEC79	.	1000MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK AND NECK ACHES	12, .	19 Days	0		MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	16, .	Not Stated	0	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	4, .	Not Stated	0	CON	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS WHEN RIDING IN ELEVATOR OR ESCALATOR	22, .	9 Days	0		MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	06OCT94	-14, .	0	88	50	80	84	60	88	98.00	60.5
BL	20OCT94	1, .	0	90	60	68	100	56	84	98.00	
1	27OCT94	8, .	0	98	60	80	90	68	100	99.75	
2	03NOV94	15, .	0	92	56	80	86	60	96	99.75	
3	10NOV94	22, .	0	92	58	80	100	60	96	101.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66	.	.	.	30 - 70	%
				Lymphocytes	25.4	.	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	2.7	H	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00062 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08NOV94	1	14NOV94	7	7
00063	Oral	2	20 MG	15NOV94	8	21NOV94	14	7
00063	Oral	3	20 MG	22NOV94	15	28NOV94	21	7
00063	Oral	4	20 MG	29NOV94	22	05DEC94	28	7
00063	Oral	4	20 MG	06DEC94	29	12DEC94	35	7
	Oral	4	20 MG	13DEC94	36	25DEC94	48	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	48	20	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
ALLERGY POLLEN	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
PAIN LEFT WRIST(POSSIBLE SPRAIN)	SPRAINS/STRAINS	INJURY/POISONING	CUR	1994
SLIGHTLY OBESE	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	29, .	06DEC94	16DEC94	750MG	EAR ACHE SORE THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-1529, .	01SEP90	.	500MG PRN	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-4086, .	01SEP83	.	25MG PRN	ALLERGY
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-4086, .	01SEP83	.	25MG PRN	ALLERGY
	Pseudoephedrine Hydrochloride	Actifed	-4086, .	01SEP83	.	1TAB PRN	ALLERGY
	Triprolidine Hydrochloride	Actifed	-4086, .	01SEP83	.	1TAB PRN	ALLERGY

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	2, .	8 Days	20	5	MIL	NO	PSR	No	No
			23, .	Not Stated	20	CON	MIL	NO	PSR	No	No
	Trauma	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENED) [SPRAIN]	-3, .	12 Days	0	CON	MIL	NO	UNR	No	No
Digestive System	Decreased Appetite	ANOREXIA	3, .	Not Stated	20	CON	MIL	NO	PSR	No	No
	Diarrhea	DIARRHEA	2, .	14 Days	20	3	MIL	NO	PSR	No	No
	Nausea	NAUSEA	23, .	Not Stated	20	CON	MIL	NO	PSR	No	No
Musculoskeletal System	Tendinous Disorder	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENED) [TENDONITIS]	-3, .	12 Days	0	CON	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZINESS	3, .	5 Mins	20	1	MIL	NO	PSR	No	No
	Manic Reaction	MANIA SYMPTOMS	34, .	Not Stated	20	CON	MOD	STP	PSR	No	No
	Paresthesia	TINGLING LEG AND FEET	3, .	7 Days	20	2	MIL	NO	PSR	No	No
	Tremor	TREMBLING JAW	3, .	7 Days	20	3	MIL	NO	PSR	No	No
		TREMORS	34, .	Not Stated	20	3	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	28, .	9 Days	20	CON	MOD	NO	UNR	Yes	No
Special Senses	Ear Pain	RIGHT EARACHE	28, .	9 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02NOV94	-6, .	0	110	80	72	126	84	88	177.50	70.0
BL	08NOV94	1, .	0	96	60	66	100	70	80	181.00	
1	15NOV94	8, .	20	120	60	86	120	60	68	178.00	
2	22NOV94	15, .	20	124	80	80	122	76	88	180.00	
3	29NOV94	22, .	20	122	64	80	120	70	104	179.20	
4	06DEC94	29, .	20	120	70	84	120	76	98	179.70	
5	13DEC94	36, .	20	100	58	68	108	78	88	183.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.6	.	.	.	30 - 70	%
				Lymphocytes	42.3	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	9.7	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	216	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00063 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	10NOV94	1	15NOV94	6	6
00064	Oral	2	0 MG	16NOV94	7	21NOV94	12	6
00064	Oral	3	0 MG	22NOV94	13	28NOV94	19	7
00064	Oral	4	0 MG	29NOV94	20	05DEC94	26	7
00064	Oral	4	0 MG	06DEC94	27	12DEC94	33	7
00064	Oral	4	0 MG	13DEC94	34	19DEC94	40	7
00064	Oral	4	0 MG	20DEC94	41	26DEC94	47	7
00064	Oral	4	0 MG	27DEC94	48	02JAN95	54	7
00050	Oral	4	0 MG	03JAN95	55	30JAN95	82	28
00050	Oral	4	0 MG	31JAN95	83	27FEB95	110	28
00050	Oral	4	0 MG	28FEB95	111	27MAR95	138	28
00064	Oral	4	0 MG	28MAR95	139	10APR95	152	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	152	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1994
BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
BROKEN RIGHT WRIST	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
COLD(HEAD)	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1994
EAR INFECTION	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1983
MYRINGOTOMY	OPERATION, EAR	OPERATIONS	PRV	1983
PNEUMONIA	PNEUMONIA, OTHER	RESPIRATORY SYST DIS	PRV	1981

CUR = Current, PRV = Past

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PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-4013,-4067	15NOV83	.	1000MG	EAR INFECTIONS, HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	14, -41	03:00 Hrs	0	1	MIL	NO	PSR	No	No
			22, -33	8 Days	0	2	MIL	NO	PSR	No	No
	Headache	HEADACHE	78, 24	6 Days	0	2	MIL	NO	PBU	No	No
	Trauma	FRACTURED LEFT INDEX FINGER	77, 23	35 Days	0	CON	MOD	NO	UNR	No	No
		SPRAINED ANKLE	56, 2	18 Days	0	CON	MOD	NO	UNR	No	No
Digestive System	Diarrhea	DIARRHEA	14, -41	03:00 Hrs	0	2	MIL	NO	PSR	No	No
			83, 29	2 Days	0	CON	MIL	NO	UNR	No	No
	Nausea	NAUSEA	83, 29	2 Days	0	CON	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZY UPON POSITION CHANGE	3, -52	6 Days	0	5	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	CONGESTED COUGH	45, -10	18 Days	0	CON	MIL	NO	UNR	No	No
	Rhinitis	NASAL CONGESTION	45, -10	18 Days	0	CON	MIL	NO	UNR	No	No
Urogenital System	Albuminuria	URINE 1+PROTEIN	139, 85	Not Stated	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04NOV94	-6, -60	0	120	60	80	130	70	84	165.00	71.5
BL	10NOV94	1, -54	0	110	60	72	106	70	88	165.00	
1	16NOV94	7, -48	0	104	68	68	122	70	80	165.00	
2	22NOV94	13, -42	0	114	72	68	104	60	88	166.00	
3	29NOV94	20, -35	0	110	70	68	128	70	80	166.00	
4	06DEC94	27, -28	0	100	70	64	120	78	74	165.00	
5	13DEC94	34, -21	0	108	70	70	106	66	84	165.00	
6	20DEC94	41, -14	0	104	68	60	110	70	88	165.50	
7	27DEC94	48, -7	0	114	70	66	120	72	72	167.00	
8	03JAN95	55, 1	0	112	60	76	118	64	92	167.00	
12	31JAN95	83, 29	0	116	80	68	110	74	84	169.80	
16	28FEB95	111, 57	0	116	70	66	110	80	84	169.00	
20	28MAR95	139, 85	0	100	70	64	112	78	82	169.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.5	.	.	.	30 - 70	%
				Lymphocytes	44.1	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	7.6	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	195000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	265	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.8	.	.	.	30 - 70	%
				Lymphocytes	32.4	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	195000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	200	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	139	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	2.4	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	197000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	189	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.001.00064 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	139	Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
			145	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	17NOV94	1	22NOV94	6	6
00065	Oral	2	20 MG	23NOV94	7	30NOV94	14	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	14	20	Adverse event, including intercurrent illness	NEEDED PSYCHIATRIC HOSPITALIZATION FOR INCREASED AGGRESSION AGAINST SELF.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DIZZINESS UPON CHANGING POSITIONS	DIZZINESS, POSTURAL	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HAND TREMORS	TREMOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1989
STOMACH UPSET(NAUSEA)	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
OSGOOD SCHLATTER DISEASE	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1991

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Codeine Phosphate	Tylenol #1	-2115, .	01FEB89	.	1000MG	HEADACHE
	Paracetamol	Tylenol #1	-2115, .	01FEB89	.	1000MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	5, .	Not Stated	20	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	2, .	Not Stated	20	4	MOD	NO	REL	No	No
	Vomiting	VOMITING	5, .	1 Mins	20	1	MIL	NO	REL	No	No
Nervous System	Depression	WORSENING OF DEPRESSION HOSPITALIZED	14, .	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Dizziness	DIZZINESS	2, .	Not Stated	20	4	MIL	NO	REL	No	No
		LIGHTHEADED	2, .	Not Stated	20	4	MIL	NO	REL	No	No
	Hostility	NEEDED 6 STITCHES TO HAND AFTER BREAKING PICTURES (DUE TO ANGER) RESULTED IN HOSPITALIZATION TO PREVENT AGGRESSION AGAINST SELF	14, .	1 Days	20	CON	MOD	STP	PBU	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07NOV94	-10, .	0	114	70	60	110	64	74	131.00	65.0
BL	17NOV94	1, .	0	120	68	60	92	64	80	128.00	
1	21NOV94	5, .	20	110	70	60	118	80	72	126.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.4	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	209	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00065 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22NOV94	1	27NOV94	6	6
00066	Oral	2	100 MG	28NOV94	7	04DEC94	13	7
	Oral	2	100 MG	05DEC94	14	13DEC94	22	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	22	100	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
MILD ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
MOLE LEFT KNEE-RAISED	NEOPLASMS BENIGN	NEOPLASMS	CUR	1994
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
MOLE EXCISED BELOW UMBILICUS/BENIGN	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1984
SUTURES IN CHIN	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1980

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Alka-Seltzer	-731, .	21NOV92	.	2	STOMACH ACHE
	Citric Acid	Alka-Seltzer	-731, .	21NOV92	.	2	STOMACH ACHE
	Paracetamol	Tylenol	-731, .	21NOV92	.	650MG	HEADACHE
	Sodium Bicarbonate	Alka-Seltzer	-731, .	21NOV92	.	2	STOMACH ACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, .	5 Days	50	2	MIL	NO	PSR	No	No
Cardiovascular System	Tachycardia	INCREASED HEART RATE	14, .	Not Stated	100	CON	MOD	STP	REL	No	No
Digestive System	Decreased Appetite	DECREASE APPETITE	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	2, .	13 Days	50	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZY	11, .	5 Mins	100	1	MIL	NO	PSR	No	No
Special Senses	Abnormal Vision	BLURRED VISION WHEN READING LONG TIME	11, .	Not Stated	100	3	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14NOV94	-8, .	0	104	60	62	110	68	100	142.00	68.0
BL	21NOV94	-1, .	0	98	60	68	92	70	80	142.00	
1	28NOV94	7, .	100	114	74	100	100	70	120	135.00	
2	05DEC94	14, .	100	120	68	96	118	78	124 H	140.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	.	.	.	30 - 70	%
				Lymphocytes	48.2	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	311000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00066 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00067 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22NOV94	1	28NOV94	7	7
00067	Oral	2	100 MG	29NOV94	8	05DEC94	14	7
	Oral	2	100 MG	06DEC94	15	13DEC94	22	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	22	100	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00067 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Postural Hypotension	POSTURAL HYPOTENSION	9, .	Not Stated	100	CON	MOD	STP	PSR	No	No
Nervous System	Dizziness	FAINTNESS	9, .	Not Stated	100	CON	MOD	STP	PSR	No	No
	Somnolence	HYPERSOMNIA	9, .	Not Stated	100	5	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15NOV94	-7, .	0	108	60	78	110	60	96	105.50	64.5
BL	22NOV94	1, .	0	100	64	64	88	60	88	106.00	
1	29NOV94	8, .	100	112	76	88	118	84	92	105.00	
2	06DEC94	15, .	100	96	70	92	92	68	118	105.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00067 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.7	L	.	-	41 - 50	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	229	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	+		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00067 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08FEB95	1	14FEB95	7	7
00068	Oral	2	20 MG	15FEB95	8	21FEB95	14	7
00068	Oral	3	20 MG	22FEB95	15	28FEB95	21	7
00068	Oral	4	20 MG	01MAR95	22	07MAR95	28	7
00068	Oral	5	30 MG	08MAR95	29	14MAR95	35	7
00068	Oral	6	40 MG	15MAR95	36	22MAR95	43	8
00068	Oral	6	40 MG	23MAR95	44	28MAR95	49	6
00068	Oral	6	40 MG	29MAR95	50	04APR95	56	7
	Oral	6	40 MG	05APR95	57	20APR95	72	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	72	40	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1993
FEVER BLISTERS	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	CUR	1990
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
NAUSEA STOMACH UPSET	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
INFECTED {BIOPSY MARK RIGHT SUPRACLAVICULAR ARM}	COMPLIC OF MED CARE	INJURY/POISONING	PRV	1991
LYMPH NODE BIOPSY (ENLARGED NODES)	OPERATION, LYMPH	OPERATIONS	PRV	1991

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Dihydroxyaluminum Sodium Carbonate	Rolaids	-982, .	01JUN92	08FEB95	2TABLET	UPSET STOMACH
	Vitamins Nos	Multiple Vitamin	-69, .	01DEC94	08FEB95	1TABLET	DIETARY SUPPLEMENT
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-617, .	01JUN93	08FEB95	2TABS PRN	HEADACHE
	Paracetamol	Tylenol	20, .	27FEB95	28MAR95	1300MG	VIRAL SORE THROAT UPPER RESPIRATORY INFE
VARIOUS	Lysine	Lysine	-366, .	07FEB94	08FEB95	1TABLET	FEVER BLISTER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	3, .	Not Stated	20	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	22, .	29 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Insomnia	MIDDLE INSOMNIA	8, .	Not Stated	20	CON	MOD	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	48, .	2 Days	40	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	VIRAL UPPER RESPIRATORY INFECTION	20, .	7 Days	20	CON	MOD	NO	UNR	Yes	No
Urogenital System	Urine Abnormality	CLOUDY URINE ON URINALYSIS	57, .	Not Stated	40	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01FEB95	-7, .	0	108	74	68	112	84	80	129.00	62.0
BL	08FEB95	1, .	0	112	80	84	120	86	80	127.00	
1	15FEB95	8, .	20	116	72	72	122	80	80	128.00	
2	22FEB95	15, .	20	108	70	82	112	84	88	128.00	
3	01MAR95	22, .	20	116	78	104	118	80	108	125.50	
4	08MAR95	29, .	30	110	78	80	120	80	100	127.70	
5	15MAR95	36, .	40	116	70	84	110	74	98	128.00	
6	22MAR95	43, .	40	124	80	80	118	84	88	131.00	
7	29MAR95	50, .	40	110	80	110	116	84	124 H	131.00	
8	05APR95	57, .	40	120	80	104	114	82	120	131.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.6	.	.	.	30 - 70	%
				Lymphocytes	39	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Platelets	291000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	43	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	3.3	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00068 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Platelets	329000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16FEB95	1	22FEB95	7	7
00069	Oral	2	0 MG	23FEB95	8	01MAR95	14	7
00069	Oral	3	0 MG	02MAR95	15	08MAR95	21	7
00069	Oral	4	0 MG	09MAR95	22	15MAR95	28	7
00069	Oral	4	0 MG	16MAR95	29	22MAR95	35	7
00069	Oral	4	0 MG	23MAR95	36	29MAR95	42	7
00069	Oral	5	0 MG	30MAR95	43	05APR95	49	7
00069	Oral	6	0 MG	06APR95	50	12APR95	56	7
	Oral	5	0 MG	13APR95	57	18APR95	62	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	62	0	Lack of Efficacy	NON RESPONDER

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
PHARYNGITIS	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1995
RIGHT OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1985
FEVER	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994
PNEUMONIA	PNEUMONIA, OTHER	RESPIRATORY SYST DIS	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-51, .	27DEC94	27JAN95#		PNEUMONIA
	Sulfamethoxazole	Septra Double Strength	1, .	16FEB95	24FEB95	1TAB	PHARYNGITIS RIGHT OTITIS MEDIA
	Trimethoprim	Septra Double Strength	1, .	16FEB95	24FEB95	1TAB	PHARYNGITIS RIGHT OTITIS MEDIA
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-51, .	27DEC94	27JAN95#	650MG	FEVER PLUS HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Syncope	FAINT UPON STANDING	30, .	22 Days	0	CON	MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	ANOREXIA	31, .	21 Days	0	CON	MIL	NO	PSR	No	No
	Dyspepsia	STOMACH UPSET	35, .	17 Days	0	2	MIL	NO	PSR	No	No
	Nausea	NAUSEA	6, .	02:30 Hrs	0	1	MIL	NO	PSR	No	No
		NAUSEA AM	35, .	17 Days	0	2	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	22, .	8 Days	0	CON	MIL	NO	UNR	No	No
	Respiratory Disorder	UPPER RESPIRATORY CONGESTION	22, .	12 Days	0	CON	MIL	NO	UNR	No	No
Urogenital System	Albuminuria	URINE 1+PROTEIN	57, .	Not Stated	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	07FEB95	-9, .	0	110	60	64	104	60	80	125.00	70.5
BL	16FEB95	1, .	0	112	72	60	106	68	72	127.00	
1	23FEB95	8, .	0	100	70	80	104	70	100	125.00	
2	02MAR95	15, .	0	112	70	68	118	78	80	127.00	
3	09MAR95	22, .	0	110	74	66	110	80	100	123.00	
4	16MAR95	29, .	0	110	70	66	116	80	84	127.00	
5	23MAR95	36, .	0	106	66	64	98	60	88	123.00	
6	30MAR95	43, .	0	110	72	72	108	80	100	126.50	
7	06APR95	50, .	0	122	84	72	128	88	76	127.00	
8	13APR95	57, .	0	110	70	72	116	80	88	132.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.9	.	.	.	30 - 70	%
				Lymphocytes	21.3	.	.	.	21 - 51	%
				Monocytes	2.7	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	104	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.7	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	2	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00069 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22FEB95	1	27FEB95	6	6
00070	Oral	2	100 MG	28FEB95	7	07MAR95	14	8
00070	Oral	3	150 MG	08MAR95	15	14MAR95	21	7
00070	Oral	3	150 MG	15MAR95	22	24MAR95	31	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	No	No	31	150	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIC TO CAFFEINE	ADVERSE EFF/PSYCHOTROPICS	EXT CAUSES OF INJURY/POISONING	CUR	1992
ALLERGIC TO CHOCOLATE	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1992
ALLERGIC TO MOLD	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1992
ENLARGED LYMPH NODES	LYMPHADENOPATHY	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991
BRUISED FOOT	CONTUSION	INJURY/POISONING	PRV	1990
BRUISED HAND	CONTUSION	INJURY/POISONING	PRV	1993
EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1983
SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1991
SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1992
SPRAINED FOOT	SPRAINS/STRAINS	INJURY/POISONING	PRV	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-8, .	14FEB95	20FEB95#		ENLARGED LYMPH NODES
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-2, .	20FEB95	20FEB95#	325MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Syncope	FAINTNESS UPON STANDING	17, .	Not Stated	150	3	MIL	NO	PSR	No	No
	Tachycardia	PULSE {INCREASED} 2 CONSECUTIVE WEEKS	15, .	Not Stated	150	CON	SEV	STP	REL	No	No
	Vasodilatation	HOT FLASHES	8, .	Not Stated	100	2	MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	15, .	Not Stated	150	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
Nervous System	Agitation	INCREASE AGITATION	7, .	Not Stated	100	CON	MIL	NO	PBU	No	No
	Insomnia	MIDDLE INSOMNIA	1, .	16 Days	50	CON	MIL	NO	PBU	No	No
		TERMINAL INSOMNIA	18, .	Not Stated	150	CON	MIL	NO	PBU	No	No
	Tremor	HAND TREMORS	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14FEB95	-8, .	0	108	70	76	112	74	88	76.00	58.0
BL	22FEB95	1, .	0	104	70	82	110	70	92	76.00	
1	28FEB95	7, .	100	100	60	100	98	60	120	76.00	
2	08MAR95	15, .	150	98	60	100	100	70	108	74.00	
3	15MAR95	22, .	150	100	60	102	92	62	118	74.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.5	L	.	-	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3	.	.	.	30 - 70	%
				Lymphocytes	48.2	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	331000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	245	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00070 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	23FEB95	1	01MAR95	7	7
00071	Oral	2	0 MG	02MAR95	8	08MAR95	14	7
00071	Oral	3	0 MG	09MAR95	15	15MAR95	21	7
00071	Oral	4	0 MG	16MAR95	22	22MAR95	28	7
00071	Oral	5	0 MG	23MAR95	29	29MAR95	35	7
00071	Oral	6	0 MG	30MAR95	36	05APR95	42	7
00071	Oral	6	0 MG	06APR95	43	12APR95	49	7
00071	Oral	6	0 MG	13APR95	50	19APR95	56	7
	Oral	6	0 MG	20APR95	57	04MAY95	71	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	71	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
FLU	INFLUENZA	RESPIRATORY SYST DIS	PRV	1995
PRESSURE EQUALIZATION TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1983
SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-20, .	03FEB95	13FEB95#	750MG	FLU/SINUSITIS
CENTRAL NERVOUS SYSTEM	Chlorphenamine Maleate	Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
	Dextromethorphan Hydrobromide	Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
	Paracetamol	Tylenol	-17, .	06FEB95	12FEB95#	650MG	HEADACHE
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
	Pseudoephedrine Hydrochloride	Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
			-17, .	06FEB95	12FEB95#	2TABS	FLU
	Dextromethorphan Hydrobromide	Nyquil	-17, .	06FEB95	10FEB95#		FLU
		Robitussin Cf	-21, .	02FEB95	08FEB95#		FLU
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
			-17, .	06FEB95	12FEB95#	2TABS	FLU
	Doxylamine Succinate	Nyquil	-17, .	06FEB95	10FEB95#		FLU
	Guaifenesin	Robitussin Cf	-21, .	02FEB95	08FEB95#		FLU
	Paracetamol	Nyquil	-17, .	06FEB95	10FEB95#		FLU
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
			-17, .	06FEB95	12FEB95#	2TABS	FLU
	Phenylpropanolamine Hydrochloride	Robitussin Cf	-21, .	02FEB95	08FEB95#		FLU
	Pseudoephedrine Hydrochloride	Nyquil	-17, .	06FEB95	10FEB95#		FLU
		Tylenol Cold Tablets	-17, .	06FEB95	12FEB95#	2TABS	FLU
			-17, .	06FEB95	12FEB95#	2TABS	FLU

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	41, .	23 Days	0	CON	MIL	NO	PSR	No	No
Hemic and Lymphatic System	Lymphadenopathy	SWOLLEN LYMPH NODES IN NECK	19, .	4 Days	0	CON	MIL	NO	UNR	No	No
Musculoskeletal System	Myalgia	ARM AND LEG MUSCLE ACHES	27, .	5 Days	0	CON	MIL	NO	PBU	No	No
Respiratory System	Pharyngitis	SORE THROAT	19, .	15 Days	0	CON	MOD	NO	UNR	No	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION	19, .	15 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02FEB95	-21, .	0	100	60	80	104	66	100	97.00	61.8
BL	23FEB95	1, .	0	90	58	72	100	60	92	99.00	
1	02MAR95	8, .	0	110	60	84	106	60	100	95.00	
2	09MAR95	15, .	0	100	54	82	102	60	88	96.50	
3	16MAR95	22, .	0	104	60	76	110	70	84	95.70	
4	23MAR95	29, .	0	106	64	74	100	60	88	96.50	
5	30MAR95	36, .	0	110	70	76	100	60	78	96.00	
6	06APR95	43, .	0	104	64	96	100	80	100	98.00	
7	13APR95	50, .	0	100	60	82	100	70	96	97.50	
8	20APR95	57, .	0	100	60	72	106	68	76	97.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.4	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	181	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00071 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	20MAR95	1	26MAR95	7	7
00072	Oral	2	20 MG	27MAR95	8	02APR95	14	7
00072	Oral	3	20 MG	03APR95	15	09APR95	21	7
00072	Oral	4	20 MG	10APR95	22	12APR95	24	3
	Oral	3	20 MG	13APR95	25	20APR95	32	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	32	20	Other reason	FAMILY WITHDREW CONSENT.SEE MISCELLANEOUS NOTES.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
STRESS FRACTURE BACK	BONE/CARTIL DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1993

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	2, .	3 Days	20	2	MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	APPETITE DECREASED	9, .	Not Stated	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07MAR95	-13, .	0	104	70	72	100	70	88	152.00	73.5
BL	20MAR95	1, .	0	108	68	72	98	60	88	153.50	
1	27MAR95	8, .	20	90	60	66	88	60	84	151.00	
2	03APR95	15, .	20	100	60	76	90	60	114	150.00	
3	10APR95	22, .	20	104	60	72	94	62	88	150.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.1	.	.	.	30 - 70	%
				Lymphocytes	48.1	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	252	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00072 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	04APR95	1	10APR95	7	7
00121	Oral	2	20 MG	11APR95	8	17APR95	14	7
00121	Oral	3	20 MG	18APR95	15	25APR95	22	8
00121	Oral	4	20 MG	26APR95	23	01MAY95	28	6
00121	Oral	5	30 MG	02MAY95	29	08MAY95	35	7
00121	Oral	5	30 MG	09MAY95	36	15MAY95	42	7
00121	Oral	5	30 MG	16MAY95	43	22MAY95	49	7
00121	Oral	5	30 MG	23MAY95	50	29MAY95	56	7
00051	Oral	5	30 MG	30MAY95	57	26JUN95	84	28
00051	Oral	5	30 MG	27JUN95	85	23JUL95	111	27
00051	Oral	5	30 MG	24JUL95	112	20AUG95	139	28
00121	Oral	5	30 MG	21AUG95	140	04SEP95	154	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	154	30	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DECREASED WHITE BLOOD CELL	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1995
BIRTHMARK REMOVED	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1989
CHICKEN POX	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	PRV	1987
CYST REMOVED FROM CHEST	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1981

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	3, -54	27 Days	20	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS	8, -49	22 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZY	50, -7	20 Mins	30	1	MIL	NO	PBU	No	No
Skin and Appendages	Acne	ACNE WORSE	9, -48	21 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22MAR95	-13, -69	0	102	62	60	98	60	86	143.50	74.0
BL	04APR95	1, -56	0	106	60	68	100	60	100	143.50	
1	11APR95	8, -49	20	104	60	60	106	64	70	141.00	
2	18APR95	15, -42	20	100	66	64	98	70	80	139.75	
3	26APR95	23, -34	20	100	68	64	104	62	88	135.50	
4	02MAY95	29, -28	30	100	60	64	100	64	80	139.00	
5	09MAY95	36, -21	30	110	70	60	100	70	88	138.70	
6	16MAY95	43, -14	30	98	70	64	104	72	84	139.50	
7	23MAY95	50, -7	30	100	60	66	108	64	68	138.00	
8	30MAY95	57, 1	30	98	66	60	100	70	80	138.00	
12	27JUN95	85, 29	30	108	62	80	110	60	112	143.70	
16	24JUL95	112, 56	30	100	60	68	96	62	80	142.70	
20	21AUG95	140, 84	30	108	66	72	100	62	92	144.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	180000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	187	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	183000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	29	White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.2	L	.	-	41 - 50	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	147000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	170	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	140	White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.9	.	.	.	30 - 70	%
				Lymphocytes	42.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	170000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	157	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 17/DOWN TITRATION	155 (1)	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00121 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 17/DOWN TITRATION	155 (1)	Hematocrit	37.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.5	.	.	.	30 - 70	%
				Lymphocytes	41.3	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	195000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	20JUN95	1	26JUN95	7	7
00122	Oral	2	100 MG	27JUN95	8	04JUL95	15	8
00122	Oral	3	150 MG	05JUL95	16	10JUL95	21	6
00122	Oral	4	200 MG	11JUL95	22	17JUL95	28	7
00122	Oral	4	200 MG	18JUL95	29	24JUL95	35	7
00122	Oral	4	200 MG	25JUL95	36	31JUL95	42	7
00122	Oral	4	200 MG	01AUG95	43	08AUG95	50	8
00122	Oral	4	200 MG	09AUG95	51	15AUG95	57	7
00052	Oral	4	200 MG	16AUG95	58	11SEP95	84	27
00052	Oral	4	200 MG	12SEP95	85	09OCT95	112	28
00052	Oral	4	200 MG	10OCT95	113	06NOV95	140	28
00052	Oral	4	200 MG	07NOV95	141	04DEC95	168	28
	Oral	4	200 MG	05DEC95	169	18DEC95	182	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	182	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
HEAVY PERSPIRATION	HYPERHIDROSIS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HERNIA REPAIR	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1988
RIGHT FOOT INFECTION {TOENAILS}	CELLULITIS/ABSCESS	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	1985

CUR = Current, PRV = Past

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PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Minerals Nos	Centrum	-80, -137	01APR95	20JUN95	ONE DAILY	HEALTH MAINTENANCE
	Vitamins Nos	Centrum	-80, -137	01APR95	20JUN95	ONE DAILY	HEALTH MAINTENANCE
ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole	Bactrim Ds	-139, -196	01FEB95	.	2TWICE DAILY	ACNE
	Trimethoprim	Bactrim Ds	-139, -196	01FEB95	.	2TWICE DAILY	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Extrasystoles	PVC'S ON EKG [PREMATURE VENTRICULAR CONTRACTIONS]	8, -50	9 Days	100	CON	MIL	NO	PBU	No	No
	Tachycardia	HEART RACING (BEATS HARD)	85, 28	30 Days	200	2	MIL	NO	REL	No	No
Digestive System	Constipation	CONSTIPATION	16, -42	4 Days	150	CON	MIL	NO	PSR	No	No
			25, -33	19 Days	200	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	114, 57	Not Stated	200	CON	MOD	NO	REL	No	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN	114, 57	Not Stated	200	CON	MOD	NO	REL	No	No
Nervous System	Amnesia	MORE FORGETFUL	22, -36	15 Days	200	CON	MIL	NO	PSR	No	No
	Hypesthesia	NUMBNESS IN HANDS AND ARMS WHEN AWAKES	29, -29	30 Days	200	CON	MIL	NO	PBU	No	No
	Myoclonus	MUSCLE TWITCH RIGHT EYE	25, -33	19 Days	200	CON	MIL	NO	PSR	No	No
		RIGHT KNEE TWITCH	25, -33	62 Days	200	CON	MIL	NO	REL	No	No
	Tremor	HAND TREMORS	50, -8	120 Days	200	CON	MOD	NO	REL	No	No
		RIGHT KNEE TREMOR	25, -33	62 Days	200	CON	MIL	NO	REL	No	No
Respiratory System	Rhinitis	CONGESTION BACK OF THROAT	110, 53	8 Days	200	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	13JUN95	-7, -64	0	120	72	68	112	70	78	166.00	68.5
BL	20JUN95	1, -57	0	110	60	64	102	70	74	166.00	
1	27JUN95	8, -50	100	110	78	76	110	60	80	163.50	
2	05JUL95	16, -42	150	102	70	80	110	70	104	164.00	
3	11JUL95	22, -36	200	114	80	90	106	84	98	165.00	
4	18JUL95	29, -29	200	110	74	88	120	80	108	164.00	
5	25JUL95	36, -22	200	110	74	90	114	80	102	164.00	
6	01AUG95	43, -15	200	120	80	78	112	86	96	166.00	
7	08AUG95	50, -8	200	116	80	84	110	82	92	168.20	
8	16AUG95	58, 1	200	120	76	96	120	80	98	171.00	
12	12SEP95	85, 28	200	118	70	96	116	80	104	171.00	
16	10OCT95	113, 56	200	110	80	82	108	76	84	171.00	
20	07NOV95	141, 84	200	120	70	88	112	80	112	179.00 H	
24	05DEC95	169, 112	200	120	80	94	114	80	106	180.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.1	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.8	.	.	.	30 - 70	%
				Lymphocytes	43.2	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	1.6	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.4	.	.	.	30 - 70	%
				Lymphocytes	46.8	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	45	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	200000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	104	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00122 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	141	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.1	L	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	04JAN96	1	11JAN96	8	8
00123	Oral	2	0 MG	12JAN96	9	17JAN96	14	6
00123	Oral	3	0 MG	18JAN96	15	24JAN96	21	7
00123	Oral	4	0 MG	25JAN96	22	31JAN96	28	7
00123	Oral	4	0 MG	01FEB96	29	07FEB96	35	7
00123	Oral	4	0 MG	08FEB96	36	14FEB96	42	7
00123	Oral	4	0 MG	15FEB96	43	21FEB96	49	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	49	0	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACTERIAL VAGINAL RASH	VAGINITIS	GENITOURINARY SYST DIS	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1992
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1993
BROKEN ANKLE	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
BROKEN WRIST	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1988
FEMORAL EPIPHYSIS RIGHT HIP{JOINT DISORDER}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1989
HIP LEFT FEMORAL EPIPHYSIS{JOINT DISORDER}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1990
SURGERY PINNING LEFT HIP	OPERATION, BONE/JOINT	OPERATIONS	PRV	1990
SURGERY REMOVAL OF PINS IN RIGHT,LEFT HIPS	OPERATION, BONE/JOINT	OPERATIONS	PRV	1991
SURGERY-PLACEMENT OF CANNULATED LOG SCREW RIGHT HIP	OPERATION, BONE/JOINT	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Azithromycin	Zithromax	10, .	13JAN96	18JAN96	1000MGX1	BRONCHITIS
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	12, .	15JAN96	.	650MG	MENSTRUAL CRAMPS
	Mepyramine Maleate	Pamprin	-20, .	15DEC95	17DEC95#	2TABS	MENSTRUAL CRAMPS
	Pamabrom	Pamprin	-20, .	15DEC95	17DEC95#	2TABS	MENSTRUAL CRAMPS
	Paracetamol	Pamprin	-20, .	15DEC95	17DEC95#	2TABS	MENSTRUAL CRAMPS
		Tylenol	49, .	21FEB96	.	650MG	HEADACHE
DERMATOLOGICALS	Methylprednisolone	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS
GU SYSTEM/SEX HORMONES	Desogestrel	Ortho-Cept 28	18, .	21JAN96	.	1TAB 1XDAY	MENSTRUAL CRAMPS
	Ethinylestradiol	Ortho-Cept 28	18, .	21JAN96	.	1TAB 1XDAY	MENSTRUAL CRAMPS
SENSORY ORGANS	Methylprednisolone	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS
SYSTEMIC HORMONAL	Methylprednisolone	Methylprednisolone	10, .	13JAN96	18JAN96	4MG-24MG DAILY	BRONCHITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	49, .	Not Stated	0	CON	MOD	NO	PSR	Yes	No
		HEADACHES	18, .	8 Days	0	CON	MIL	NO	UNR	No	No
	Pain	BODY ACHES	19, .	7 Days	0	CON	MIL	NO	UNR	No	No
Digestive System	Nausea	NAUSEA	19, .	7 Days	0	CON	MIL	NO	UNR	No	No
			49, .	Not Stated	0	CON	MIL	NO	PSR	No	No
		NAUSEA (POST TAKING MEDS)	2, .	04:30 Hrs	0	2	MIL	NO	PSR	No	No
			26, .	5 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Depression	WORSENING OF DEPRESSION	46, .	Not Stated	0	CON	SEV	STP	REL	No	Yes
	Emotional Lability	SUICIDAL THOUGHTS	46, .	Not Stated	0	CON	SEV	STP	REL	No	Yes
	Tremor	HAND TREMORS	32, .	Not Stated	0	3	MIL	NO	PSR	No	No
Respiratory System	Bronchitis	BRONCHITIS WITH BRONCHOSPASMS	10, .	13 Days	0	CON	MOD	NO	UNR	Yes	No
	Cough Increased	DRY COUGH	4, .	19 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14DEC95	-21, .	0	122	68	64	120	70	84	183.00	69.3
BL	04JAN96	1, .	0	108	72	64	110	70	78	185.00	
1	12JAN96	9, .	0	112	70	80	110	70	100	185.50	
2	18JAN96	15, .	0	104	64	82	108	70	68	184.00	
3	25JAN96	22, .	0	100	60	78	102	70	80	182.75	
4	01FEB96	29, .	0	120	70	66	116	70	80	186.50	
5	08FEB96	36, .	0	106	62	68	114	72	70	187.00	
6	15FEB96	43, .	0	120	70	62	110	68	92	187.50	
7	22FEB96	50, .	0	102	68	66	90	60	96	184.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	30.7	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	297000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00123 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07FEB96	1	14FEB96	8	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	No	No	8	20	Adverse event, including intercurrent illness	MANIA/HYPOMANIA SYMPTOMS

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1984
FACIAL LACERATIONS{DOG BITE}	OPEN WOUND	INJURY/POISONING	PRV	1986
PLASTIC SURGERY FOR FACIAL SCARS	OPERATION, SKIN/SUBCUT	OPERATIONS	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Chlorphenamine Maleate	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Paracetamol	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
			-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
			-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Paracetamol	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
			-27, .	11JAN96	11JAN96#	5TSP.	SINUS
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-27, .	11JAN96	11JAN96#	5TSP.	SINUS
			-27, .	11JAN96	11JAN96#	5TSP.	SINUS

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Decreased Appetite	SLIGHT DECREASE APPETITE	3, .	Not Stated	20	CON	MIL	NO	PSR	No	No
Nervous System	Manic Reaction	MANIA AND HYPOMANIA SYMPTOMS	4, .	Not Stated	20	CON	SEV	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	29JAN96	-9, .	0	100	70	68	98	68	88	132.30	60.3
BL	07FEB96	1, .	0	100	66	82	96	70	90	131.00	
1	14FEB96	8, .	20	100	70	80	100	70	92	132.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	33.6	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	349	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	60 - 110	MG/DL
				Globulin	2.5	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00205 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	21FEB96	1	27FEB96	7	7
00206	Oral	2	20 MG	28FEB96	8	05MAR96	14	7
00206	Oral	3	20 MG	06MAR96	15	12MAR96	21	7
00206	Oral	4	20 MG	13MAR96	22	19MAR96	28	7
00206	Oral	5	30 MG	20MAR96	29	25MAR96	34	6
00206	Oral	6	40 MG	26MAR96	35	02APR96	42	8
00206	Oral	6	40 MG	03APR96	43	09APR96	49	7
00206	Oral	6	40 MG	10APR96	50	16APR96	56	7
	Oral	5	30 MG	17APR96	57	18APR96	58	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	58	30	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	19, .	2 Days	20	CON	MIL	NO	PBU	No	No
Digestive System	Dyspepsia	STOMACH UPSET	19, .	2 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12FEB96	-9, .	0	122	80	68	124	86	76	158.00	70.5
BL	21FEB96	1, .	0	118	76	72	122	86	80	157.50	
1	28FEB96	8, .	20	112	70	68	118	78	84	155.00	
2	06MAR96	15, .	20	118	74	66	120	80	72	157.00	
3	13MAR96	22, .	20	104	70	68	100	68	74	155.50	
4	20MAR96	29, .	30	108	70	68	112	74	76	160.00	
5	26MAR96	35, .	40	110	70	80	110	68	96	156.50	
6	03APR96	43, .	40	110	70	72	106	68	84	156.00	
7	10APR96	50, .	40	114	68	76	120	70	84	161.00	
8	17APR96	57, .	30	106	70	78	112	70	92	160.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.1	.	.	.	30 - 70	%
				Lymphocytes	33.7	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	187000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	129	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	116	H	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	33.4	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	130	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00206 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	35	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28FEB96	1	05MAR96	7	7
00207	Oral	2	0 MG	06MAR96	8	12MAR96	14	7
00207	Oral	3	0 MG	13MAR96	15	19MAR96	21	7
00207	Oral	4	0 MG	20MAR96	22	25MAR96	27	6
00207	Oral	4	0 MG	26MAR96	28	02APR96	35	8
00207	Oral	4	0 MG	03APR96	36	09APR96	42	7
00207	Oral	4	0 MG	10APR96	43	16APR96	49	7
00207	Oral	4	0 MG	17APR96	50	23APR96	56	7
	Oral	3	0 MG	24APR96	57	25APR96	58	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	No	58	0	Lack of Efficacy	NON RESPONDER

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
MUSCLE STRAIN	SPRAINS/STRAINS	INJURY/POISONING	PRV	1996
SORE THROAT WITH COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Clarithromycin	Biaxin	56, .	23APR96	02MAY96	1000MG	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	53, .	20APR96	25APR96	650MG	HEADACHE SORE THROAT
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	-7, .	21FEB96	28FEB96	1TAB	STRAINED MUSCLE
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	-21, .	07FEB96	28FEB96	60MG	COLD SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH CRAMPS	5,	.	23:00 Hrs	0	CON	MIL	NO	UNR	No	No
		STOMACH CRAMPS (SINCE STARTING BIAXIN)	57,	.	3 Days	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	51,	.	8 Days	0	CON	MOD	NO	PBU	Yes	No
	Pain	BODY ACHES	51,	.	7 Days	0	CON	MIL	NO	UNR	No	No
Digestive System	Decreased Appetite	DECREASED APPETITE	23,	.	15 Days	0	CON	MIL	NO	PBU	No	No
	Diarrhea	DIARRHEA	5,	.	15:00 Hrs	0	3	MOD	NO	UNR	No	No
			39,	.	13:00 Hrs	0	4	MIL	NO	PBU	No	No
			57,	.	3 Days	0	CON	MIL	NO	UNR	No	No
Respiratory System	Cough Increased	COUGH	38,	.	7 Days	0	CON	MIL	NO	UNR	No	No
	Pharyngitis	SORE THROAT	43,	.	2 Days	0	CON	MIL	NO	UNR	No	No
	Rhinitis	STUFFY NOSE	38,	.	7 Days	0	CON	MIL	NO	UNR	No	No
	Sinusitis	HEAD CONGESTION	24,	.	4 Days	0	CON	MIL	NO	UNR	No	No
			38,	.	7 Days	0	CON	MIL	NO	UNR	No	No
		SINUS INFECTION	51,	.	15 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19FEB96	-9, .	0	120	76	76	116	72	80	217.00	70.5
BL	28FEB96	1, .	0	118	70	72	120	78	80	215.00	
1	06MAR96	8, .	0	120	78	84	120	76	98	220.00	
2	13MAR96	15, .	0	116	70	92	124	80	100	220.00	
3	20MAR96	22, .	0	122	76	84	118	82	92	217.50	
4	26MAR96	28, .	0	112	62	80	116	70	90	217.50	
5	03APR96	36, .	0	122	74	88	118	78	96	214.00	
6	10APR96	43, .	0	122	80	88	116	82	96	217.50	
7	17APR96	50, .	0	116	70	88	114	80	94	220.00	
8	24APR96	57, .	0	114	72	84	118	78	94	213.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	238	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	42	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37.3	.	.	.	30 - 70	%
				Lymphocytes	50.7	.	.	.	21 - 51	%
				Monocytes	9.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	225	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.001.00207 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	122	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	09MAR95	1	15MAR95	7	7
00049	Oral	2	0 MG	16MAR95	8	22MAR95	14	7
00049	Oral	3	0 MG	23MAR95	15	29MAR95	21	7
00049	Oral	4	0 MG	30MAR95	22	05APR95	28	7
00049	Oral	5	0 MG	06APR95	29	12APR95	35	7
00049	Oral	6	0 MG	13APR95	36	19APR95	42	7
00049	Oral	6	0 MG	20APR95	43	27APR95	50	8
00049	Oral	6	0 MG	28APR95	51	05MAY95	58	8
	Oral	6	0 MG	06MAY95	59	21MAY95	74	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	74	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BILATERAL HERNIORRHAPHY	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	19, .	27MAR95	27MAR95	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	17, .	3 Days	0	3	MIL	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03MAR95	-6, .	0	110	65	64	110	80	96	210.00	75.0
BL	08MAR95	-1, .	0	110	60	80	110	75	104	211.00	
1	15MAR95	7, .	0	130	65	88	125	70	100	211.50	
2	22MAR95	14, .	0	115	60	84	115	70	96	211.00	
3	29MAR95	21, .	0	100	65	68	100	70	92	210.00	
4	05APR95	28, .	0	100	70	72	100	70	84	211.00	
5	12APR95	35, .	0	110	65	76	100	75	96	210.50	
6	19APR95	42, .	0	100	68	82	112	68	105	212.56	
7	27APR95	50, .	0	110	60	80	100	70	104	208.00	
8	05MAY95	58, .	0	115	61	81	115	65	106	210.36	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	1000.PRE	-13	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.7	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	27.5	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	123	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	68	L	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	1000.PRE	-13	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/SCREENING (WEEK -1)	-6	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3	.	.	.	30 - 70	%
				Lymphocytes	33	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00049 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	58		Platelets	246000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	117	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
					Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	25	L	.	.	70 - 115	MG/DL
					Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	91	(17)	Glucose - Random	96	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	23MAR95	1	29MAR95	7	7
00050	Oral	2	100 MG	30MAR95	8	05APR95	14	7
00050	Oral	3	150 MG	06APR95	15	12APR95	21	7
	Oral	3	150 MG	14APR95	23	26APR95	35	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	No	No	35	150	Adverse event, including intercurrent illness	MULTIPLE SIDE EFFECTS-INCREASED HEART RATE URINARY HESITANCY DIZZINESS

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1991
INTERMITTENT GLUCOSE(DECREASED)	HYPOGLYCEMIA	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
HYPOSPADIAS {MALE}	CONG ANOM, GU	ANOMALIES	PRV	1978
LEFT URETERAL DUPLICATION	CONG ANOM, GU	ANOMALIES	PRV	1978
RIGHT VESICOURETERAL REFLUX	KIDNEY DISORD	GENITOURINARY SYST DIS	PRV	1978

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	5, .	27MAR95	28MAR95	250MG	SORE THROAT
			6, .	28MAR95	08APR95	1500MG	SORE THROAT
	Clindamycin Hydrochloride	Cleocin	-1177, .	01JAN92	.	1%LOTION	ACNE
	Minocycline	Minocycline	-1177, .	01JAN92	.	100MG	ACNE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	4, .	26MAR95	26MAR95	650MG	FEVER
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	5, .	27MAR95	28MAR95	1-2TABS	FEVER/SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Fever	FEVER	1, .	6 Days	50	CON	MOD	NO	PBU	Yes	No
	Headache	HEADACHE	1, .	5 Days	50	CON	MIL	NO	PBU	Yes	No
Carciovascular System	Postural Hypotension	DIZZINESS WITH ORTHOSTATIC HYPOTENSION	8, .	6 Days	100	CON	MIL	STP	PSR	No	No
	Tachycardia	HEART RATE INCREASE	1, .	22 Days	50	CON	MOD	STP	PSR	No	No
Respiratory System	Cough Increased	COUGHING	1, .	12 Days	50	CON	MIL	NO	PBU	Yes	No
	Pharyngitis	SORE THROAT	1, .	6 Days	50	CON	MOD	NO	PBU	Yes	No
Urogenital System	Urination Impaired	URINARY HESITANCY	8, .	6 Days	100	CON	MIL	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	10MAR95	-13, .	0	140	74	70	149	82	76	152.15	67.5
BL	22MAR95	-1, .	0	135	75	88	135	75	96	154.00	
1	29MAR95	7, .	50	115	70	92	115	70	104	154.00	
2	05APR95	14, .	100	139	69	94	123	73	111	154.00	
3	12APR95	21, .	150	120	80	104	120	85	112	153.00	
5	28APR95	37, .	150	139	68	95	122	76	102	155.67	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4	.	.	.	30 - 70	%
				Lymphocytes	25.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	275000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	186	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	46	L	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13		Urine Squamous Epithelial Cells	3	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-6		Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.6	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	203	H	.	.	22 - 180	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	80	.	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 6/ACUTE PHASE-WEEK 4	37	(2)	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	39	L	.	.	41 - 50	%
					Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	56.8	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00050 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 6/ACUTE PHASE-WEEK 4	37 (2)	Lymphocytes	35.3	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	199	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	41	L	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	24JUN94	1	29JUN94	6	6
00055	Oral	2	20 MG	30JUN94	7	06JUL94	13	7
00055	Oral	3	20 MG	07JUL94	14	13JUL94	20	7
00055	Oral	4	20 MG	14JUL94	21	20JUL94	27	7
00055	Oral	5	30 MG	21JUL94	28	27JUL94	34	7
00055	Oral	6	40 MG	28JUL94	35	03AUG94	41	7
00055	Oral	6	40 MG	04AUG94	42	10AUG94	48	7
00055	Oral	6	40 MG	11AUG94	49	17AUG94	55	7
00068	Oral	6	40 MG	18AUG94	56	14SEP94	83	28
00068	Oral	6	40 MG	15SEP94	84	13OCT94	112	29
00068	Oral	6	40 MG	14OCT94	113	10NOV94	140	28
00055	Oral	5	30 MG	11NOV94	141	12NOV94	142	2
00055	Oral	4	20 MG	13NOV94	143	14NOV94	144	2
00055	Oral	3	20 MG	15NOV94	145	16NOV94	146	2
00055	Oral	2	20 MG	17NOV94	147	19NOV94	149	3
00055	Oral	1	20 MG	20NOV94	150	26NOV94	156	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	156	20	Lack of Efficacy	RELAPSE IN CONTINUATION PHASE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES-BEE STING	TOXIC EFFECTS, VENOM	INJURY/POISONING	CUR	1987
ALLERGY-CAT FUR(MILD)	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1987
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	123, 68	24OCT94	.	ESTIMATE 650MG PM	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	123, 68	24OCT94	.	800-1200MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Hostility	ALLEGATIONS OF SEXUAL AGGRESSION	32, -24	1 Days	30		MIL	NO	UNR	No	No
Skin and Appendages	Photosensitivity	SUNBURN,APPROPRIATE TO DEGREE OF EXPOSURE(BEACH)	20, -36	3 Days	20	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	09JUN94	-15, -70	0	110	70	85	110	75	88	175.00	65.0
BL	23JUN94	-1, -56	0	115	75	80	120	70	85	174.00	
1	30JUN94	7, -49	20	104	68	64	110	70	75	174.50	
2	07JUL94	14, -42	20	105	68	86	90	75	92	175.00	
3	14JUL94	21, -35	20	100	66	72	100	72	96	173.00	
4	21JUL94	28, -28	30	102	50	92	98	68	112	171.00	
5	28JUL94	35, -21	40	102	60	72	100	62	102	168.00	
6	04AUG94	42, -14	40	98	68	80	94	60	102	169.50	
7	11AUG94	49, -7	40	92	58	72	94	60	100	169.00	
8	18AUG94	56, 1	40	90	60	54	90	68	72	166.00	
12	15SEP94	84, 29	40	94	60	68	92	64	98	170.00	
16	13OCT94	112, 57	40	100	60	60	104	54	80	171.50	
20	10NOV94	140, 85	40	112	70	72	104	68	84	173.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.6	.	.	.	12 - 16	G/DL
				Hematocrit	39.4	.	.	.	36 - 49	%
				Red Blood Cell Count	4.87	.	.	.	4 - 5.2	10^12/L
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	10^9/L
				Neutrophil Bands	56	.	.	+	30 - 70	%
				Segmented Neutrophils	56	.	.	.	30 - 70	%
				Lymphocytes	31	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	3640000	H	.	+	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 33	PG
				Mean Corpuscle Volume	81	.	.	.	77 - 95	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	12	H	.	+	0.7 - 1.4	MG/DL
				Uric Acid	6.6	.	.	.	4 - 8.5	MG/DL
				Alkaline Phosphatase	328	.	.	.	60 - 500	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 42	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 45	U/L
				Total Bilirubin	1	.	.	.	0 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6 - 8.5	GM/DL
				Albumin	4.2	.	.	.	3.2 - 5	GM/DL
				Glucose - Random	108	.	.	.	70 - 113	MG/DL
				Globulin	2.3	.	.	.	2.2 - 4.2	GM/DL
				Urine Blood - Random	NEG	.	.	.		
				Urine Bilirubin	NEG	.	.	.		
				Urine Ketones (Acetone)	NEG	.	.	.		
				Urine PH	5.0	.	.	.		
				Total Protein in Urine	TRACE	.	.	.		
				Urine Specific Gravity	1.030	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Appearance	CLEAR	.	.	.		
				Urine Color	YELLOW	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	33.3	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	6.6	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	295	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	27	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	284	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00055 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	140	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19JUL94	1	25JUL94	7	7
00056	Oral	2	100 MG	26JUL94	8	01AUG94	14	7
00056	Oral	3	150 MG	02AUG94	15	08AUG94	21	7
00056	Oral	4	200 MG	09AUG94	22	16AUG94	29	8
	Oral	3	150 MG	17AUG94	30	23AUG94	36	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	36	150	Adverse event, including intercurrent illness	INCREASED HEART RATE

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MISCARRIAGE	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994
PREGNANCY	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1994

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Tachycardia	INCREASED HEART RATE	15, .	22 Days	150	CON	MIL	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JUN94	-25, .	0	90	52	84	80	50	108	111.00	59.4
BL	19JUL94	1, .	0	82	40	100	84	44	102	113.00	
1	26JUL94	8, .	100	84	58	100	84	56	120	110.00	
2	02AUG94	15, .	150	90	50	108	72	40	112	109.00	
3	09AUG94	22, .	200	92	60	132 H	90	60	104	110.00	
4	16AUG94	29, .	200	84	52	120	78	42	140 H	112.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	11.8	L	.	.	12 - 15.6	G/DL
				Hematocrit	35.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	62	.	.	.	40 - 75	%
				Lymphocytes	27.9	.	.	.	16 - 46	%
				Monocytes	7.2	.	.	.	0 - 12	%
				Eosinophils	2.2	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	406000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	25.6	L	.	.	27 - 33	PG
				Mean Corpuscle Volume	77	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00056 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	08SEP94	1	14SEP94	7	7
00057	Oral	2	100 MG	15SEP94	8	21SEP94	14	7
00057	Oral	3	150 MG	22SEP94	15	28SEP94	21	7
00057	Oral	4	200 MG	29SEP94	22	05OCT94	28	7
00057	Oral	5	250 MG	06OCT94	29	12OCT94	35	7
00057	Oral	6	300 MG	13OCT94	36	19OCT94	42	7
00057	Oral	6	300 MG	20OCT94	43	26OCT94	49	7
00057	Oral	6	300 MG	27OCT94	50	03NOV94	57	8
00067	Oral	6	300 MG	04NOV94	58	30NOV94	84	27
00067	Oral	6	300 MG	01DEC94	85	29DEC94	113	29
00057	Oral	5	250 MG	30DEC94	114	31DEC94	115	2
00057	Oral	4	200 MG	01JAN95	116	02JAN95	117	2
00057	Oral	3	150 MG	03JAN95	118	04JAN95	119	2
00057	Oral	2	100 MG	05JAN95	120	07JAN95	122	3
00057	Oral	1	50 MG	08JAN95	123	14JAN95	129	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	129	50	Adverse event, including intercurrent illness	PT. BECAME PREGNANT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEARTBURN	HEARTBURN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SCHEUERMANN'S KYPHOSIS	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
STOMACH PROBLEMS	STOMACH/DUODENUM DISORD	DIGESTIVE SYST	CUR	1994
CHILDHOOD MIGRAINES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	PRV	1984
CONCUSSION	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1985
HERNIA OPERATION	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1985
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1983
TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1983

CUR = Current, PRV = Past

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PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Bayer Aspirin	83, 26	29NOV94	29NOV94	1500MG	HEADACHE
	Cannabis	Cannabis	., .		.	UNKNOWN	
			53, -5	30OCT94	30OCT94	UNKNOWN	
	Paracetamol	Acetaminophen	-38, -95	01AUG94	.	650MG PRN	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Motrin	22, -36	29SEP94	29SEP94	800MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Vomiting	NAUSEA, VOMITING	29, -29	20 Mins	250	CON	MIL	NO	UNR	No	No
Nervous System	Hyperkinesia	SENSATION OF RESTLESSNESS IN LEGS NO OBSERVABLE TREMORS	20, -38	45 Mins	150	CON	MIL	NO	PBU	No	No
Urogenital System	Unintended Pregnancy	PREGNANCY NAUSEA VOMITING	94, 37	Not Stated	300	CON	MOD	STP	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11AUG94	-28, -85	0	98	62	72	88	60	88	162.50	66.5
BL	08SEP94	1, -57	0	99	62	73	92	61	89	163.00	
1	15SEP94	8, -50	100	90	60	88	84	60	84	160.50	
2	22SEP94	15, -43	150	102	70	102	94	60	140 H	158.00	
3	29SEP94	22, -36	200	90	60	100	94	60	100	158.00	
4	06OCT94	29, -29	250	112	68	96	110	66	100	157.00	
5	13OCT94	36, -22	300	104	60	100	88	50	102	159.50	
6	20OCT94	43, -15	300	100	62	100	98	60	104	159.00	
7	27OCT94	50, -8	300	102	64	100	94	62	102	160.00	
8	03NOV94	57, -1	300	90	60	120	80	58	140 H	160.00	
12	01DEC94	85, 28	300	110	60	100	90	60	128 H	163.00	
16	29DEC94	113, 56	300	104	64	100	102	60	120	157.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-28	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	28.8	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	321000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-28	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-21	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEC	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		1010.ZZ2	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	1010.ZZ2	-14	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEC	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	48	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		

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PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 8/ACUTE PHASE-WEEK 6	48	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	23.6	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	347000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	100	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	85	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEC	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	113	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 12/CONTINUATION-WEEK 16	113	Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	29.2	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	375000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	75	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00057 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 12/CONTINUATION-WEEK 16	113	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	20SEP94	1	28SEP94	9	9
00058	Oral	2	20 MG	29SEP94	10	06OCT94	17	8
00058	Oral	3	20 MG	07OCT94	18	12OCT94	23	6
00058	Oral	4	20 MG	13OCT94	24	19OCT94	30	7
00058	Oral	5	30 MG	20OCT94	31	26OCT94	37	7
00058	Oral	6	40 MG	27OCT94	38	02NOV94	44	7
00058	Oral	6	40 MG	03NOV94	45	09NOV94	51	7
00058	Oral	6	40 MG	10NOV94	52	16NOV94	58	7
00070	Oral	6	40 MG	17NOV94	59	14DEC94	86	28
00070	Oral	6	40 MG	15DEC94	87	12JAN95	115	29
00070	Oral	6	40 MG	13JAN95	116	16JAN95	119	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	119	40	Adverse event, including intercurrent illness	INTENTIONAL OVERDOSE OF TYLENOL ON 1/19/95.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
ATTENTION DEFICIT DISORDER	MENTAL STATUS, IMPAIRED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1983

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	60, 2	18NOV94	28NOV94	500MG	STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	122, 64	19JAN95	19JAN95	26,650MG	INTENTIONAL OVERDOSE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	REPORT OF SORE THROAT.POSITIVE CULTURE,THROAT.BETA HEMOLYTIC STREP,GROUP A.	58, -1	3 Days	40	CON	MIL	NO	UNR	Yes	No
Nervous System	Emotional Lability	INTENTIONAL OVERDOSE {TYLENOL OVERDOSE TOOK 80 PILLS}	122, 64	1 Days	40	CON	MOD	STP	PBU	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08SEP94	-12, -70	0	102	70	88	104	70	92	203.50	62.6
BL	20SEP94	1, -58	0	102	70	88	104	70	92	203.50	
1	29SEP94	10, -49	20	100	74	88	94	66	94	198.50	
2	07OCT94	18, -41	20	110	80	100	102	60	84	195.50	
3	13OCT94	24, -35	20	102	84	88	100	82	80	196.00	
4	20OCT94	31, -28	30	100	60	72	98	54	84	197.00	
5	27OCT94	38, -21	40	104	86	88	100	84	80	199.00	
6	03NOV94	45, -14	40	102	80	84	100	78	86	195.00	
7	10NOV94	52, -7	40	100	60	92	102	78	102	194.50	
8	17NOV94	59, 1	40	110	80	80	112	82	100	194.50	
12	15DEC94	87, 29	40	100	70	84	100	70	88	194.00	
16	13JAN95	116, 58	40	120	72	80	122	74	82	190.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	25.7	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	197000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	4	.	.	.	4 - 12	%
				Segmented Neutrophils	85	H	.	.	30 - 70	%
				Lymphocytes	5	L	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	183000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59		Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
					Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	86	.	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	5	.	.	+		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	130	(11)	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
					Hematocrit	40.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	62.4	.	.	.	30 - 70	%
					Lymphocytes	26.4	.	.	.	21 - 51	%
					Monocytes	8.4	.	.	.	0 - 10	%
					Eosinophils	2.2	.	.	.	0 - 5	%
					Basophils	0.6	.	.	.	0 - 2	%
					Platelets	193000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00058 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	130 (11)	Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	10NOV94	1	16NOV94	7	7
00059	Oral	2	0 MG	17NOV94	8	22NOV94	13	6
00059	Oral	3	0 MG	23NOV94	14	30NOV94	21	8
00059	Oral	4	0 MG	01DEC94	22	07DEC94	28	7
00059	Oral	5	0 MG	08DEC94	29	14DEC94	35	7
00059	Oral	6	0 MG	15DEC94	36	21DEC94	42	7
00059	Oral	6	0 MG	22DEC94	43	28DEC94	49	7
00059	Oral	6	0 MG	29DEC94	50	05JAN95	57	8
	Oral	6	0 MG	06JAN95	58	21JAN95	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	73	0	Lack of Efficacy	NON-RESPONSE TO TREATMENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HISTORY OF MITRAL VALVE PROLAPSE-NO FUNCTIONAL IMPAIRMENT	MITRAL VALVE DISORD	CIRCULATORY SYST	CUR	1987

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	03NOV94	-7, .	0	90	60	72	100	70	88	124.00	71.0
BL	10NOV94	1, .	0	102	64	80	94	60	88	123.50	
1	17NOV94	8, .	0	100	72	88	98	68	112	125.00	
2	23NOV94	14, .	0	102	60	72	90	60	96	126.00	
3	01DEC94	22, .	0	90	60	80	110	60	100	126.00	
4	08DEC94	29, .	0	92	52	80	98	60	96	124.00	
5	15DEC94	36, .	0	100	68	86	98	60	92	125.00	
6	22DEC94	43, .	0	106	66	88	108	70	80	126.00	
7	29DEC94	50, .	0	90	60	84	102	78	92	125.00	
8	05JAN95	57, .	0	104	60	88	100	60	92	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.7	.	.	.	30 - 70	%
				Lymphocytes	40.9	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	121	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	16.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	50.1	H	.	.	41 - 50	%
				Red Blood Cell Count	5.8	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.7	.	.	.	30 - 70	%
				Lymphocytes	32.7	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	112	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00059 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	31JAN95	1	06FEB95	7	7
00060	Oral	2	0 MG	07FEB95	8	13FEB95	14	7
00060	Oral	3	0 MG	14FEB95	15	20FEB95	21	7
00060	Oral	4	0 MG	21FEB95	22	27FEB95	28	7
00060	Oral	5	0 MG	28FEB95	29	06MAR95	35	7
00060	Oral	6	0 MG	07MAR95	36	13MAR95	42	7
00060	Oral	6	0 MG	14MAR95	43	20MAR95	49	7
00060	Oral	6	0 MG	21MAR95	50	27MAR95	56	7
00065	Oral	6	0 MG	28MAR95	57	25APR95	85	29

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	85	0	Lack of Efficacy	PT.FELT MEDICATION WASN'T WORKING

* Relative to Start of Study Medication

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	31JAN95	1, -56	0	108	74	88	112	76	88	117.00	64.0
1	07FEB95	8, -49	0	92	50	88	92	54	84	120.00	
2	14FEB95	15, -42	0	90	60	80	90	62	80	119.00	
3	21FEB95	22, -35	0	90	68	80	90	68	80	117.50	
4	28FEB95	29, -28	0	96	64	84	92	64	84	118.00	
5	07MAR95	36, -21	0	88	56	80	70 L	58	84	117.70	
6	14MAR95	43, -14	0	110	64	84	106	64	82	120.00	
7	21MAR95	50, -7	0	110	70	100	102	70	100	120.50	
8	28MAR95	57, 1	0	104	64	74	94	60	74	120.20	
12	25APR95	85, 29	0	100	62	90	100	60	90	117.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	32.7	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	141	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	127	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00060 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03JAN95	1	09JAN95	7	7
00097	Oral	2	0 MG	10JAN95	8	17JAN95	15	8
00097	Oral	3	0 MG	18JAN95	16	24JAN95	22	7
00097	Oral	4	0 MG	25JAN95	23	31JAN95	29	7
00097	Oral	5	0 MG	01FEB95	30	06FEB95	35	6
00097	Oral	6	0 MG	07FEB95	36	13FEB95	42	7
00097	Oral	6	0 MG	14FEB95	43	20FEB95	49	7
00097	Oral	6	0 MG	21FEB95	50	01MAR95	58	9
00026	Oral	6	0 MG	02MAR95	59	29MAR95	86	28
00026	Oral	6	0 MG	30MAR95	87	26APR95	114	28
00026	Oral	6	0 MG	27APR95	115	22MAY95	140	26
00026	Oral	6	0 MG	23MAY95	141	28JUN95	177	37
00026	Oral	6	0 MG	29JUN95	178	01AUG95	211	34
00026	Oral	6	0 MG	02AUG95	212	04SEP95	245	34
00097	Oral	5	0 MG	05SEP95	246	06SEP95	247	2
00097	Oral	4	0 MG	07SEP95	248	08SEP95	249	2
00097	Oral	3	0 MG	09SEP95	250	10SEP95	251	2
00097	Oral	2	0 MG	11SEP95	252	13SEP95	254	3
00097	Oral	1	0 MG	14SEP95	255	20SEP95	261	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	261	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES,DAILY 2-3 TIMES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
UPPER RESPIRATORY INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-15, -73	19DEC94	26DEC94#	200MG PRN	UPPER RESPIRATORY INFECTION
			14, -45	16JAN95	17JAN95	325MG	FLU SYMPTOMS
			29, -30	31JAN95	07FEB95	650MG	HEADACHE
			87, 29	30MAR95	.	650PRN	HEADACHES
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-15, -73	19DEC94	26DEC94#	25MG PRN	UPPER RESPIRATORY INFECTION
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-15, -73	19DEC94	26DEC94#	25MG PRN	UPPER RESPIRATORY INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	80, 22	20 Mins	0	3	MIL	NO	PSR	No	No
	Infection	FLU SYMPTOMS	14, -45	3 Days	0	CON	MIL	NO	UNR	Yes	No
Carciovascular System	Vasodilatation	HOT FLASHES	23, -36	5 Mins	0	4	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS (WHEN STANDS QUICKLY)	80, 22	1 Mins	0	3	MIL	NO	PSR	No	No
Skin and Appendages	Sweating	SWEATY HANDS	15, -44	127 Days	0		MIL	NO	PBU	No	No
Special Senses	Abnormal Vision	BLURRING VISION	16, -43	126 Days	0	99	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20DEC94	-14, -72	0	104	64	83	100	64	89	122.00	60.0
1	10JAN95	8, -51	0	110	65	80	108	55	88	123.00	
2	18JAN95	16, -43	0	100	64	100	106	68	106	123.00	
3	24JAN95	22, -37	0	102	62	84	106	64	86	121.30	
4	31JAN95	29, -30	0	104	60	84	100	60	90	122.75	
5	07FEB95	36, -23	0	118	72	64	116	70	66	124.50	
6	14FEB95	43, -16	0	118	80	72	115	78	84	123.50	
7	21FEB95	50, -9	0	118	80	72	114	77	83	122.00	
8	02MAR95	59, 1	0	104	70	70	100	70	70	124.00	
12	30MAR95	87, 29	0	114	72	80	112	70	72	124.75	
16	27APR95	115, 57	0	104	66	67	106	66	76	126.50	
20	23MAY95	141, 83	0	114	70	78	114	70	98	126.25	
24	29JUN95	178, 120	0	110	68	76	106	64	78	128.00	
28	01AUG95	211, 153	0	110	70	90	108	66	96	133.00 H	
32	05SEP95	246, 188	0	100	68	74	92	66	70	131.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.7	.	.	.	30 - 70	%
				Lymphocytes	32.9	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	277000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	11.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5	.	.	.	30 - 70	%
				Lymphocytes	33.6	.	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	1.8	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	178	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.7	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	304000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 14/CONTINUATION-WEEK 24	178	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	109	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	246	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	34.6	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	250000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00097 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	246	Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	107	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	03JAN95	1	09JAN95	7	7
00098	Oral	2	100 MG	10JAN95	8	17JAN95	15	8
00098	Oral	3	150 MG	18JAN95	16	23JAN95	21	6
00098	Oral	4	200 MG	24JAN95	22	30JAN95	28	7
00098	Oral	5	250 MG	31JAN95	29	06FEB95	35	7
00098	Oral	6	300 MG	07FEB95	36	13FEB95	42	7
00098	Oral	5	250 MG	14FEB95	43	20FEB95	49	7
00098	Oral	5	250 MG	21FEB95	50	22FEB95	51	2
00098	Oral	4	200 MG	23FEB95	52	01MAR95	58	7
	Oral	5	250 MG	02MAR95	59	16MAR95	73	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	73	250	Lack of Efficacy	NOT RESPONDING TO TREATMENT AND DISCOMFORT DUE TO POSSIBLE SIDE EFFECTS.

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	50, .	9 Days	250	CON	MOD	DCR	PSR	No	No
Digestive System	Constipation	CONSTIPATION	59, .	Not Stated	250	CON	MIL	DCR	PSR	No	No
	Dry Mouth	DRY MOUTH	8, .	Not Stated	100	CON	MOD	DCR	PSR	No	No
Nervous System	Tremor	SHAKING	43, .	Not Stated	250	CON	MOD	DCR	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20DEC94	-14, .	0	98	58	88	96	58	92	127.50	61.0
BL	03JAN95	1, .	0	98	58	88	96	58	92	127.50	
1	10JAN95	8, .	100	100	58	84	95	60	104	127.00	
2	18JAN95	16, .	150	118	68	84	110	68	88	126.00	
3	24JAN95	22, .	200	108	66	84	100	64	86	126.00	
4	31JAN95	29, .	250	110	72	100	106	72	104	127.50	
5	07FEB95	36, .	300	116	78	74	106	74	80	128.00	
6	14FEB95	43, .	250	118	78	108	116	78	112	127.00	
7	21FEB95	50, .	250	118	70	70	120	72	76	127.00	
8	02MAR95	59, .	250	102	64	100	102	68	100	127.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	27.9	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.2	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00098 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	02MAR95	1	06MAR95	5	5
00099	Oral	2	20 MG	07MAR95	6	13MAR95	12	7
00099	Oral	3	20 MG	14MAR95	13	20MAR95	19	7
00099	Oral	4	20 MG	21MAR95	20	27MAR95	26	7
00099	Oral	4	20 MG	28MAR95	27	03APR95	33	7
00099	Oral	5	30 MG	04APR95	34	11APR95	41	8
00099	Oral	6	40 MG	12APR95	42	18APR95	48	7
00099	Oral	6	40 MG	19APR95	49	25APR95	55	7
00025	Oral	6	40 MG	26APR95	56	22MAY95	82	27
00025	Oral	6	40 MG	23MAY95	83	26JUN95	117	35
00025	Oral	6	40 MG	27JUN95	118	31JUL95	152	35
00025	Oral	6	40 MG	01AUG95	153	30AUG95	182	30
00025	Oral	6	40 MG	31AUG95	183	27SEP95	210	28
00025	Oral	6	40 MG	28SEP95	211	26OCT95	239	29
00099	Oral	5	30 MG	27OCT95	240	28OCT95	241	2
00099	Oral	4	20 MG	29OCT95	242	30OCT95	243	2
00099	Oral	3	20 MG	31OCT95	244	01NOV95	245	2
00099	Oral	2	20 MG	02NOV95	246	04NOV95	248	3
00099	Oral	1	20 MG	05NOV95	249	11NOV95	255	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	Yes	255	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	33, -23	03APR95	03APR95	325MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	34, -22	04APR95	11APR95	100 MG	SEASONAL ALLERGIES
RESPIRATORY	Aminoacetic Acid	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
	Benzalkonium Chloride	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
	Dextromethorphan Hydrobromide	Nyquil	18, -38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
	Diphenhydramine Hydrochloride	Benadryl	34, -22	04APR95	11APR95	100 MG	SEASONAL ALLERGIES
	Doxylamine Succinate	Nyquil	18, -38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
	Oxymetazoline Hydrochloride	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
	Paracetamol	Nyquil	18, -38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
	Phenylmercuric Acetate	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD
	Pseudoephedrine Hydrochloride	Nyquil	18, -38	19MAR95	21MAR95	2PILLS/DAY	HEAD COLD
		Sudafed	28, -28	29MAR95	29MAR95	60MG	STUFFY NOSE
	Sorbitol	Afrin Spray	15, -41	16MAR95	21MAR95	ONE SPRAY EACH NOSTRIL	HEAD COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	33, -23	02:00 Hrs	20	CON	MIL	NO	PSR	Yes	No
Cardiovascular System	Palpitation	HEART PALPITATIONS	121, 66	63 Days	40	3	MOD	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	48, -8	7 Days	40	21	MIL	NO	PSR	No	No
		NAUSEA (FOR 10 MINUTES DAILY BEFORE BREAKFAST)	121, 66	63 Days	40	25	MIL	NO	PSR	No	No
		NAUSEATED	3, -53	11 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Amnesia	"FORGETFUL"	121, 66	63 Days	40	3	MIL	NO	PBU	No	No
	Dizziness	CONSTANT DIZZINESS (DAILY)	119, 64	93 Days	40	CON	MOD	NO	PSR	No	No
		DIZZINESS ARISING FROM LAYING SITTING OR SOMETIMES WHEN SITTING	27, -29	28 Days	20	78	MOD	NO	PSR	No	No
		DIZZINESS WHEN ARISING SUDDENLY	13, -43	11 Days	20	33	MOD	NO	PSR	No	No
		DIZZY	3, -53	30 Mins	20	CON	MIL	NO	PSR	No	No
	Insomnia	INITIAL INSOMNIA (INCREASE 2 HOURS)	84, 29	02:00 Hrs	40	39	SEV	NO	PBU	No	No
		INITIAL INSOMNIA MOST NIGHTS INCREASE 2 HOURS	104, 49	33 Days	40	10	MOD	NO	PSR	No	No
		RESTLESS AT NIGHT	4, -52	10 Days	20	2	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	HEAD COLD	15, -41	6 Days	20	CON	MIL	NO	UNR	Yes	No
	Rhinitis	STUFFY NOSE	28, -28	16:00 Hrs	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23FEB95	-7, -62	0	110	68	70	108	68	80	192.25	67.0
1	07MAR95	6, -50	20	122	70	70	118	70	90	190.50	
2	14MAR95	13, -43	20	102	64	64	106	64	60	189.00	
3	21MAR95	20, -36	20	110	70	80	106	70	80	189.25	
4	28MAR95	27, -29	20	110	70	64	108	70	64	189.50	
5	04APR95	34, -22	30	94	66	76	90	68	80	190.00	
6	11APR95	41, -15	30	108	70	66	104	70	64	188.50	
7	18APR95	48, -8	40	90	60	90	90	60	95	188.25	
8	25APR95	55, -1	40	98	60	80	92	60	80	188.75	
12	23MAY95	83, 28	40	96	60	88	96	60	82	192.00	
16	27JUN95	118, 63	40	108	60	100	102	56	100	196.00	
20	01AUG95	153, 98	40	102	68	87	104	70	80	200.00	
24	31AUG95	183, 128	40	90	58	68	94	62	92	203.00	
28	28SEP95	211, 156	40	112	70	66	110	72	68	208.00 H	
32	26OCT95	239, 184	40	108	70	79	110	72	78	207.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.8	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	30.5	.	.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	80	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1.4	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1	.	.	.	30 - 70	%
				Lymphocytes	33.9	.	.	.	21 - 51	%
				Monocytes	9.9	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	16	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6	.	.	.	30 - 70	%
				Lymphocytes	32.1	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	153	Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	239	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	1	L	.	.	4 - 12	%
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	22	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00099 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 16/CONTINUATION-WEEK 32	239	Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	07MAR95	1	13MAR95	7	7
00100	Oral	2	100 MG	14MAR95	8	20MAR95	14	7
00100	Oral	3	150 MG	21MAR95	15	27MAR95	21	7
00100	Oral	4	200 MG	28MAR95	22	03APR95	28	7
00100	Oral	4	200 MG	04APR95	29	10APR95	35	7
00100	Oral	5	250 MG	11APR95	36	17APR95	42	7
00100	Oral	5	250 MG	18APR95	43	24APR95	49	7
00100	Oral	5	250 MG	25APR95	50	03MAY95	58	9
00069	Oral	5	250 MG	04MAY95	59	29MAY95	84	26
00069	Oral	5	250 MG	30MAY95	85	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	85	250	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DEPRESSION	DEPRESSION	MENTAL DISORD	CUR	1995
HAND TREMOR	TREMOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
SWEATING AT BROW	HYPERHIDROSIS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

CUR = Current, PRV = Past

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PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-34, -92	01FEB95	01MAR95#	PRN 650MG	HEADACHE
			41, -18	16APR95	30MAY95	325MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	-34, -92	01FEB95	01MAR95#	400MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	39, -20	10 Mins	250	12	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS"OFF AND ON"	39, -20	15 Mins	250	15	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	07MAR95	1, -58	0	130	70	96	132	70	98	144.00	
1	14MAR95	8, -51	100	116	70	78	112	70	90	145.00	
2	21MAR95	15, -44	150	120	80	90	118	80	96	148.00	
3	28MAR95	22, -37	200	120	80	80	114	80	80	146.25	
4	04APR95	29, -30	200	116	78	110	120	78	112	147.25	
5	11APR95	36, -23	250	110	80	84	114	80	86	145.25	
6	18APR95	43, -16	250	118	80	100	112	80	114	147.75	
7	25APR95	50, -9	250	110	62	98	108	62	100	147.50	
8	04MAY95	59, 1	250	108	78	90	100	76	98	148.75	
12	30MAY95	85, 27	250	126	80	100	108	80	112	146.50	
16	27JUN95	113, 55#	0	112	80	100	118	80	116	145.25	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.5	.	.	.	30 - 70	%
				Lymphocytes	23.3	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	156000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	115	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	16.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.1	.	.	.	30 - 70	%
				Lymphocytes	23.9	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	175000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00100 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28MAR95	1	03APR95	7	7
00101	Oral	2	0 MG	04APR95	8	12APR95	16	9
00101	Oral	3	0 MG	13APR95	17	19APR95	23	7
00101	Oral	4	0 MG	20APR95	24	26APR95	30	7
00101	Oral	5	0 MG	27APR95	31	03MAY95	37	7
00101	Oral	6	0 MG	04MAY95	38	10MAY95	44	7
00101	Oral	6	0 MG	11MAY95	45	17MAY95	51	7
00101	Oral	6	0 MG	18MAY95	52	24MAY95	58	7
00066	Oral	6	0 MG	25MAY95	59	21JUN95	86	28
	Oral	6	0 MG	22JUN95	87	26JUN95	91	5
00101	Oral	5	0 MG	27JUN95	92	27JUN95	92	1
00101	Oral	4	0 MG	28JUN95	93	29JUN95	94	2
00101	Oral	3	0 MG	30JUN95	95	01JUL95	96	2
00101	Oral	2	0 MG	02JUL95	97	04JUL95	99	3
00101	Oral	1	0 MG	05JUL95	100	11JUL95	106	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	106	0	Protocol violation, including non-compliance	MARIJUANA USE WITH POSITIVE URINE SCREEN, SEE LAB PG. ON WEEK 12 AND SEE A.E. PG. 408.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HISTORY OF APNEA AND RESUSCITATION IN FIRST YEAR OF LIFE(SIDS)	SUDDEN INFANT DEATH SYNDROME	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1979

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Drug Dependence	POSITIVE MARIJUANA URINE SCREEN (PROTOCOL DEVIATION)	87, 29	1 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	20MAR95	-8, -66	0	.	.	.	.	.	.		68.0
BL	28MAR95	1, -58	0	116	78	84	114	78	80	147.00	
1	04APR95	8, -51	0	124	76	100	122	72	88	149.00	
2	13APR95	17, -42	0	122	78	84	124	80	96	147.00	
3	20APR95	24, -35	0	122	70	68	120	72	66	150.20	
4	27APR95	31, -28	0	110	80	64	102	80	68	150.50	
5	04MAY95	38, -21	0	122	70	86	110	70	100	152.70	
6	11MAY95	45, -14	0	122	68	60	118	66	88	149.00	
7	18MAY95	52, -7	0	102	64	60	100	60	68	150.00	
8	25MAY95	59, 1	0	98	72	64	90	68	61	150.00	
12	22JUN95	87, 29	0	108	60	88	102	60	88	145.20	
12	27JUN95	92, 34	0	108	66	88	102	60	88	145.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.4	.	.	.	30 - 70	%
				Lymphocytes	44.7	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	258000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	108	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	31	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.9	.	.	.	30 - 70	%
				Lymphocytes	41.3	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Basophils	0.5	.	.	.	0 - 2	%
				Platelets	203000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	96	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	87	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	92	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H	.	.	30 - 70	%
				Lymphocytes	15.5	L	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00101 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 12/CONTINUATION-WEEK 16	92	Alkaline Phosphatase	91	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	13APR95	1	17APR95	5	5
00102	Oral	2	20 MG	18APR95	6	24APR95	12	7
00102	Oral	3	20 MG	25APR95	13	01MAY95	19	7
00102	Oral	4	20 MG	02MAY95	20	08MAY95	26	7
00102	Oral	5	30 MG	09MAY95	27	15MAY95	33	7
00102	Oral	6	40 MG	16MAY95	34	22MAY95	40	7
00102	Oral	6	40 MG	23MAY95	41	29MAY95	47	7
00102	Oral	6	40 MG	30MAY95	48	05JUN95	54	7
00071	Oral	6	40 MG	06JUN95	55	12JUL95	91	37
00071	Oral	6	40 MG	13JUL95	92	09AUG95	119	28
00071	Oral	6	40 MG	10AUG95	120	11SEP95	152	33
00071	Oral	6	40 MG	12SEP95	153	09OCT95	180	28
00071	Oral	6	40 MG	10OCT95	181	08NOV95	210	30
00071	Oral	6	40 MG	09NOV95	211	04DEC95	236	26
00102	Oral	5	30 MG	05DEC95	237	06DEC95	238	2
00102	Oral	4	20 MG	07DEC95	239	08DEC95	240	2
00102	Oral	3	20 MG	09DEC95	241	12DEC95	244	4
00102	Oral	2	20 MG	13DEC95	245	16DEC95	248	4
00102	Oral	1	20 MG	17DEC95	249	20DEC95	252	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	252	20		

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES	146, 92	36 Days	40	1	MOD	NO	REL	No	No
	Trauma	MOTOR VEHICLE ACCIDENT	112, 58	1 Days	40	1	MIL	NO	UNR	No	No
Digestive System	Dyspepsia	HEARTBURN ON AN EMPTY STOMACH WHEN TAKING MEDS.	27, -28	7 Days	30	7	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	146, 92	36 Days	40	1	MOD	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	13APR95	1, -54	0	88	70	80	92	70	84	102.50	60.0
1	18APR95	6, -49	20	90	50	92	98	58	95	100.50	
2	25APR95	13, -42	20	88	60	62	92	60	70	101.00	
3	02MAY95	20, -35	20	102	70	88	98	68	86	100.00	
4	09MAY95	27, -28	30	98	60	88	92	60	84	103.50	
5	16MAY95	34, -21	40	94	60	92	98	60	80	102.50	
6	23MAY95	41, -14	40	92	60	110	96	60	120	101.70	
7	30MAY95	48, -7	40	90	58	86	88	56	90	103.00	
8	06JUN95	55, 1	40	90	60	100	92	60	90	104.20	
12	13JUL95	92, 38	40	110	60	86	106	64	100	103.50	
16	10AUG95	120, 66	40	90	64	84	84	60	88	104.00	
20	12SEP95	153, 99	40	84	60	80	86	62	74	105.50	
24	10OCT95	181, 127	40	80	64	80	84	64	80	107.50	
28	09NOV95	211, 157	40	92	60	100	88	60	92	109.50	
32	05DEC95	237, 183	30	84	62	80	80	60	86	108.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	389000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37.9	.	.	.	30 - 70	%
				Lymphocytes	44.1	.	.	.	21 - 51	%
				Monocytes	10.7	H	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	323000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.3	.	.	.	30 - 70	%
				Lymphocytes	31.7	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	7.1	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	380000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	153	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	237	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5	.	.	.	30 - 70	%
				Lymphocytes	32.9	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	361000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00102 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	237	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	20APR95	1	26APR95	7	7
00103	Oral	2	100 MG	27APR95	8	01MAY95	12	5
00103	Oral	3	150 MG	02MAY95	13	08MAY95	19	7
00103	Oral	4	200 MG	09MAY95	20	15MAY95	26	7
00103	Oral	4	200 MG	16MAY95	27	24MAY95	35	9
00103	Oral	4	200 MG	25MAY95	36	29MAY95	40	5
00103	Oral	5	250 MG	30MAY95	41	05JUN95	47	7
00103	Oral	5	250 MG	06JUN95	48	14JUN95	56	9
00072	Oral	5	250 MG	15JUN95	57	12JUL95	84	28
00072	Oral	5	250 MG	13JUL95	85	09AUG95	112	28
00103	Oral	5	250 MG	10AUG95	113	11AUG95	114	2
00103	Oral	4	200 MG	12AUG95	115	13AUG95	116	2
00103	Oral	3	150 MG	14AUG95	117	15AUG95	118	2
00103	Oral	2	100 MG	16AUG95	119	18AUG95	121	3
00103	Oral	1	50 MG	19AUG95	122	25AUG95	128	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	128	50	Lack of Efficacy	RELAPSE OF DEPRESSED SYMPTOMS AND SUICIDAL IDEATION.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES(DAILY)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	4, -53	23APR95	23APR95	200MG	HEADACHE
			7, -50	26APR95	26APR95	200MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
		STOMACH ACHE FOLLOWING INGESTION OF MEDS	2, -55	21 Days	50	14	MIL	NO	PSR	No	No
		STOMACH ACHE FOLLOWING INGESTION OF STUDY MEDS	62, 6	52 Days	250	2	MIL	NO	PSR	No	No
	Chills	CHILLS / GOOSE BUMPS WHILE EXERCISING (1X)	19, -38	2 Mins	150	CON	MIL	NO	PSR	No	No
		FEELING HOT/COLD	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	34, -23	8 Days	200	CON	MOD	NO	PSR	No	No
		DIZZINESS (WHEN GOING FROM SIT TO STAND)	113, 57	16 Days	250		MIL	NO	PSR	No	No
Skin and Appendages	Rash	RED SPOTS / BLOTCHES ON SKIN ARMS, THROAT, CHEST	22, -35	35 Days	200		MIL	NO	PSR	No	No
Special Senses	Abnormal Vision	BLURRED VISION WHEN STANDS QUICKLY	50, -7	36 Days	250	10	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11APR95	-9, -65	0	110	64	65	110	64	66	116.50	60.0
BL	20APR95	1, -56	0	94	62	68	90	62	68	115.00	
1	27APR95	8, -49	100	92	62	70	90	60	68	114.00	
2	02MAY95	13, -44	150	100	70	70	100	70	72	117.25	
3	09MAY95	20, -37	200	102	70	100	102	70	92	114.25	
4	16MAY95	27, -30	200	112	80	80	112	76	80	116.50	
5	25MAY95	36, -21	200	98	68	60	90	64	74	115.00	
6	30MAY95	41, -16	250	102	70	80	98	70	100	115.00	
7	06JUN95	48, -9	250	100	66	88	96	60	84	111.25	
8	15JUN95	57, 1	250	94	68	72	80	64	70	110.50	
12	13JUL95	85, 29	250	102	70	88	96	68	80	112.00	
16	10AUG95	113, 57	250	100	68	90	100	64	84	114.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.6	.	.	.	30 - 70	%
				Lymphocytes	22.2	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	319000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	82	H	.	.	30 - 70	%
				Lymphocytes	15	L	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	331000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00103 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	04MAY95	1	10MAY95	7	7
00104	Oral	2	100 MG	11MAY95	8	17MAY95	14	7
00104	Oral	3	150 MG	18MAY95	15	24MAY95	21	7
00104	Oral	4	200 MG	25MAY95	22	31MAY95	28	7
00104	Oral	5	250 MG	01JUN95	29	08JUN95	36	8
00104	Oral	6	300 MG	09JUN95	37	15JUN95	43	7
00104	Oral	6	300 MG	16JUN95	44	21JUN95	49	6
00104	Oral	6	300 MG	22JUN95	50	28JUN95	56	7
00027	Oral	6	300 MG	29JUN95	57	24JUL95	82	26
00027	Oral	6	300 MG	25JUL95	83	28AUG95	117	35
00027	Oral	6	300 MG	29AUG95	118	02OCT95	152	35
00027	Oral	6	300 MG	03OCT95	153	05NOV95	186	34
00027	Oral	6	300 MG	06NOV95	187	05DEC95	216	30
00027	Oral	6	300 MG	06DEC95	217	01JAN96	243	27
00104	Oral	5	250 MG	02JAN96	244	03JAN96	245	2
00104	Oral	4	200 MG	04JAN96	246	05JAN96	247	2
00104	Oral	3	150 MG	06JAN96	248	07JAN96	249	2
00104	Oral	2	100 MG	08JAN96	250	10JAN96	252	3
00104	Oral	1	50 MG	11JAN96	253	17JAN96	259	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	Yes	259	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	232, 176	21DEC95	31DEC95	1500 MG	STREP THROAT
	Minocycline	Monocycline	-123, -179	01JAN95	.	150 MGS	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT	232, 176	11 Days	300	1	MOD	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	8, -49	76 Days	100	CON	MOD	NO	REL	No	No
	Vomiting	NAUSEA AND VOMITING DURING DOWN TITRATION	252, 196	6 Days	100	1	MOD	NO	PSR	No	No
		VOMITING WHEN FORGOT DOSE	83, 27	1 Days	300	1	MOD	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	21, -36	133 Days	150	CON	MIL	NO	REL	No	No
Urogenital System	Urination Impaired	DIFFICULTY INITIATING URINATION	1, -56	8 Days	50	2	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	28APR95	-6, -62	0	100	60	94	98	58	90	128.50	67.0
1	11MAY95	8, -49	100	120	68	80	118	66	84	127.70	
2	18MAY95	15, -42	150	106	74	76	100	70	80	130.50	
3	25MAY95	22, -35	200	110	76	81	100	70	74	130.00	
4	01JUN95	29, -28	250	122	80	92	120	72	100	126.00	
5	09JUN95	37, -20	300	90	60	88	102	64	80	128.00	
6	16JUN95	44, -13	300	90	66	80	82	64	74	129.00	
7	22JUN95	50, -7	300	88	60	90	80	60	100	128.20	
8	29JUN95	57, 1	300	122	76	100	100	70	68	130.00	
12	25JUL95	83, 27	300	110	70	109	90	64	94	130.00	
16	29AUG95	118, 62	300	102	76	90	96	60	130 H	128.00	
20	03OCT95	153, 97	300	94	68	84	80	68	78	131.00	
28	06NOV95	187, 131	300	108	70	106	112	72	80	129.50	
32	06DEC95	217, 161	300	120	72	100	110	74	84	130.50	
32	02JAN96	244, 188	250	110	60	100	108	60	92	127.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	29.4	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	329000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	401	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.6	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	348	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	153	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.5	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	334000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	272	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	153	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	244	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	15.1	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	82.2	H	.	.	30 - 70	%
				Lymphocytes	10.8	L	.	.	21 - 51	%
				Monocytes	3.6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	476000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	24	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00104 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 16/CONTINUATION-WEEK 32	244	Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	WHITE/HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	27JUL95	1	02AUG95	7	7
00105	Oral	2	20 MG	03AUG95	8	09AUG95	14	7
00105	Oral	3	20 MG	10AUG95	15	16AUG95	21	7
00105	Oral	4	20 MG	17AUG95	22	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	No	No	22	20	Protocol violation, including non-compliance	PATIENT RAN AWAY FROM HOME WITHOUT MEDS. WAS OFF MEDS SEVERAL DAYS BEFORE HE RETURNED HOME. UNABLE TO REACH FAMILY TO RETRIEVE MED PAK/DO WK. 32 VISIT. SEE PROGRESS NOTE FROM WEEK 4

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES{CATS,POLLEN}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1990
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
HEARTBURN	HEARTBURN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	16, .	11AUG95	24AUG95	650 MG	HEADACHE
	Paracetamol	Tylenol	1, .	27JUL95	03AUG95	1950 MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-329, .	01SEP94	.	2 TBSP PRN	ALLERGIES
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-329, .	01SEP94	.	2 TBSP PRN	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Diarrhea	DIARRHEA	8, .	8 Days	20	4	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	27JUL95	1, .	0	110	78	62	112	80	84	162.00	69.3
1	03AUG95	8, .	20	132	70	100	138	78	108	162.50	
2	10AUG95	15, .	20	122	74	88	112	70	80	161.00	
3	17AUG95	22, .	20	120	74	80	130	80	82	158.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	19	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	93	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00105 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	27JUL95	1	02AUG95	7	7
00106	Oral	2	20 MG	03AUG95	8	07AUG95	12	5
00106	Oral	3	20 MG	08AUG95	13	16AUG95	21	9
00106	Oral	4	20 MG	17AUG95	22	23AUG95	28	7
00106	Oral	4	20 MG	24AUG95	29	30AUG95	35	7
	Oral	5	30 MG	31AUG95	36	04SEP95	40	5
00106	Oral	6	40 MG	05SEP95	41	11SEP95	47	7
00106	Oral	6	40 MG	12SEP95	48	12SEP95	48	1

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	48	40	Other reason	PT D/C ON OWN -- OPPOSITIONAL DEFIANT DISORDER

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES	8, .	10 Mins	20	10	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	8, .	03:00 Hrs	20	CON	MIL	NO	REL	No	No
Nervous System	Hostility	OPPOSITIONAL DEFIANT DISORDER	51, .	16 Days	40	CON	SEV	NO	PBU	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	27JUL95	1, .	0	86	68	72	84	62	90	148.00	68.0
1	03AUG95	8, .	20	110	60	80	106	60	84	149.50	
2	08AUG95	13, .	20	102	60	96	102	68	100	154.00	
3	17AUG95	22, .	20	80	60	68	78	58	75	152.00	
4	24AUG95	29, .	20	100	64	70	100	60	68	152.00	
5	31AUG95	36, .	30	98	70	66	100	64	74	153.00	
6	05SEP95	41, .	40	98	68	64	96	70	78	153.00	
7	12SEP95	48, .	40	90	64	80	86	64	72	153.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.4	.	.	.	30 - 70	%
				Lymphocytes	26.9	.	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00106 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	25JAN96	1	31JAN96	7	7
00107	Oral	2	0 MG	01FEB96	8	07FEB96	14	7
00107	Oral	3	0 MG	08FEB96	15	12FEB96	19	5
00107	Oral	4	0 MG	13FEB96	20	19FEB96	26	7
00107	Oral	4	0 MG	20FEB96	27	26FEB96	33	7
00107	Oral	4	0 MG	27FEB96	34	04MAR96	40	7
00107	Oral	5	0 MG	05MAR96	41	14MAR96	50	10
00107	Oral	6	0 MG	15MAR96	51	20MAR96	56	6
00176	Oral	6	0 MG	21MAR96	57	22APR96	89	33
00176	Oral	6	0 MG	23APR96	90	20MAY96	117	28
00176	Oral	6	0 MG	21MAY96	118	19JUN96	147	30
00176	Oral	6	0 MG	20JUN96	148	24JUL96	182	35
00176	Oral	6	0 MG	25JUL96	183	28AUG96	217	35
00176	Oral	6	0 MG	29AUG96	218	25SEP96	245	28
00176	Oral	5	0 MG	26SEP96	246	08OCT96	258	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	Yes	258	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EPIGASTRIC DISTRESS	DYSPEPSIA	DIGESTIVE SYST	CUR	1995
FAINTING{OCCASIONAL}	SYNCOPE AND COLLAPSE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MISSED MENSES	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	236, 180	16SEP96	26SEP96	1500 MG	STREP THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT	236, 180	46 Days	0	CON	MOD	NO	UNR	Yes	No
Hemic and Lymphatic System	Wbc Abnormality	ELEVATED ATYPICAL LYMPHS	236, 180	46 Days	0	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS (WHEN STANDING)	214, 158	Not Stated	0	CON	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	TONSILLITIS	236, 180	46 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JAN96	-7, -63	0	112	74	70	110	72	68	167.00	65.0
1	01FEB96	8, -49	0	108	78	66	106	76	60	172.00	
2	08FEB96	15, -42	0	110	76	64	106	72	62	174.00	
3	13FEB96	20, -37	0	108	74	64	110	76	80	173.00	
4	20FEB96	27, -30	0	110	68	68	104	70	62	174.50	
5	27FEB96	34, -23	0	106	70	66	100	66	62	174.00	
6	05MAR96	41, -16	0	114	74	70	110	72	68	179.00 H	
7	15MAR96	51, -6	0	106	72	64	104	70	64	179.50 H	
8	21MAR96	57, 1	0	94	72	70	92	68	92	178.00	
12	23APR96	90, 34	0	104	68	60	110	76	64	178.00	
16	21MAY96	118, 62	0	106	64	64	100	68	78	177.00	
20	20JUN96	148, 92	0	110	62	48	104	64	70	167.00	
24	18JUL96	176, 120	0	110	62	60	100	60	62	162.00	
32	29AUG96	218, 162	0	108	64	62	104	64	70	157.00	
32	26SEP96	246, 190	0	100	62	60	94	60	78	156.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67	.	.	.	30 - 70	%
				Lymphocytes	24.9	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.6	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.6	.	.	.	30 - 70	%
				Lymphocytes	35.6	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	148	Uric Acid	5.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	246	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00107 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/CONTINUATION-WEEK 32	246	Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	167	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	58	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	101	H	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	PORTUGUESE

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	06FEB96	1	12FEB96	7	7
00241	Oral	2	0 MG	13FEB96	8	21FEB96	16	9
00241	Oral	3	0 MG	22FEB96	17	26FEB96	21	5
00241	Oral	4	0 MG	27FEB96	22	04MAR96	28	7
00241	Oral	4	0 MG	05MAR96	29	11MAR96	35	7
00241	Oral	5	0 MG	12MAR96	36	18MAR96	42	7
00241	Oral	5	0 MG	19MAR96	43	25MAR96	49	7
00241	Oral	6	0 MG	26MAR96	50	01APR96	56	7
00145	Oral	6	0 MG	02APR96	57	30APR96	85	29
00145	Oral	6	0 MG	01MAY96	86	23MAY96	108	23

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	108	0	Adverse event, including intercurrent illness	PT HOSPITALIZED DUE TO HOMICIDAL / SUICIDAL IDEATION

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES {TO PENICILLIN}	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	1991
ALLERGIES {TO POLLEN, POULTRY DUST}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1991
NASAL CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1996
SINUS RHYTHM ALTERNATING WITH ECTOPIC ATRIAL RHYTHM	EXTRASYSTOLES, ATRIAL	CIRCULATORY SYST	CUR	1996

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Fluoxetine	Prozac	108, 52	23MAY96	.	10 MG	DEPRESSION
RESPIRATORY	Chlorphenamine Maleate	Dristan	-36, -92	01JAN96	25JAN96#	2 SPRAYS	NASAL CONGESTION
	Cough Syrup/Med	Cough Medicine	64, 8	09APR96	30APR96	18 TBSP	COUGH
	Paracetamol	Dristan	-36, -92	01JAN96	25JAN96#	2 SPRAYS	NASAL CONGESTION
	Phenylephrine Hydrochloride	Dristan	-36, -92	01JAN96	25JAN96#	2 SPRAYS	NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Vomiting	NAUSEA AND VOMITING	27, -30	3 Days	0	2	MIL	NO	PBU	No	No
Nervous System	Emotional Lability	PT. HOSPITALIZED FOR SUICIDAL IDEATION	108, 52	Not Stated	0	CON	SEV	STP	PBU	Yes	Yes
	Hostility	PT. HOSPITALIZED FOR HOMICIDAL IDEATION	108, 52	Not Stated	0	CON	SEV	STP	PBU	No	Yes
Respiratory System	Cough Increased	COUGH	64, 8	22 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25JAN96	-12, -68	0	110	70	66	106	70	80	202.00	69.0
BL	06FEB96	1, -56	0	110	72	64	110	70	80	202.00	
1	13FEB96	8, -49	0	108	60	60	110	70	70	205.00	
2	22FEB96	17, -40	0	110	60	62	108	60	66	205.00	
3	27FEB96	22, -35	0	112	78	64	106	74	72	202.00	
4	05MAR96	29, -28	0	110	70	62	104	68	60	205.00	
5	12MAR96	36, -21	0	120	68	60	114	70	58	205.00	
6	19MAR96	43, -14	0	120	64	64	112	60	68	205.00	
7	26MAR96	50, -7	0	122	70	70	120	72	62	204.00	
8	02APR96	57, 1	0	110	64	64	108	68	72	199.00	
12	30APR96	85, 29	0	106	60	60	100	62	61	207.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	6.6	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.5	.	.	.	30 - 70	%
				Lymphocytes	27.6	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00241 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Basophils	0.8	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	115	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	30	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07FEB96	1	14FEB96	8	8
00242	Oral	2	20 MG	15FEB96	9	21FEB96	15	7
00242	Oral	3	20 MG	22FEB96	16	28FEB96	22	7
00242	Oral	4	20 MG	29FEB96	23	05MAR96	28	6
00242	Oral	5	30 MG	06MAR96	29	13MAR96	36	8
00242	Oral	5	30 MG	14MAR96	37	20MAR96	43	7
00242	Oral	6	40 MG	21MAR96	44	28MAR96	51	8
00242	Oral	6	40 MG	29MAR96	52	04APR96	58	7
	Oral	6	40 MG	05APR96	59	07MAY96	91	33
00136	Oral	6	40 MG	08MAY96	92	05JUN96	120	29
00242	Oral	.		06JUN96	121	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	120	40	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {RECURRENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-6, -64	01FEB96	01FEB96#	650 MG	HEADACHE
	Paracetamol	Tylenol	42, -17	19MAR96	19MAR96	650 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Somnolence	MILD SEDATION	30, -29	8 Days	30	1	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26JAN96	-12, -70	0	130	80	92	120	70	88	166.48	65.0
1	14FEB96	8, -51	20	100	70	88	105	65	92	162.07	
2	21FEB96	15, -44	20	110	70	92	115	75	100	158.76	
3	29FEB96	23, -36	20	110	70	96	115	75	100	161.41	
4	06MAR96	29, -30	30	110	70	96	115	75	100	159.86	
5	14MAR96	37, -22	30	105	70	76	110	80	80	156.56	
6	20MAR96	43, -16	30	110	75	84	110	80	108	158.76	
7	28MAR96	51, -8	40	110	70	88	120	80	100	159.86	
8	05APR96	59, 1	40	110	70	88	120	80	100	159.86	
12	08MAY96	92, 34	40	125	80	80	125	85	96	161.41	
16	05JUN96	120, 62	40	125	80	80	125	85	92	161.63	
20	10JUL96	155, 97#	0	116	62	77	108	58	79	159.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	389000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.8	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	391000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	59		Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	84	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
		VISIT 17/DOWN TITRATION	155	(35)	Hemoglobin	14.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	42.8	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	60	.	.	.	30 - 70	%
					Lymphocytes	26.6	.	.	.	21 - 51	%
					Monocytes	8.1	.	.	.	0 - 10	%
					Eosinophils	4.7	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	316000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	113	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	57	L	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00242 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 17/DOWN TITRATION	155 (35)	Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	14MAR96	1	20MAR96	7	7
00243	Oral	2	100 MG	21MAR96	8	27MAR96	14	7
00243	Oral	3	150 MG	28MAR96	15	04APR96	22	8
00243	Oral	3	150 MG	05APR96	23	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	23	150	Adverse event, including intercurrent illness	HIT HEAD DURING A FALL

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SHAKINESS	NERVOUSNESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SORE THROAT-TONSILLITIS	TONSILLITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Phenoxymethylpenicillin	Pen-Vee-K	1, .	14MAR96	21MAR96	250 4XDAY	TONSILLITIS
			1, .	14MAR96	21MAR96	1000 MG	PROBABLE STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	22, .	04APR96	04APR96	650 MG PRN	HEADACHES
DERMATOLOGICALS	Calamine	Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
	Camphor	Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
	Diphenhydramine Hydrochloride	Benadryl	4, .	17MAR96	24MAR96	25 MG	RASH
		Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
	Glycerol	Caladryl	4, .	17MAR96	24MAR96	1 APPL PRN	RASH
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	4, .	17MAR96	24MAR96	25 MG	RASH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES	8, .	Not Stated	100	CON	MIL	NO	REL	No	No
	Asthenia	TIREDNESS AND DROWSINESS	1, .	Not Stated	50	CON	MOD	NO	PSR	No	No
	Trauma	DIZZINESS - (HIT HEAD DURING FALL)	4, .	Not Stated	50	CON	MOD	STP	PSR	No	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	15, .	Not Stated	150	CON	MIL	NO	PSR	No	No
Digestive System	Constipation	CONSTIPATION	22, .	Not Stated	150	CON	SEV	NO	PSR	No	No
	Nausea	NAUSEA	8, .	Not Stated	100	CON	MIL	NO	REL	No	No
Nervous System	Tremor	(WORSENING) ENTIRE BODY SHAKES AND SHAKY HAND	9, .	Not Stated	100	CON	MOD	NO	PSR	No	No
Skin and Appendages	Rash	ITCHING AND RASH TO RIGHT FOREARM AND BOTH CALVES	4, .	6 Days	50	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	27FEB96	-16, .	0	94	64	68	92	60	64	112.50	62.0
1	21MAR96	8, .	100	98	66	66	98	64	68	111.00	
2	28MAR96	15, .	150	90	60	78	88	60	64	111.00	
3	04APR96	22, .	150	90	62	74	88	64	76	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5	.	.	.	30 - 70	%
				Lymphocytes	36.1	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00243 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	21MAR96	1	27MAR96	7	7
00244	Oral	2	100 MG	28MAR96	8	03APR96	14	7
00244	Oral	3	150 MG	04APR96	15	10APR96	21	7
00244	Oral	4	200 MG	11APR96	22	17APR96	28	7
00244	Oral	5	250 MG	18APR96	29	24APR96	35	7
00244	Oral	4	200 MG	25APR96	36	01MAY96	42	7
00244	Oral	5	250 MG	02MAY96	43	08MAY96	49	7
00244	Oral	6	300 MG	09MAY96	50	16MAY96	57	8
00138	Oral	6	300 MG	17MAY96	58	23MAY96	64	7
00138	Oral	5	250 MG	24MAY96	65	28MAY96	69	5
00244	Oral	4	200 MG	29MAY96	70	31MAY96	72	3
00244	Oral	3	150 MG	01JUN96	73	02JUN96	74	2
00244	Oral	2	100 MG	03JUN96	75	05JUN96	77	3
00244	Oral	1	50 MG	06JUN96	78	12JUN96	84	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	84	50	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEAVY CRAMPS DUE TO MENSES	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	P&C	1990
NAUSEA DUE TO MENSES	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	P&C	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FEELS MORE TIRED AFTER TAKING MEDS	2, -56	14 Days	50	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY THROAT, MOUTH	9, -49	61 Days	100	CON	MOD	NO	PSR	No	No
Metabolic and Nutritional Disorders	Thirst	INCREASED THIRST	9, -49	61 Days	100	CON	MOD	NO	PBU	No	No
Nervous System	Depersonalization	"SPACEY" 1X	3, -55	02:00 Hrs	50	7	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS UPON STANDING {1-2X/DAILY}	9, -49	24 Days	100	48	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14MAR96	-7, -64	0	122	72	84	120	70	80	141.00	63.0
BL	21MAR96	1, -57	0	110	66	80	112	70	98	143.00	
1	28MAR96	8, -50	100	120	78	78	118	70	70	142.00	
2	04APR96	15, -43	150	122	74	89	120	76	82	143.00	
3	11APR96	22, -36	200	112	70	99	110	72	110	143.00	
4	18APR96	29, -29	250	106	74	106	100	72	100	144.00	
5	25APR96	36, -22	200	110	64	75	108	68	80	145.00	
6	02MAY96	43, -15	250	120	70	84	116	70	86	144.00	
7	09MAY96	50, -8	300	110	70	94	112	70	88	144.50	
8	16MAY96	57, -1	300	104	68	106	92	70	104	144.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.2	.	.	.	30 - 70	%
				Lymphocytes	32.8	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.8	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	70	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00244 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28MAR96	1	04APR96	8	8
00245	Oral	1	20 MG	05APR96	9	09APR96	13	5
	Oral	1	20 MG	10APR96	14	14APR96	18	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	18	20	Adverse event, including intercurrent illness	DOWN TITRATED (PER S. FRITSH, M.D.) 3.A.M. DOSES, LEVEL 1.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MIGRAINE HEADACHES {ACCORDING TO PATIENT}	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-452, .	01JAN95	.	PRN	HEADACHE
	Sertraline Hydrochloride	Zoloft	-27, .	01MAR96	14MAR96#	25 MG	DEPRESSION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Emotional Lability	TYLENOL OVERDOSE {INTENTIONAL}	14, .	1 Days	20	1	SEV	STP	UNR	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21MAR96	-7, .	0	100	60	66	96	64	70	131.00	66.0
BL	28MAR96	1, .	0	98	60	60	90	62	70	127.00	
1	04APR96	8, .	20	98	62	62	96	60	68	126.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	220000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	159	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	118	H	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00245 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	18APR96	1	24APR96	7	7
00246	Oral	2	0 MG	25APR96	8	01MAY96	14	7
00246	Oral	3	0 MG	02MAY96	15	08MAY96	21	7
00246	Oral	4	0 MG	09MAY96	22	15MAY96	28	7
00246	Oral	5	0 MG	16MAY96	29	22MAY96	35	7
00246	Oral	5	0 MG	23MAY96	36	29MAY96	42	7
00246	Oral	5	0 MG	30MAY96	43	03JUN96	47	5
00246	Oral	6	0 MG	04JUN96	48	17JUN96	61	14
	Oral	6	0 MG	18JUN96	62	28JUN96	72	11

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	72	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
GASTROINTESTINAL DISTRESS	GASTROINTEST PROB, NEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
{PAST} ALCOHOL USE	ALCOHOL INGESTION, OTHER	FAMILY/PERSONAL HISTORY	PRV	1994
{PAST} MARIJUANA USE	DRUG ABUSE	MENTAL DISORD	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid	-838, .	01JAN94	.	PRN-10MGS	GASTROINTESTINAL DISTRESS
MUSCULO-SKELETAL	Ibuprofen	Advil	48, .	04JUN96	04JUN96		HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES (IF TAKES MEDS WITHOUT FOOD)	33, .	Not Stated	0		MIL	NO	PSR	No	No
	Asthenia	FATIGUE	8, .	Not Stated	0	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES (WORSENING)	23, .	Not Stated	0		MIL	NO	PSR	Yes	No
	Trauma	CAR ACCIDENT (NO INJURIES)	28, .	1 Days	0	CON	MIL	NO	UNR	No	No
		FALL FROM ROPE RESULTING IN DIZZINESS,HEADACHES, AND FATIGUE	39, .	5 Days	0		MOD	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	8, .	Not Stated	0	CON	MIL	NO	REL	No	No
	Vomiting	VOMITING	15, .	2 Days	0	2	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	36, .	7 Days	0	CON	MIL	NO	PSR	No	No
Skir and Appendages	Herpes Zoster	VARICELLA	56, .	5 Days	0		MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	01APR96	-17, .	0	126	74	62	120	70	66	190.00	61.0
1	25APR96	8, .	0	122	68	72	120	64	66	191.00	
2	02MAY96	15, .	0	122	66	72	120	68	80	187.00	
3	09MAY96	22, .	0	104	64	76	100	60	72	189.00	
4	16MAY96	29, .	0	108	85	88	115	88	95	189.50	
5	23MAY96	36, .	0	110	80	70	118	78	88	189.00	
6	30MAY96	43, .	0	108	62	88	110	66	88	194.00	
7	04JUN96	48, .	0	102	64	88	98	62	90	191.00	
8	18JUN96	62, .	0	130	70	74	124	72	86	194.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-17	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	25.4	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-17	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	30 - 70	%
				Lymphocytes	30.6	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	90	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	45	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00246 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	114	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	30APR96	1	06MAY96	7	7
00319	Oral	2	20 MG	07MAY96	8	13MAY96	14	7
00319	Oral	3	20 MG	14MAY96	15	20MAY96	21	7
00319	Oral	4	20 MG	21MAY96	22	27MAY96	28	7
00319	Oral	5	30 MG	28MAY96	29	03JUN96	35	7
00319	Oral	5	30 MG	04JUN96	36	10JUN96	42	7
00319	Oral	5	30 MG	11JUN96	43	17JUN96	49	7
00319	Oral	5	30 MG	18JUN96	50	24JUN96	56	7
00162	Oral	5	30 MG	25JUN96	57	22JUL96	84	28
00162	Oral	5	30 MG	23JUL96	85	14AUG96	107	23
00162	Oral	5	30 MG	15AUG96	108	23SEP96	147	40
00162	Oral	5	30 MG	24SEP96	148	21OCT96	175	28
00162	Oral	5	30 MG	22OCT96	176	18NOV96	203	28
00162	Oral	5	30 MG	19NOV96	204	16DEC96	231	28
00319	Oral	5	30 MG	17DEC96	232	17DEC96	232	1
00319	Oral	4	20 MG	18DEC96	233	19DEC96	234	2
00319	Oral	3	20 MG	20DEC96	235	21DEC96	236	2
00319	Oral	2	20 MG	22DEC96	237	24DEC96	239	3
00319	Oral	1	20 MG	25DEC96	240	30DEC96	245	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	245	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {FRONTAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	203, 147	18NOV96	18NOV96	1 TABLET	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH PAIN	71, 15	16:00 Hrs	30	1	MIL	NO	UNR	No	No
	Asthenia	FATIGUE	2, -55	202 Days	20	CON	MIL	NO	REL	No	No
	Chest Pain	CHEST PAIN	71, 15	16:00 Hrs	30	1	MIL	NO	UNR	No	No
	Headache	HEADACHE	203, 147	04:00 Hrs	30	1	MOD	NO	PBU	Yes	No
	Infection	FLU SYMPTOMS - FEVER, HEADACHES, MUSCLE ACHES	221, 165	6 Days	30	1	MOD	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	2, -55	202 Days	20	CON	MIL	NO	REL	No	No
Respiratory System	Pharyngitis	THROAT PAIN	71, 15	16:00 Hrs	30	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23APR96	-7, -63	0	110	60	100	108	66	94	109.00	61.0
1	07MAY96	8, -49	20	112	70	78	110	66	84	109.00	
2	14MAY96	15, -42	20	128	68	70	120	70	64	111.50	
3	21MAY96	22, -35	20	110	62	64	106	64	80	109.00	
4	28MAY96	29, -28	30	110	70	66	106	72	68	111.00	
5	04JUN96	36, -21	30	102	64	80	98	64	76	112.50	
6	11JUN96	43, -14	30	100	68	64	98	68	72	115.00	
7	18JUN96	50, -7	30	108	68	80	112	76	64	113.50	
8	25JUN96	57, 1	30	112	70	72	100	74	80	114.00	
12	23JUL96	85, 29	30	102	70	66	108	68	68	116.00	
16	15AUG96	108, 52	30	98	60	80	98	62	88	115.00	
20	24SEP96	148, 92	30	108	68	66	110	66	68	117.00 H	
24	22OCT96	176, 120	30	104	66	64	106	64	68	113.50	
28	19NOV96	204, 148	30	92	64	80	94	68	80	117.00 H	
32	17DEC96	232, 176	30	100	70	76	98	70	72	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.8	H	.	.	30 - 70	%
				Lymphocytes	19.5	L	.	.	21 - 51	%
				Monocytes	2.7	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	251000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.4	.	.	.	30 - 70	%
				Lymphocytes	27.5	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	184000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.5	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	3.4	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	148	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	232	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	171000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00319 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	232	Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16MAY96	1	22MAY96	7	7
00320	Oral	2	0 MG	23MAY96	8	29MAY96	14	7
00320	Oral	3	0 MG	30MAY96	15	03JUN96	19	5
00320	Oral	4	0 MG	04JUN96	20	17JUN96	33	14
00320	Oral	5	0 MG	18JUN96	34	24JUN96	40	7
00320	Oral	5	0 MG	25JUN96	41	01JUL96	47	7
00320	Oral	6	0 MG	02JUL96	48	08JUL96	54	7
00320	Oral	6	0 MG	09JUL96	55	15JUL96	61	7
00182	Oral	6	0 MG	16JUL96	62	12AUG96	89	28
00182	Oral	6	0 MG	13AUG96	90	16SEP96	124	35
00182	Oral	6	0 MG	17SEP96	125	25SEP96	133	9
00320	Oral	5	0 MG	26SEP96	134	08OCT96	146	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	146	0	Lack of Efficacy	ESCALATING DEPRESSIVE SYMPTOMS

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BILATERAL KNEE PAIN	PAIN, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
CHRONIC BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
DIZZINESS	DIZZINESS AND GIDDINESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
FRACTURED LEFT FEMUR	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
FRACTURED RIGHT TIBIA	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1990
FRACTURED SKULL	FRACTURE, SKULL	INJURY/POISONING	PRV	1990
LYME DISEASE	ARTHROPOD-BORNE DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995
SPRAINED WRIST	SPRAINS/STRAINS	INJURY/POISONING	PRV	1990
SUBDURAL HEMATOMA	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1990

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	117, 56	09SEP96	19SEP96		EAR INFECTION
	Clavulanic Acid	Augmentin	117, 56	09SEP96	19SEP96		EAR INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	32, -30	16JUN96	22JUN96	PRN	PAIN IN (EST) SHOULDER

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK PAIN	125, 64	Not Stated	0	CON	MOD	NO	UNR	No	No
	Trauma	SHOULDER TRAUMA	32, -30	1 Days	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	30, -32	11 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	FAINTING	111, 50	Not Stated	0	CON	MOD	NO	UNR	No	No
Special Senses	Otitis Media	EAR INFECTION	117, 56	11 Days	0	1	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	16MAY96	1, -61	0	94	62	96	78	60	115	154.00	
1	23MAY96	8, -54	0	96	60	84	90	58	92	154.50	
2	30MAY96	15, -47	0	106	62	68	90	60	72	155.50	
3	04JUN96	20, -42	0	98	64	64	100	68	70	154.50	
5	18JUN96	34, -28	0	122	70	68	120	74	64	155.00	
6	25JUN96	41, -21	0	98	62	100	96	64	116	156.25	
7	02JUL96	48, -14	0	120	64	80	116	66	102	158.00	
8	09JUL96	55, -7	0	108	70	75	106	72	86	160.00	
8	16JUL96	62, 1	0	108	70	84	110	74	100	160.00	
12	13AUG96	90, 29	0	110	70	66	108	68	88	160.00	
16	17SEP96	125, 64	0	92	70	80	90	68	86	159.40	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.6	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	7.5	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	198	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	30.1	.	.	.	21 - 51	%
				Monocytes	11.2	H	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	175	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00320 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	23MAY96	1	03JUN96	12	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	12	50	Adverse event, including intercurrent illness	PT WAS HOSPITALIZED ON 6-2-96 AT BRADLEY HOSPITAL FOLLOWING ASSAULTIVE BEHAVIOR NO DOWN TITRATION SINCE PT WAS ONLY ON LEVEL 1.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-508, .	01JAN95	.	PRN	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Hostility	PSYCHIATRIC HOSPITALIZATION FOLLOWING ASSAULTIVE BEHAVIOR	11, .	Not Stated	50	1	SEV	STP	UNR	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	23MAY96	1, .	0	96	64	64	100	70	66	112.00	65.0
1	30MAY96	8, .	50	88	64	66	88	64	80	114.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.2	.	.	.	30 - 70	%
				Lymphocytes	39.6	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	249000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	100	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00321 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	09JAN97	1	15JAN97	7	7
00322	Oral	2	100 MG	16JAN97	8	22JAN97	14	7
00322	Oral	3	150 MG	23JAN97	15	29JAN97	21	7
00322	Oral	4	200 MG	30JAN97	22	03FEB97	26	5
00322	Oral	4	200 MG	04FEB97	27	13FEB97	36	10
	Oral	4	200 MG	14FEB97	37	23FEB97	46	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	46	200	Adverse event, including intercurrent illness	ORTHOSTATIC SIDE EFFECTS

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	13, .	02:00 Hrs	100	1	MOD	NO	PBU	No	No
		STOMACH ACHE, RE-OCCURRING	29, .	Not Stated	200		MIL	NO	PSR	No	No
Cardiovascular System	Arrhythmia	ORTHOSTATIC CHANGES [IRREGULAR PULSE]	36, .	Not Stated	200	CON	MOD	STP	PSR	No	No
Nervous System	Dizziness	DIZZINESS	3, .	Not Stated	50	CON	MOD	STP	PBU	No	No
		ORTHOSTATIC CHANGES [DIZZINESS]	36, .	Not Stated	200	CON	MOD	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06JAN97	-3, .	0	120	84	80	120	80	86	136.00	68.5
1	16JAN97	8, .	100	120	68	108	114	68	130 H	136.00	
2	23JAN97	15, .	150	120	76	80	110	70	84	135.00	
3	30JAN97	22, .	200	90	70	86	88 L	70	82	132.00	
4	04FEB97	27, .	200	112	68	80	108	70	74	134.00	
5	13FEB97	36, .	200	125	70	110	100	90	132 H	132.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	9.2	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	294	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00322 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-3	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	12NOV96	1	18NOV96	7	7
00323	Oral	2	0 MG	19NOV96	8	25NOV96	14	7
00323	Oral	3	0 MG	26NOV96	15	04DEC96	23	9
00323	Oral	4	0 MG	05DEC96	24	09DEC96	28	5
00323	Oral	4	0 MG	10DEC96	29	16DEC96	35	7
00323	Oral	4	0 MG	17DEC96	36	25DEC96	44	9
00323	Oral	4	0 MG	26DEC96	45	01JAN97	51	7
00323	Oral	4	0 MG	02JAN97	52	08JAN97	58	7
00175	Oral	4	0 MG	09JAN97	59	03FEB97	84	26
00175	Oral	4	0 MG	04FEB97	85	03MAR97	112	28
00175	Oral	5	0 MG	04MAR97	113	02APR97	142	30
00175	Oral	5	0 MG	03APR97	143	29APR97	169	27
00175	Oral	5	0 MG	30APR97	170	26MAY97	196	27
00175	Oral	5	0 MG	27MAY97	197	11JUN97	212	16
00323	Oral	5	0 MG	12JUN97	213	14JUN97	215	3
00323	Oral	4	0 MG	15JUN97	216	16JUN97	217	2
00323	Oral	3	0 MG	17JUN97	218	18JUN97	219	2
00323	Oral	2	0 MG	19JUN97	220	20JUN97	221	2
00323	Oral	1	0 MG	21JUN97	222	26JUN97	227	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	Yes	227	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
ELEVATED CHOLESTEROL	CHOLEST/TRIGLYCERIDE, ELEVATED	ENDOCR/METAB/IMMUNITY DISORD	PRV	
HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	151, 93	11APR97	18APR97	250 MG	PHARYNGITIS
CENTRAL NERVOUS SYSTEM	Analgesics	Unknown {Analgesic Nos}	-1, -59	11NOV96	01DEC96		BACK PAIN
		Unknown {Analgesic}	49, -10	30DEC96	.	UNKNOWN	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	113, 55	Not Stated	0	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	82, 24	4 Days	0	1	MIL	NO	PSR	No	No
		HEADACHES	49, -10	11 Days	0	CON	MIL	NO	PSR	Yes	No
Metabolic and Nutritional Disorders	Thirst	INCREASED THIRST	15, -44	10 Days	0	CON	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS (ESPECIALLY DURING AEROBICS AND HEAVY LIFTING)	8, -51	37 Days	0	CON	MOD	NO	PSR	No	No
	Somnolence	FALLING ASLEEP IN THE AFTERNOON	4, -55	42 Days	0	CON	MOD	NO	PSR	No	No
Respiratory System	Pharyngitis	PHARYNGITIS	151, 93	8 Days	0	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04NOV96	-8, -66	0	92	68	84	90	64	90	118.00	63.0
BL	12NOV96	1, -58	0	92	68	84	90	64	90	118.00	
1	19NOV96	8, -51	0	94	66	88	98	64	80	117.00	
2	26NOV96	15, -44	0	102	78	84	100	78	78	109.00 L	
3	05DEC96	24, -35	0	96	70	80	94	66	82	112.00	
4	10DEC96	29, -30	0	100	68	66	96	66	64	112.00	
5	17DEC96	36, -23	0	98	60	90	94	62	84	114.00	
6	26DEC96	45, -14	0	88	66	74	88	64	76	112.00	
7	02JAN97	52, -7	0	102	72	80	104	60	84	112.00	
8	09JAN97	59, 1	0	100	68	74	100	66	80	114.50	
12	04FEB97	85, 27	0	102	64	74	102	60	84	116.00	
16	04MAR97	113, 55	0	108	68	84	104	66	88	118.00	
20	03APR97	143, 85	0	108	62	100	112	70	106	120.00	
24	30APR97	170, 112	0	116	58	82	116	58	92	119.00	
28	27MAY97	197, 139	0	110	70	72	110	80	100	118.50	
32	12JUN97	213, 155	0	110	80	76	105	75	76	114.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.7	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	198000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.9	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	56	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.6	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	143	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	30 - 70	%
				Lymphocytes	27.2	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	143	Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	53	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	213	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.002.00323 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 16/CONTINUATION-WEEK 32	213	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19JAN95	1	24JAN95	6	6
00073	Oral	2	100 MG	25JAN95	7	02FEB95	15	9
00073	Oral	3	150 MG	03FEB95	16	06FEB95	19	4
00073	Oral	4	200 MG	07FEB95	20	13FEB95	26	7
00073	Oral	4	200 MG	14FEB95	27	21FEB95	34	8
00073	Oral	5	250 MG	22FEB95	35	28FEB95	41	7
00073	Oral	5	250 MG	01MAR95	42	04MAR95	45	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	45	250	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Caffeine	Dexatrim	13, .	31JAN95	03FEB95	UNKNOWN	DIETING
	Dicycloverine Hydrochloride	Bentyl	45, .	04MAR95	06MAR95	UNKNOWN	NAUSEA
	Phenylpropanolamine Hydrochloride	Dexatrim	13, .	31JAN95	03FEB95	UNKNOWN	DIETING
CENTRAL NERVOUS SYSTEM	Analgesics	Pain Medication {Nos}	-11, .	08JAN95	.	4 TABLETS	SPRAINED ANKLE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Postural Hypotension	ORTHOSTATIC SYMPTOMS {ORTHOSTATIC HYPOTENSION}	16, .	Not Stated	150	CON	MOD	NO	PSR	No	No
Digestive System	Gastrointestinal Disorder	NAUSEA,VOMITING HEADACHES,DIARRHEA{GASTROINTESTINAL ILLNESS}	36, .	Not Stated	250	CON	MOD	NO	UNR	No	No
	Vomiting	VOMITING	45, .	Not Stated	250	CON	SEV	STP	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11JAN95	-8, .	0	110	72	86	112	72	88	138.92	63.8
BL	18JAN95	-1, .	0	100	70	82	90	68	87	140.00	
1	25JAN95	7, .	100	110	68	100	100	70	120	136.70	
2	03FEB95	16, .	150	114	74	92	96	70	120	135.61	
3	07FEB95	20, .	200	114	72	120	96	78	132 H	136.27	
4	14FEB95	27, .	200	112	78	92	102	66	120	134.73	
5	22FEB95	35, .	250	116	82	116	114	90	130 H	135.61	
6	01MAR95	42, .	250	128	72	114	116	68	128 H	134.73	
7	08MAR95	49, .	250	100	76	120	104	80	140 H	128.11 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.2	.	.	.	30 - 70	%
				Lymphocytes	31.6	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00073 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	COLUMBIAN YUGOSLAVIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	25JAN95	1	31JAN95	7	7
00074	Oral	2	0 MG	01FEB95	8	07FEB95	14	7
00074	Oral	3	0 MG	08FEB95	15	14FEB95	21	7
00074	Oral	4	0 MG	15FEB95	22	20FEB95	27	6
00074	Oral	5	0 MG	21FEB95	28	28FEB95	35	8
00074	Oral	6	0 MG	01MAR95	36	14MAR95	49	14
00074	Oral	6	0 MG	15MAR95	50	21MAR95	56	7
00043	Oral	6	0 MG	22MAR95	57	18APR95	84	28
00043	Oral	6	0 MG	19APR95	85	16MAY95	112	28
00043	Oral	6	0 MG	17MAY95	113	18JUN95	145	33
00043	Oral	6	0 MG	19JUN95	146	23JUL95	180	35
00043	Oral	6	0 MG	24JUL95	181	29AUG95	217	37
00043	Oral	6	0 MG	30AUG95	218	11OCT95	260	43
00074	Oral	5	0 MG	25OCT95	274	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	Yes	274	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
STATUS POST ACUTE APPENDICITIS	APPENDICITIS	DIGESTIVE SYST	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	16, -41	01:30 Hrs	0	2	MIL	NO	PSR	No	No
Digestive System	Constipation	CONSTIPATION	25, -32	12 Days	0	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JAN95	-7, -63	0	110	66	76	106	58	76	91.07	61.4
BL	25JAN95	1, -56	0	104	86	75	98	78	90	94.20	
1	01FEB95	8, -49	0	110	76	72	108	80	82	95.48	
2	08FEB95	15, -42	0	110	84	84	110	70	96	94.82	
3	15FEB95	22, -35	0	100	70	76	100	78	88	95.70	
4	21FEB95	28, -29	0	102	78	88	102	80	117	95.48	
5	01MAR95	36, -21	0	100	72	76	110	66	84	96.36	
7	15MAR95	50, -7	0	110	86	76	104	88	98	97.02	
8	22MAR95	57, 1	0	104	74	68	100	78	92	96.80	
12	19APR95	85, 29	0	106	76	72	92	70	104	98.34	
16	17MAY95	113, 57	0	94	66	80	98	72	78	98.34	
20	19JUN95	146, 90	0	100	72	60	94	76	80	97.46	
24	24JUL95	181, 125	0	104	74	85	100	76	104	101.65 H	
32	30AUG95	218, 162	0	108	74	68	96	70	88	103.19 H	
32	11OCT95	260, 204	0	90	70	96	100	76	100	102.53 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	2	L	.	.	4 - 12	%
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	152000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	344	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	106	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1	.	.	.	30 - 70	%
				Lymphocytes	25.4	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	2.9	H	.	.	0 - 2	%
				Platelets	185000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	406	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	146	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.2	.	.	.	30 - 70	%
				Lymphocytes	45.1	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	148000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	359	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	146	Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	260	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.4	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	34	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	99	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00074 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 16/CONTINUATION-WEEK 32	260	Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	316	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	25JAN95	1	31JAN95	7	7
00075	Oral	2	20 MG	01FEB95	8	07FEB95	14	7
00075	Oral	3	20 MG	08FEB95	15	14FEB95	21	7
00075	Oral	4	20 MG	15FEB95	22	20FEB95	27	6
00075	Oral	5	30 MG	21FEB95	28	28FEB95	35	8
00075	Oral	3	20 MG	01MAR95	36	07MAR95	42	7
00075	Oral	2	20 MG	08MAR95	43	14MAR95	49	7
00075	Oral	4	20 MG	15MAR95	50	21MAR95	56	7
00041	Oral	4	20 MG	22MAR95	57	18APR95	84	28
00041	Oral	4	20 MG	19APR95	85	16MAY95	112	28
00041	Oral	4	20 MG	17MAY95	113	13JUN95	140	28
00041	Oral	4	20 MG	14JUN95	141	11JUL95	168	28
00041	Oral	4	20 MG	12JUL95	169	09AUG95	197	29
00041	Oral	4	20 MG	10AUG95	198	12SEP95	231	34
00075	Oral	3	20 MG	13SEP95	232	14SEP95	233	2
00075	Oral	2	20 MG	15SEP95	234	17SEP95	236	3
00075	Oral	1	20 MG	18SEP95	237	21SEP95	240	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	Yes	240	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-7, -63	18JAN95	.	PRN	HEADACHE
			16, -41	09FEB95	14FEB95	PRN	HEADACHES
MUSCULO-SKELETAL	Ibuprofen	Motrin	-7, -63	18JAN95	.	PRN	HEADACHE
			16, -41	09FEB95	14FEB95	PRN 200-400	HEADACHE
RESPIRATORY	Salbutamol	Proventil	., .		.	PRN	ASTHMA
			., .		.	PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	TIRED	141, 85	2 Days	20		MIL	NO	UNR	No	No
	Headache	HEADACHES	15, -42	Not Stated	20	CON	MIL	NO	PBU	No	No
Carciovascular System	Tachycardia	HEART RACING	102, 46	12 Days	20	CON	MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	APPETITE SUPPRESSION	71, 15	98 Days	20	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	1, -56	4 Days	20	CON	MIL	NO	PSR	No	No
	Gastrointestinal Disorder	NAUSEA AND REFLUX {ESOPHAGEAL}	22, -35	24:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	43, -14	128 Days	20	CON	MIL	INC	PSR	No	No
			234, 178	6 Days	20		MOD	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	43, -14	15 Days	20	CON	MOD	INC	PSR	No	No
			158, 102	10 Days	20	CON	MIL	NO	PBU	No	No
			234, 178	6 Days	20		MOD	NO	PBU	No	No
	Hyperkinesia	HYPERACTIVITY	170, 114	70 Days	20	CON	MIL	NO	PBU	No	No
	Insomnia	TROUBLE SLEEPING	234, 178	6 Days	20		MOD	NO	PBU	No	No
	Nervousness	NERVOUS JITTERY	1, -56	8 Days	20	CON	MIL	NO	PSR	No	No
		TREMULOUS									
		TEETH CHATTERING(JITTERINESS)	51, -6	13 Days	20	CON	MIL	NO	REL	No	No
	Somnolence	DROWSINESS	37, -20	5 Days	20	CON	MIL	DCR	PSR	No	No
Urogenital System	Amenorrhea	AMENORRHEA	8, -49	161 Days	20	CON	MOD	NO	PSR	No	No
	Female Genital Disorders	ANORGASMIA {FEMALE}	1, -56	57 Days	20	CON	SEV	DCR	REL	No	No
			58, 2	56 Days	20	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JAN95	-7, -63	0	124	66	82	124	70	82	145.75	60.6
BL	25JAN95	1, -56	0	120	76	88	118	80	85		
1	01FEB95	8, -49	20	130	78	78	132	88	82	143.55	
2	08FEB95	15, -42	20	130	88	72	126	86	76	142.22	
3	15FEB95	22, -35	20	120	66	78	126	64	90	141.34	
4	21FEB95	28, -29	30	116	88	80	112	90	70	142.44	
5	01MAR95	36, -21	20	130	76	88	138	80	92	142.22	
6	08MAR95	43, -14	20	120	82	72	126	80	82	143.10	
7	15MAR95	50, -7	20	120	82	74	130	84	76	142.22	
8	22MAR95	57, 1	20	130	76	72	118	84	78	143.33	
12	19APR95	85, 29	20	112	78	72	128	88	84	141.56	
16	17MAY95	113, 57	20	114	70	72	118	68	76	142.00	
20	14JUN95	141, 85	20	124	70	72	110	72	72	141.12	
24	12JUL95	169, 113	20	130	62	80	120	64	86	142.22	
28	09AUG95	197, 141	20	120	80	72	110	70	76	140.68	
32	13SEP95	232, 176	20	120	78	64	130	86	72	140.24	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35.8	.	.	.	30 - 70	%
				Lymphocytes	54.7	H	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	304000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.8	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	141	Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	232	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	41.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	0.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	335000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00075 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 16/CONTINUATION-WEEK 32	232	Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	140	H	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	31JAN95	1	06FEB95	7	7
00076	Oral	2	100 MG	07FEB95	8	13FEB95	14	7
00076	Oral	3	150 MG	14FEB95	15	20FEB95	21	7
00076	Oral	4	200 MG	21FEB95	22	26FEB95	27	6
00076	Oral	4	200 MG	27FEB95	28	05MAR95	34	7
00076	Oral	4	200 MG	06MAR95	35	12MAR95	41	7
00076	Oral	4	200 MG	13MAR95	42	19MAR95	48	7
00076	Oral	4	200 MG	20MAR95	49	26MAR95	55	7
00045	Oral	4	200 MG	27MAR95	56	02MAY95	92	37
00045	Oral	4	200 MG	03MAY95	93	30MAY95	120	28
00045	Oral	4	200 MG	31MAY95	121	27JUN95	148	28
00045	Oral	4	200 MG	28JUN95	149	01AUG95	183	35
00045	Oral	4	200 MG	02AUG95	184	05SEP95	218	35
00045	Oral	4	200 MG	06SEP95	219	27SEP95	240	22

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	240	200		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	
GLASSES FOR DISTANCE SINCE GRADE 4	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	PRV	1988
HISTORY FUNCTIONAL HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	
SPRAINED ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	.,	.	.		CRAMPS
	Caffeine	Midol	.,	.	.		CRAMPS
	Cinnamedrine Hydrochloride	Midol	.,	.	.		CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	2, -54	48 Days	50	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	188, 133	66 Days	200	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JAN95	-7, -62	0	126	66	80	132	66	86	200.66	65.4
BL	31JAN95	1, -55	0	114	76	76	110	72	80	197.70	
1	07FEB95	8, -48	100	118	82	100	120	78	118	201.76	
2	14FEB95	15, -41	150	126	80	88	130	78	112	198.01	
3	21FEB95	22, -34	200	110	78	117	104	70	112	200.66	
4	27FEB95	28, -28	200	128	68	112	120	80	118	201.76	
5	06MAR95	35, -21	200	128	76	102	124	80	112	202.20	
6	13MAR95	42, -14	200	130	66	96	132	82	108	203.52	
7	20MAR95	49, -7	200	112	84	96	110	80	112	206.17	
8	27MAR95	56, 1	200	124	80	112	130	82	120	206.17	
12	03MAY95	93, 38	200	116	60	86	114	66	100	205.07	
16	31MAY95	121, 66	200	114	60	92	104	68	112	205.07	
20	28JUN95	149, 94	200	102	60	110	104	68	122 H	209.92	
28	02AUG95	184, 129	200	124	70	100	120	76	104	206.39	
32	06SEP95	219, 164	200	122	68	120	120	74	120	209.25	
32	11OCT95	254, 199	0	120	52	100	130	64	108	218.30 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	317000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	44	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	0.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	15.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	38	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	286000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	149		Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	51	H	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	19	L	.	.	70 - 115	MG/DL
					Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	254	(14)	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	42.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54.5	.	.	.	30 - 70	%
					Lymphocytes	37.3	.	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	1.8	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	300000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00076 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	254	(14)	Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	67	H	.	.	0 - 48	U/L
					Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	119	H	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00077 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	06MAR95	1	12MAR95	7	7
00077	Oral	2	20 MG	13MAR95	8	19MAR95	14	7
00077	Oral	3	20 MG	20MAR95	15	26MAR95	21	7
00077	Oral	4	20 MG	27MAR95	22	04APR95	30	9
00077	Oral	5	30 MG	05APR95	31	11APR95	37	7
00077	Oral	5	30 MG	12APR95	38	18APR95	44	7
00077	Oral	5	30 MG	19APR95	45	26APR95	52	8
00077	Oral	5	30 MG	27APR95	53	03MAY95	59	7
00042	Oral	5	30 MG	04MAY95	60	06JUN95	93	34
00042	Oral	5	30 MG	07JUN95	94	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00077 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	94	30	Lost to follow-up	[redacted] DID NOT ARRIVE FOR MONTH 2VISIT,FAMILY DID NOT RESPOND TO ATTEMPTS TO CONTACT THEM.

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Tachycardia	HEART RACING	46, -14	3 Days	30	3	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	42, -18	10 Days	30		MIL	NO	PSR	No	No
	Dyspepsia	UPSET STOMACH AND HEARTBURN	7, -53	08:30 Hrs	20	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	47, -13	3 Days	30	3	MIL	NO	PSR	No	No
			58, -2	35 Days	30	2	MIL	NO	PSR	No	No
Nervous System	Insomnia	INSOMNIA	80, 21	Not Stated	30	CON	SEV	DCR	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00077 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	01MAR95	-5, -64	0	138	70	76	138	72	72	132.30	68.9
BL	06MAR95	1, -59	0	138	70	76	138	72	72	132.30	
1	13MAR95	8, -52	20	134	86	76	148	78	90	134.51	
2	20MAR95	15, -45	20	118	88	76	116	86	88	134.51	
3	27MAR95	22, -38	20	124	82	82	126	76	88	137.37	
4	05APR95	31, -29	30	128	84	78	126	88	78	136.27	
5	12APR95	38, -22	30	128	66	80	134	78	86	138.47	
6	19APR95	45, -15	30	130	76	80	138	84	84	138.03	
7	26APR95	52, -8	30	120	82	84	130	80	90	139.58	
8	03MAY95	59, -1	30	114	78	78	130	86	78	140.68	
12	07JUN95	94, 35	30	126	76	78	122	80	80	136.71	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	26APR95	1	01MAY95	6	6
00078	Oral	2	0 MG	02MAY95	7	09MAY95	14	8
00078	Oral	3	0 MG	10MAY95	15	16MAY95	21	7
00078	Oral	4	0 MG	17MAY95	22	23MAY95	28	7
00078	Oral	5	0 MG	24MAY95	29	29MAY95	34	6
00078	Oral	6	0 MG	30MAY95	35	06JUN95	42	8
00078	Oral	6	0 MG	07JUN95	43	14JUN95	50	8
00078	Oral	6	0 MG	15JUN95	51	21JUN95	57	7
	Oral	6	0 MG	22JUN95	58	28JUN95	64	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	64	0	Lack of Efficacy	

* Relative to Start of Study Medication

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	11APR95	-15, .	0	110	65	72	110	65	72	195.00	68.5
BL	26APR95	1, .	0	120	75	80	.	.	.	198.00	
1	02MAY95	7, .	0	110	78	80	105	75	90	198.00	
2	10MAY95	15, .	0	110	70	80	120	80	84	200.00	
3	17MAY95	22, .	0	118	70	80	110	80	88	195.50	
4	24MAY95	29, .	0	122	76	80	114	80	88	194.00	
5	30MAY95	35, .	0	120	80	82	110	78	88	196.00	
6	07JUN95	43, .	0	118	68	82	110	76	84	192.00	
7	15JUN95	51, .	0	110	80	90	112	80	78	192.00	
8	21JUN95	57, .	0	112	80	80	110	84	84	196.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.4	H	.	.	30 - 70	%
				Lymphocytes	19.9	L	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00078 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/UNSCHEDULED LAB 1	78	(14)	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	66.7	.	.	.	30 - 70	%
					Lymphocytes	23.8	.	.	.	21 - 51	%
					Monocytes	7.3	.	.	.	0 - 10	%
					Eosinophils	1.5	.	.	.	0 - 5	%
					Basophils	0.7	.	.	.	0 - 2	%
					Platelets	198000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	87	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	03MAY95	1	09MAY95	7	7
00079	Oral	2	100 MG	10MAY95	8	18MAY95	16	9
00079	Oral	3	150 MG	19MAY95	17	19MAY95	17	1

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	17	150	Other reason	PATIENT WITHDREW BY OWN VOLITION

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	15, .	17MAY95	17MAY95		SORE THROAT
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	15, .	17MAY95	17MAY95		SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Insomnia	INSOMNIA (FREQUENT AWAKENING)	9, .	Not Stated	100	CON	MOD	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	15, .	Not Stated	100	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	03MAY95	1, .	0	112	78	64	100	70	84	152.15	68.1
1	10MAY95	8, .	100	110	74	78	100	80	86	150.38	
2	19MAY95	17, .	150	124	74	90	112	80	112	149.28	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	38.2	.	.	.	30 - 70	%
				Lymphocytes	49	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00079 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	27NOV95	1	03DEC95	7	7
00080	Oral	2	0 MG	04DEC95	8	10DEC95	14	7
00080	Oral	3	0 MG	11DEC95	15	17DEC95	21	7
00080	Oral	4	0 MG	18DEC95	22	28DEC95	32	11
	Oral	4	0 MG	29DEC95	33	03JAN96	38	6
00080	Oral	5	0 MG	04JAN96	39	09JAN96	44	6
00080	Oral	6	0 MG	10JAN96	45	16JAN96	51	7
00080	Oral	6	0 MG	17JAN96	52	23JAN96	58	7
00080	Oral	5	0 MG	24JAN96	59	09FEB96	75	17

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	75	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FATIGUE	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
GU SYSTEM/SEX HORMONES	Injectable Contraceptive, Nos	Injectable Contraceptive {Nos}	-51, .	07OCT95	.		BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	39, .	Not Stated	0	CON	SEV	NO	PBU	No	No
	Headache	HEADACHES	38, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	39, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	39, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS	27, .	12 Days	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22NOV95	-5, .	0	110	70	68	124	62	84	177.94	62.6
1	04DEC95	8, .	0	122	72	80	110	80	96	178.61	
1	07DEC95	11, .	0	124	64	94	120	62	100	179.27	
3	18DEC95	22, .	0	114	58	88	110	66	100	177.50	
5	29DEC95	33, .	0	134	48 L	98	112	60	106	181.03	
5	04JAN96	39, .	0	128	58	86	126	74	90	179.05	
6	10JAN96	45, .	0	122	58	82	110	48	88	179.71	
7	17JAN96	52, .	0	122	68	82	120	74	100	181.47	
8	24JAN96	59, .	0	120	64	102	110	60	112	179.27	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	205000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	RESULT IS AN	U	.	U	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	34.5	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00080 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	106	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11DEC95	1	17DEC95	7	7
00081	Oral	2	20 MG	18DEC95	8	27DEC95	17	10
00081	Oral	3	20 MG	28DEC95	18	02JAN96	23	6
00081	Oral	4	20 MG	03JAN96	24	09JAN96	30	7
00081	Oral	5	30 MG	10JAN96	31	16JAN96	37	7
00081	Oral	5	30 MG	17JAN96	38	23JAN96	44	7
00081	Oral	5	30 MG	24JAN96	45	30JAN96	51	7
00081	Oral	6	40 MG	31JAN96	52	06FEB96	58	7
	Oral	6	40 MG	07FEB96	59	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	59	40	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{DAILY}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-193, .	01JUN95	.	500MGS	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Increased Appetite	INCREASED APPETITE	9, .	16 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	18, .	14 Days	20	CON	MIL	NO	PBU	No	No
	Somnolence	SOMNOLENCE	9, .	23 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
BL	11DEC95	1, .	0	110	70	92	110	80	92	110.00	63.5
1	18DEC95	8, .	20	92	50	100	110	60	102	111.79	
2	28DEC95	18, .	20	104	64	86	106	70	96	109.15	
3	03JAN96	24, .	20	104	58	92	104	66	102	111.35	
4	10JAN96	31, .	30	104	70	102	106	80	114	110.25	
5	17JAN96	38, .	30	104	58	104	110	70	108	113.56	
6	24JAN96	45, .	30	104	60	96	110	62	108	113.34	
7	31JAN96	52, .	40	100	58	100	94	56	112	110.69	
8	07FEB96	59, .	40	110	66	84	102	74	82	111.79	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
				Hematocrit	35.8	.	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	188	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59 (1)	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.2	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.6	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	156	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00081 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	59 (1)	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	H	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11DEC95	1	27DEC95	17	17
00082	Oral	2	100 MG	28DEC95	18	02JAN96	23	6
00082	Oral	3	150 MG	03JAN96	24	10JAN96	31	8
00082	Oral	4	200 MG	11JAN96	32	16JAN96	37	6
00082	Oral	5	250 MG	17JAN96	38	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	38	250	Lost to follow-up	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
GU SYSTEM/SEX HORMONES	Desogestrel	Desogen-28	-344, .	01JAN95	.	X 1	BIRTH CONTROL
	Ethinylestradiol	Desogen-28	-344, .	01JAN95	.	X 1	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	23, .	04:00 Hrs	100	1	MOD	NO	PSR	No	No
			38, .	Not Stated	250	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	38, .	Not Stated	250	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZY	24, .	Not Stated	150	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11DEC95	1, .	0	108	66	56	110	67	93	120.00	63.5
2	28DEC95	18, .	100	100	65	70	110	70	90	118.50	
3	03JAN96	24, .	150	116	60	88	104	58	118	119.07	
4	11JAN96	32, .	200	132	63	93	121	55	89	120.25	
5	17JAN96	38, .	250	124	80	92	114	74	116	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	10.5	H	.	+	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00082 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	08NOV94	1	14NOV94	7	7
00085	Oral	2	0 MG	15NOV94	8	20NOV94	13	6
00085	Oral	3	0 MG	21NOV94	14	27NOV94	20	7
00085	Oral	4	0 MG	28NOV94	21	05DEC94	28	8
00085	Oral	5	0 MG	06DEC94	29	12DEC94	35	7
00085	Oral	6	0 MG	13DEC94	36	19DEC94	42	7
00085	Oral	6	0 MG	20DEC94	43	27DEC94	50	8
00085	Oral	6	0 MG	28DEC94	51	03JAN95	57	7
	Oral	5	0 MG	04JAN95	58	17JAN95	71	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	71	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EKG SHOWS RAPID HEART RATE DUE TO PREVIOUS BLOOD DRAWING-NORMAL	TACHYCARDIA, UNSPEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1988

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	45, .	4 Days	0	1	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	26OCT94	-13, .	0	110	70	110	100	80	120	199.00	63.8
BL	07NOV94	-1, .	0	90	60	96	90	60	96	207.50	
1	14NOV94	7, .	0	98	58	104	.	.	104	204.50	
2	21NOV94	14, .	0	110	70	100	110	70	100	203.00	
3	28NOV94	21, .	0	110	80	100	106	80	100	206.00	
4	05DEC94	28, .	0	110	70	104	110	70	104	208.00	
5	12DEC94	35, .	0	108	74	96	108	74	96	209.00	
6	19DEC94	42, .	0	110	70	96	110	72	96	203.00	
7	27DEC94	50, .	0	110	76	92	112	76	92	205.00	
8	03JAN95	57, .	0	130	86	100	120	86	100	207.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	25.7	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-13	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	3	L	.	.	4 - 12	%
				Segmented Neutrophils	70	.	.	.	30 - 70	%
				Lymphocytes	13	L	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00085 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	4.6	H	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	63	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	.	.	.	30 - 70	%
				Lymphocytes	23.6	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	276000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28NOV94	1	04DEC94	7	7
00086	Oral	2	0 MG	05DEC94	8	12DEC94	15	8
00086	Oral	3	0 MG	13DEC94	16	19DEC94	22	7
00086	Oral	4	0 MG	20DEC94	23	27DEC94	30	8
00086	Oral	5	0 MG	28DEC94	31	03JAN95	37	7
00086	Oral	6	0 MG	04JAN95	38	09JAN95	43	6
00086	Oral	6	0 MG	10JAN95	44	17JAN95	51	8
00086	Oral	6	0 MG	18JAN95	52	23JAN95	57	6
00038	Oral	6	0 MG	24JAN95	58	19FEB95	84	27
00038	Oral	6	0 MG	20FEB95	85	28MAR95	121	37
00038	Oral	6	0 MG	29MAR95	122	25APR95	149	28
00038	Oral	6	0 MG	26APR95	150	30MAY95	184	35
00038	Oral	6	0 MG	31MAY95	185	11JUL95	226	42
00038	Oral	6	0 MG	12JUL95	227	16AUG95	262	36
00086	Oral	5	0 MG	17AUG95	263	18AUG95	264	2
00086	Oral	4	0 MG	19AUG95	265	20AUG95	266	2
00086	Oral	3	0 MG	21AUG95	267	22AUG95	268	2
00086	Oral	2	0 MG	23AUG95	269	25AUG95	271	3
00086	Oral	1	0 MG	26AUG95	272	02SEP95	279	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	Yes	279	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ABDOMINAL PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
RHINORRHEA	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-58, -115	01OCT94	08OCT94#	500MG	ABD.PAIN
			36, -22	02JAN95	03JAN95	500MG	FEVER
DERMATOLOGICALS	Calamine	Caladryl Lotion	78, 21	13FEB95	25APR95	LOCAL TOPICAL	RASH
	Camphor	Caladryl Lotion	78, 21	13FEB95	25APR95	LOCAL TOPICAL	RASH
	Diphenhydramine Hydrochloride	Caladryl Lotion	78, 21	13FEB95	25APR95	LOCAL TOPICAL	RASH
	Glycerol	Caladryl Lotion	78, 21	13FEB95	25APR95	LOCAL TOPICAL	RASH
RESPIRATORY	Aminoacetic Acid	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
	Benzalkonium Chloride	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
	Clemastine Fumarate	Tavist D	15, -43	12DEC94	14DEC94		COLD
		Tavist-D	169, 112	15MAY95	19MAY95	2 TSP	COLD
	Oxymetazoline Hydrochloride	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
	Phenylmercuric Acetate	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA
	Phenylpropanolamine Hydrochloride	Tavist D	15, -43	12DEC94	14DEC94		COLD
		Tavist-D	169, 112	15MAY95	19MAY95	2 TSP	COLD
	Sorbitol	Afrin	-423, -480	01OCT93	09NOV94#	1 SPRAY PRN	RHINORRHEA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Fever	FEVER	36, -22	02:00 Hrs	0		MIL	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	4, -54	Not Stated	0	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	15, -43	Not Stated	0	CON	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	15, -43	3 Days	0	CON	MIL	NO	UNR	Yes	No
			169, 112	5 Days	0	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Rash	RASH ON BACK	78, 21	72 Days	0	CON	MOD	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	09NOV94	-19, -76	0	127	70	71	123	76	78	93.70	58.0
BL	21NOV94	-7, -64	0	78	54	64	78	54	64	100.00	
1	05DEC94	8, -50	0	92	60	72	90	60	72	96.00	
2	12DEC94	15, -43	0	88	62	72	88	62	76	96.00	
3	19DEC94	22, -36	0	84	56	80	84	56	84	97.50	
4	27DEC94	30, -28	0	76	48	72	76	48	72	97.00	
5	03JAN95	37, -21	0	86	50	88	86	50	84	97.00	
6	09JAN95	43, -15	0	86	56	70	86	56	70	96.50	
7	17JAN95	51, -7	0	90	58	84	90	58	84	98.50	
8	23JAN95	57, -1	0	84	56	72	84	56	76	98.00	
12	13FEB95	78, 21	0	84	56	80	84	56	80	98.00	
16	28MAR95	121, 64	0	86	54	72	86	54	72	100.00	
20	25APR95	149, 92	0	84	54	80	84	54	80	100.00	
28	30MAY95	184, 127	0	80	50	84	80	50	84	100.50	
32	11JUL95	226, 169	0	82	52	84	80	50	84	100.00	
32	17AUG95	263, 206	0	84	52	84	80	52	84	95.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-19	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	20000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	178	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-19	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	17.1	H	.	.	12 - 15.6	G/DL
				Hematocrit	52.3	H	.	.	35 - 46	%
				Red Blood Cell Count	5.9	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	215000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	173	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	144	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	149	Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	263	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.9	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	199000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	124	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00086 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	263	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00087 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	31JAN95	1	03FEB95	4	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	4	20	Other reason	VOLUNTARY WITHDRAWAL

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00087 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1994

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23JAN95	-8, .	0	110	70	84	110	70	84	135.00	67.0
BL	30JAN95	-1, .	0	110	70	84	110	70	84	135.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00087 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	24.9	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	10.8	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00087 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-4	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28FEB95	1	08MAR95	9	9
00088	Oral	2	100 MG	09MAR95	10	14MAR95	15	6
00088	Oral	3	150 MG	15MAR95	16	20MAR95	21	6
00088	Oral	4	200 MG	21MAR95	22	29MAR95	30	9
	Oral	4	200 MG	30MAR95	31	03APR95	35	5
00088	Oral	4	200 MG	04APR95	36	09APR95	41	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	41	200	Adverse event, including intercurrent illness	URINARY RETENTION

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	13, .	1 Days	100	1	MIL	NO	PSR	No	No
Digestive System	Constipation	CONSTIPATION	15, .	Not Stated	100	CON	MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	22, .	Not Stated	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	15, .	764 Days	100	CON	MIL	NO	PBU	No	No
Special Senses	Abnormal Vision	BLURRED VISION	15, .	Not Stated	100	CON	MIL	NO	PSR	No	No
	Taste Perversion	BAD TASTE	11, .	21 Days	100	CON	MIL	NO	PSR	No	No
Urogenital System	Urinary Retention	URINARY RETENTION	15, .	Not Stated	100	CON	SEV	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06FEB95	-22, .	0	.	.	.	110	62	84	109.00	52.3
BL	28FEB95	1, .	0	90	60	80	90	60	80	113.00	
1	09MAR95	10, .	100	90	60	96	90	60	96	111.00	
2	14MAR95	15, .	100	96	56	100	96	56	100	111.00	
3	21MAR95	22, .	200	90	60	96	90	60	96	112.00	
4	30MAR95	31, .	200	80	50	96	80	50	96	111.00	
5	04APR95	36, .	200	82	50	96	82	50	96	110.00	
6	11APR95	43, .	200	84	58	96	84	58	96	109.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-22	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	58.5	.	.	.	30 - 70	%
				Lymphocytes	29.2	.	.	.	21 - 51	%
				Monocytes	11.2	H	.	.	0 - 10	%
				Eosinophils	0.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	45000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	5	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00088 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-22	Urine Protein - Dipstick	NEG	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07MAR95	1	13MAR95	7	7
00089	Oral	2	20 MG	14MAR95	8	21MAR95	15	8
00089	Oral	3	20 MG	22MAR95	16	27MAR95	21	6
00089	Oral	4	20 MG	28MAR95	22	04APR95	29	8
00089	Oral	4	20 MG	05APR95	30	11APR95	36	7
00089	Oral	4	20 MG	12APR95	37	18APR95	43	7
00089	Oral	4	20 MG	19APR95	44	25APR95	50	7
00089	Oral	4	20 MG	26APR95	51	01MAY95	56	6
	Oral	3	20 MG	02MAY95	57	05MAY95	60	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	60	20	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	8, .	14MAR95	.	500MG	HEADACHE
			42, .	17APR95	18APR95	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	TIRED	4, .	Not Stated	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	8, .	8 Days	20	CON	MIL	NO	PSR	Yes	No
			42, .	24:00 Hrs	20		MOD	NO	UNR	Yes	No
Digestive System	Constipation	CONSTIPATION	15, .	7 Days	20		MIL	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	15, .	Not Stated	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	4, .	Not Stated	20	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS WHEN STANDING	8, .	24:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Euphoria	ELATION AND EXPANSIVE MOOD	29, .	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Insomnia	SLEEP PROBLEMS-EXAMPLE WAKES UP TOO EARLY	8, .	Not Stated	20	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	27, .	Not Stated	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24FEB95	-11, .	0	110	70	72	.	.	.	115.00	67.5
BL	07MAR95	1, .	0	96	66	84	96	66	84	115.00	
1	14MAR95	8, .	20	90	62	92	90	62	92	115.50	
2	21MAR95	15, .	20	90	60	84	90	60	84	116.00	
3	28MAR95	22, .	20	90	62	88	90	62	88	117.00	
4	04APR95	29, .	20	90	60	84	90	60	84	117.00	
5	11APR95	36, .	20	100	62	96	100	62	96	118.00	
6	18APR95	43, .	20	100	60	92	100	60	92	116.50	
7	25APR95	50, .	20	96	60	88	96	60	88	119.00	
8	02MAY95	57, .	20	100	60	100	100	60	100	120.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-63	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	42	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	188	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-63	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3	.	.	.	30 - 70	%
				Lymphocytes	23.9	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	319000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00089 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	14MAR95	1	18MAR95	5	5
00090	Oral	1	50 MG	19MAR95	6	23MAR95	10	5
00090	Oral	1	50 MG	24MAR95	11	27MAR95	14	4
00090	Oral	2	100 MG	28MAR95	15	03APR95	21	7
00090	Oral	3	150 MG	04APR95	22	10APR95	28	7
00090	Oral	4	200 MG	11APR95	29	17APR95	35	7
00090	Oral	4	200 MG	18APR95	36	25APR95	43	8
00090	Oral	5	250 MG	26APR95	44	01MAY95	49	6
00090	Oral	4	200 MG	02MAY95	50	08MAY95	56	7
00090	Oral	4	200 MG	09MAY95	57	15MAY95	63	7
	Oral	3	150 MG	16MAY95	64	21MAY95	69	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	69	150	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
IRRITABLE BOWEL SYNDROME	DIGESTIVE DISORD, OTHER	DIGESTIVE SYST	CUR	1987

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Mylanta	50, .	02MAY95	.	UNKNOWN	INDIGESTION
	Dimeticone, Activated	Mylanta	50, .	02MAY95	.	UNKNOWN	INDIGESTION
	Enema, Nos	Enema Nos	49, .	01MAY95	01MAY95		CONSTIPATION
	Magnesium Hydroxide	Mylanta	50, .	02MAY95	.	UNKNOWN	INDIGESTION
	Senna Fruit	Senokot	50, .	02MAY95	.	UNKNOWN	CONSTIPATION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	., .		.		HEADACHE
			50, .	02MAY95	02MAY95	650MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	3, .	16MAR95	.	400MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	3, .	13 Days	50	CON	SEV	DCR	PSR	Yes	No
		HEADACHES	29, .	15 Days	200	CON	MIL	NO	PSR	Yes	No
			44, .	9 Days	250	CON	MOD	DCR	PSR	Yes	No
			53, .	1 Days	200	3	MIL	NO	PSR	Yes	No
Digestive System	Constipation	CONSTIPATION	44, .	6 Days	250	CON	SEV	DCR	PSR	Yes	No
			50, .	Not Stated	200	CON	MOD	NO	PSR	Yes	No
	Dry Mouth	DRY MOUTH	15, .	15 Days	100	CON	MIL	NO	PSR	No	No
	Dyspepsia	HEARTBURN	50, .	Not Stated	200	CON	MIL	NO	PSR	Yes	No
		INDIGESTION	44, .	6 Days	250	CON	MOD	DCR	PSR	No	No
			50, .	Not Stated	200	CON	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	15, .	29 Days	100	CON	MIL	NO	PSR	No	No
			57, .	Not Stated	200	CON	MIL	NO	PSR	No	No
Special Senses	Taste Perversion	BAD TASTE	3, .	5 Days	50	CON	MIL	DCR	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08MAR95	-6, .	0	100	60	70	100	60	72	137.00	64.0
BL	14MAR95	1, .	0	70	44	80	70	44	80	140.00	
2	28MAR95	15, .	100	96	60	84	96	60	84	139.00	
3	04APR95	22, .	150	100	60	80	100	60	80	138.00	
4	11APR95	29, .	200	96	60	84	90	60	84	140.00	
5	18APR95	36, .	200	96	60	84	80	60	84	137.50	
6	25APR95	43, .	200	90	60	84	90	60	84	139.50	
7	02MAY95	50, .	200	100	60	88	100	60	88	138.00	
8	09MAY95	57, .	200	96	56	84	96	56	84	139.00	
8	16MAY95	64, .	150	92	58	96	92	58	96	140.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.9	.	.	.	30 - 70	%
				Lymphocytes	42.3	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	275000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	128	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	45	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00090 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	64		Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/UNSCHEDULED LAB 1	78	(9)	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
					Hematocrit	40.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.9	.	.	.	30 - 70	%
					Lymphocytes	39.7	.	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	0.8	.	.	.	0 - 5	%
					Basophils	0.6	.	.	.	0 - 2	%
					Platelets	310000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	24MAR95	1	28MAR95	5	5
00091	Oral	2	20 MG	29MAR95	6	04APR95	12	7
00091	Oral	3	20 MG	05APR95	13	11APR95	19	7
00091	Oral	4	20 MG	12APR95	20	18APR95	26	7
00091	Oral	5	30 MG	19APR95	27	25APR95	33	7
00091	Oral	6	40 MG	26APR95	34	01MAY95	39	6
00091	Oral	6	40 MG	02MAY95	40	09MAY95	47	8
00091	Oral	6	40 MG	10MAY95	48	16MAY95	54	7
00033	Oral	6	40 MG	17MAY95	55	16JUN95	85	31
00033	Oral	6	40 MG	17JUN95	86	14JUL95	113	28
00033	Oral	6	40 MG	15JUL95	114	10AUG95	140	27
00033	Oral	6	40 MG	11AUG95	141	05SEP95	166	26
00033	Oral	6	40 MG	06SEP95	167	02OCT95	193	27
00033	Oral	6	40 MG	03OCT95	194	07NOV95	229	36
00091	Oral	5	30 MG	08NOV95	230	09NOV95	231	2
00091	Oral	4	20 MG	10NOV95	232	11NOV95	233	2
00091	Oral	3	20 MG	12NOV95	234	13NOV95	235	2
00091	Oral	2	20 MG	14NOV95	236	16NOV95	238	3
00091	Oral	1	20 MG	17NOV95	239	23NOV95	245	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	245	20		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	211, 157	20OCT95	30OCT95	1000 MG	COLD AND SORE THROAT
	Penicillin Nos	Penicillin	182, 128	21SEP95	01OCT95	1000 MG	SORE THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	9, -46	01APR95	01APR95	650MG	HEADACHE
			36, -19	28APR95	02MAY95	650MG	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, -53	15 Mins	20		MIL	NO	PBU	No	No
Digestive System	Nausea	NAUSEA	3, -52	10 Mins	20		MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS"FELT LIKE FAINTING"	9, -46	01:30 Hrs	20		MOD	NO	PSR	Yes	No
Respiratory System	Pharyngitis	SORE THROAT	182, 128	11 Days	40	1	MOD	NO	UNR	Yes	No
	Respiratory Disorder	COLD {SYMPTOMS}	36, -19	5 Days	40	1	MIL	NO	UNR	Yes	No
			211, 157	11 Days	40	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14MAR95	-10, -64	0	108	64	72	110	70	72	126.00	67.0
BL	24MAR95	1, -54	0	90	60	72	90	60	72	131.00	
1	28MAR95	5, -50	20	90	56	72	90	56	72	131.00	
2	04APR95	12, -43	20	100	60	84	100	60	84	130.00	
3	11APR95	19, -36	20	100	60	84	100	60	84	131.50	
4	18APR95	26, -29	20	90	60	84	90	60	84	132.00	
5	25APR95	33, -22	30	110	60	80	100	60	80	133.00	
6	02MAY95	40, -15	40	120	66	80	120	66	80	132.00	
7	09MAY95	47, -8	40	116	64	84	116	64	84	132.00	
8	16MAY95	54, -1	40	110	60	80	110	60	80	132.00	
12	16JUN95	85, 31	40	110	60	76	110	60	76	131.50	
16	14JUL95	113, 59	40	110	70	84	100	60	84	128.00	
20	10AUG95	140, 86	40	106	66	72	100	66	72	132.00	
24	05SEP95	166, 112	40	98	58	72	98	58	72	127.00	
28	03OCT95	194, 140	40	96	54	80	96	54	80	128.00	
32	07NOV95	229, 175	40	86	54	84	86	54	84	129.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	7.8	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	103	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-10	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.5	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	9.9	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	140	Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	229	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.5	.	.	.	30 - 70	%
				Lymphocytes	20	L	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	250000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00091 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	229	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	03MAY95	1	11MAY95	9	9
00092	Oral	2	100 MG	12MAY95	10	16MAY95	14	5
00092	Oral	3	150 MG	17MAY95	15	25MAY95	23	9
00092	Oral	4	200 MG	26MAY95	24	02JUN95	31	8
00092	Oral	4	200 MG	03JUN95	32	05JUN95	34	3
00092	Oral	4	200 MG	06JUN95	35	13JUN95	42	8
00092	Oral	4	200 MG	14JUN95	43	20JUN95	49	7
00092	Oral	4	200 MG	21JUN95	50	29JUN95	58	9
00035	Oral	4	200 MG	30JUN95	59	08AUG95	98	40
00035	Oral	4	200 MG	09AUG95	99	05SEP95	126	28
00035	Oral	4	200 MG	06SEP95	127	26SEP95	147	21
00035	Oral	4	200 MG	27SEP95	148	21OCT95	172	25
00035	Oral	0	0 MG	22OCT95	173	23OCT95	174	2
00035	Oral	4	200 MG	24OCT95	175	07NOV95	189	15
00035	Oral	4	200 MG	08NOV95	190	05DEC95	217	28
00035	Oral	4	200 MG	06DEC95	218	02JAN96	245	28
00092	Oral	5	250 MG	03JAN96	246	04JAN96	247	2
00092	Oral	4	200 MG	05JAN96	248	06JAN96	249	2
00092	Oral	3	150 MG	07JAN96	250	08JAN96	251	2
00092	Oral	2	100 MG	09JAN96	252	11JAN96	254	3
00092	Oral	1	50 MG	12JAN96	255	18JAN96	261	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	Yes	261	50		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Mylanta	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Bismuth Subsalicylate	Pepto Bismol	39, -20	10JUN95	10JUN95	2TBP	CRAMPS
	Caffeine	Coke Syrup	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Corn Syrup	Coke Syrup	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Dimeticone, Activated	Mylanta	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Magnesium Hydroxide	Milk Of Magnesia	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
		Mylanta	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.
	Natural Flavors	Coke Syrup	173, 115	22OCT95	23OCT95	UNKNOWN	STOMACH PROB.

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	234, 176	02:00 Hrs	200	1	MIL	NO	PBU	No	No
		STOMACH CRAMPS	19, -40	30 Mins	150	2	MIL	NO	PBU	No	No
			39, -20	1 Days	200	1	MOD	NO	PBU	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	2, -57	146 Days	50	CON	MIL	NO	PSR	No	No
	Gastrointestinal Disorder	STOMACH PROBLEMS	173, 115	2 Days	0		MOD	DCR	PBU	Yes	No
Nervous System	Somnolence	DROWSINESS	15, -44	16 Days	150	CON	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	-2, -60	16 Days	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	13APR95	-20, -78	0	104	60	68	104	62	72	99.00	60.5
BL	02MAY95	-1, -59	0	94	56	72	94	56	72	102.00	
1	11MAY95	9, -50	50	88	56	76	88	56	76	101.00	
2	16MAY95	14, -45	100	90	60	96	90	60	96	101.50	
3	26MAY95	24, -35	200	90	60	88	90	60	88	99.50	
4	02JUN95	31, -28	200	90	64	96	90	64	96	99.50	
5	06JUN95	35, -24	200	100	60	88	.	.	.	100.00	
6	13JUN95	42, -17	200	106	66	88	106	66	88	98.50	
7	20JUN95	49, -10	200	100	60	84	100	60	84	99.00	
8	30JUN95	59, 1	200	100	60	84	100	60	84	99.50	
12	08AUG95	98, 40	200	96	62	84	90	62	84	97.00	
16	05SEP95	126, 68	200	92	66	84	90	66	84	98.00	
20	26SEP95	147, 89	200	96	62	96	90	60	96	101.00	
28	07NOV95	189, 131	200	90	58	88	90	58	88	98.00	
32	05DEC95	217, 159	200	90	60	84	90	60	84	103.00	
32	02JAN96	245, 187	200	100	60	84	100	60	84	102.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-20	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.2	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.3	.	.	.	30 - 70	%
				Lymphocytes	46.2	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	192000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	320	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	60 - 110	MG/DL
				Globulin	2.8	.	.	.	2.1 - 3.8	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-5	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/UNSCHEDULED LAB 1	-5	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	40	.	.	.	30 - 70	%
				Lymphocytes	52	H	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	245	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	65	Glucose - Random	101	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	42.4	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	223	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	60	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.9	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 16/CONTINUATION-WEEK 32	245	Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	7000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	225	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	2.8	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00092 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 16/CONTINUATION-WEEK 32	245	Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/UNSCHEDULED LAB 1	259	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	27.6	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	187000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	21JUN95	1	26JUN95	6	6
00093	Oral	2	100 MG	27JUN95	7	06JUL95	16	10
00093	Oral	3	150 MG	07JUL95	17	21JUL95	31	15
00093	Oral	4	200 MG	22JUL95	32	25JUL95	35	4
00093	Oral	5	250 MG	26JUL95	36	01AUG95	42	7
00093	Oral	6	300 MG	02AUG95	43	10AUG95	51	9
00093	Oral	6	300 MG	11AUG95	52	16AUG95	57	6
00093	Oral	6	300 MG	17AUG95	58	22AUG95	63	6
00053	Oral	6	300 MG	23AUG95	64	08SEP95	80	17

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	80	300	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1989
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Butalbital	Butalbital	-171, -234	01JAN95	.	1 DAILY PRN	HEADACHES
RESPIRATORY	Salbutamol	Albuterol	-1997,-2060	01JAN90	.	8 PUFFS DAILY PRN	ASTHMA
			-1997,-2060	01JAN90	.	8 PUFFS DAILY PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	-1, -64	106 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	49, -15	20 Mins	300	1	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08JUN95	-13, -76	0	106	70	64	110	70	70	127.00	61.5
BL	20JUN95	-1, -64	0	90	60	84	90	60	84	125.00	
1	27JUN95	7, -57	100	90	60	84	90	60	84	122.50	
2	06JUL95	16, -48	100	90	60	84	90	60	84	125.00	
4	21JUL95	31, -33	150	86	60	84	80	60	84	125.00	
5	25JUL95	35, -29	200	92	56	88	90	56	88	125.00	
6	01AUG95	42, -22	250	84	54	100	86	54	100	126.00	
7	10AUG95	51, -13	300	86	54	96	80	54	96	126.00	
8	22AUG95	63, -1	300	90	60	88	86	60	88	126.00	
16	03OCT95	105, 42#	0	90	60	80	90	60	80	128.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	27	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-8	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.5	.	.	.	30 - 70	%
				Lymphocytes	36.2	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	361000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/UNSCHEDULED LAB	-8	Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
	1									
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	30	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	108	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	63		Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	77	.	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF NEG		.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/UNSCHEDULED LAB 1	72		Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.7	.	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
					Platelets	344000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
		VISIT 11/CONTINUATION-WEEK 12	105	(25)	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.4	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	59.6	.	.	.	30 - 70	%
					Lymphocytes	29.7	.	.	.	21 - 51	%
					Monocytes	5	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00093 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/CONTINUATION-WEEK 12	105 (25)	Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	370000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	109	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	24OCT95	1	30OCT95	7	7
00094	Oral	2	0 MG	31OCT95	8	06NOV95	14	7
00094	Oral	3	0 MG	07NOV95	15	13NOV95	21	7
00094	Oral	4	0 MG	14NOV95	22	20NOV95	28	7
00094	Oral	5	0 MG	21NOV95	29	27NOV95	35	7
00094	Oral	6	0 MG	28NOV95	36	04DEC95	42	7
00094	Oral	6	0 MG	05DEC95	43	11DEC95	49	7
00094	Oral	6	0 MG	12DEC95	50	19DEC95	57	8
	Oral	5	0 MG	20DEC95	58	04JAN96	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	73	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGY TO PENICILLIN {PATIENT GETS A RASH}	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	
SKIN CUTS MULTIPLE {SUPERFICIAL ON LEFT FOREARM}	OPEN WOUND	INJURY/POISONING	CUR	1995
SKIN CUTS MULTIPLE {SUPERFICIAL ON RIGHT THIGH}	OPEN WOUND	INJURY/POISONING	CUR	1995
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Omeprazole	Prilosec	32, .	24NOV95	.	PRN	ACIDITY
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	49, .	11DEC95	11DEC95	500MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	WEAKNESS	49, .	02:00 Hrs	0	1	MOD	NO	PSR	No	No
			50, .	Not Stated	0	CON	MIL	NO	PBU	No	No
	Headache	HEADACHE	49, .	02:00 Hrs	0	1	MOD	NO	PSR	No	No
			50, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Digestive System	Dyspepsia	STOMACH ACIDITY	32, .	Not Stated	0	CON	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	49, .	02:00 Hrs	0	1	MOD	NO	PSR	No	No
Skin and Appendages	Rash	RASH {MINOR OF UNKNOWN CAUSES}	5, .	24:00 Hrs	0	1	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	20OCT95	-4, .	0	108	62	.	100	70	70	112.00	64.5
BL	24OCT95	1, .	0	110	20	84	110	70	84	118.00	
1	31OCT95	8, .	0	116	74	108	116	74	108	113.00	
2	07NOV95	15, .	0	110	70	88	110	70	84	111.00	
3	14NOV95	22, .	0	114	78	84	114	78	84	111.50	
4	21NOV95	29, .	0	110	70	84	110	70	84	112.00	
5	28NOV95	36, .	0	112	74	104	112	74	104	113.00	
6	05DEC95	43, .	0	114	74	84	114	74	84	111.00	
7	12DEC95	50, .	0	100	64	96	100	64	96	110.50	
8	19DEC95	57, .	0	100	66	96	100	66	96	111.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73	H	.	.	30 - 70	%
				Lymphocytes	19.4	L	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	71	Hemoglobin	13		.	.	12 - 15.6	G/DL
				Hematocrit	37.2		.	.	35 - 46	%
				Red Blood Cell Count	4.4		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.7		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H	.	.	30 - 70	%
				Lymphocytes	19.3	L	.	.	21 - 51	%
				Monocytes	3		.	.	0 - 10	%
				Eosinophils	3.3		.	.	0 - 5	%
				Basophils	0.9		.	.	0 - 2	%
				Platelets	206000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4		.	.	25 - 35	PG
				Mean Corpuscle Volume	84		.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	115		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00094 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	71	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	01FEB96	1	06FEB96	6	6
00247	Oral	2	100 MG	07FEB96	7	12FEB96	12	6
00247	Oral	3	150 MG	13FEB96	13	20FEB96	20	8
00247	Oral	4	200 MG	21FEB96	21	27FEB96	27	7
00247	Oral	4	200 MG	28FEB96	28	07MAR96	36	9
00247	Oral	4	200 MG	08MAR96	37	11MAR96	40	4
00247	Oral	4	200 MG	12MAR96	41	21MAR96	50	10
00247	Oral	4	200 MG	22MAR96	51	25MAR96	54	4
00128	Oral	4	200 MG	26MAR96	55	29APR96	89	35
00128	Oral	4	200 MG	30APR96	90	20MAY96	110	21
00128	Oral	4	200 MG	21MAY96	111	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	111	200	Protocol violation, including non-compliance	CHOSE TO LEAVE STUDY EARLY

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Phenol	Chloraseptic	34, -21	05MAR96	.		COLD
RESPIRATORY	Dextromethorphan Hydrobromide	Nyquil	34, -21	05MAR96	.		COLD
	Doxylamine Succinate	Nyquil	34, -21	05MAR96	.		COLD
	Paracetamol	Nyquil	34, -21	05MAR96	.		COLD
	Pseudoephedrine Hydrochloride	Nyquil	34, -21	05MAR96	.		COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	TIRED	90, 36	1 Days	200	1	MIL	NO	UNR	No	No
Cardiovascular System	Postural Hypotension	DIZZINESS WHEN STANDING UP ORTHOSTATIC HYPOTENSION	9, -46	33 Days	100	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	10, -45	23 Days	100	CON	MIL	NO	PSR	No	No
			36, -19	15 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS WHEN WAKING UP IN AM	10, -45	32 Days	100		MIL	NO	PSR	No	No
	Nervousness	IRRITABLE EDGY BURNT SELF WITH CIGARETTE	45, -10	11 Days	200	1	MIL	DCR	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	34, -21	3 Days	200	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05JAN96	-27, -81	0	90	62	.	.	.	.	132.00	70.5
BL	30JAN96	-2, -56	0	100	60	72	100	60	72	130.00	
1	06FEB96	6, -49	50	100	60	72	100	60	72	130.00	
2	13FEB96	13, -42	150	96	60	84	80	56	84	131.00	
3	20FEB96	20, -35	150	98	56	88	100	56	88	131.00	
4	27FEB96	27, -28	200	96	68	112	90	64	112	130.00	
5	07MAR96	36, -19	200	102	60	96	102	60	96	135.00	
6	12MAR96	41, -14	200	96	62	96	96	60	96	132.00	
7	21MAR96	50, -5	200	94	60	96	94	60	96	132.00	
8	26MAR96	55, 1	200	90	60	84	90	60	84	131.00	
12	30APR96	90, 36	200	100	60	84	96	60	88	135.00	
16	21MAY96	111, 57	200	90	60	96	90	60	96	131.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.2	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	139	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	30.2	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00247 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	01MAR96	1	05MAR96	5	5
00248	Oral	2	20 MG	06MAR96	6	11MAR96	11	6
00248	Oral	3	20 MG	12MAR96	12	18MAR96	18	7
00248	Oral	4	20 MG	19MAR96	19	25MAR96	25	7
00248	Oral	5	30 MG	26MAR96	26	01APR96	32	7
00248	Oral	6	40 MG	02APR96	33	10APR96	41	9
00248	Oral	6	40 MG	11APR96	42	15APR96	46	5
00248	Oral	6	40 MG	16APR96	47	22APR96	53	7
	Oral	5	30 MG	23APR96	54	02MAY96	63	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	63	30	Lack of Efficacy	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	60, .	29APR96	.		HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU	33, .	10 Days	40	CON	MIL	NO	UNR	No	No
Cardiovascular System	Arrhythmia	IRREGULAR PULSE	-8, .	Not Stated	0	CON	MIL	NO	UNR	No	No
Hemic and Lymphatic System	Anemia	ANEMIA	54, .	Not Stated	30	CON	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	26, .	17 Days	30	CON	MIL	NO	PSR	No	No
	Withdrawal Syndrome	MIGRAINE HEADACHE {WITHDRAWAL SYMPTOM}	60, .	6 Days	30	CON	SEV	NO	REL	Yes	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14FEB96	-16, .	0	100	60	.	.	.	.	121.00	65.5
BL	22FEB96	-8, .	0	80	50	64	80	50	64	129.00	
1	05MAR96	5, .	20	88	54	64	80	50	64	125.00	
2	12MAR96	12, .	20	94	58	68	94	58	68	124.00	
3	19MAR96	19, .	20	90	60	72	90	60	72	125.00	
4	26MAR96	26, .	30	96	56	80	90	56	80	126.00	
5	02APR96	33, .	40	96	62	80	90	60	80	126.00	
6	11APR96	42, .	40	94	60	80	90	60	80	122.00	
7	16APR96	47, .	40	94	62	80	90	60	80	124.00	
8	23APR96	54, .	30	86	62	80	80	60	80	123.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.5	.	.	.	30 - 70	%
				Lymphocytes	37.6	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	210000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	156	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	11.9	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.4	L	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2	.	.	.	30 - 70	%
				Lymphocytes	39.9	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	7.3	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	228000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	137	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00248 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	07MAR96	1	11MAR96	5	5
00249	Oral	2	100 MG	12MAR96	6	18MAR96	12	7
00249	Oral	3	150 MG	19MAR96	13	25MAR96	19	7
00249	Oral	4	200 MG	26MAR96	20	01APR96	26	7
00249	Oral	5	250 MG	02APR96	27	08APR96	33	7
00249	Oral	6	300 MG	09APR96	34	15APR96	40	7
00249	Oral	6	300 MG	16APR96	41	22APR96	47	7
00249	Oral	6	300 MG	23APR96	48	29APR96	54	7
	Oral	5	250 MG	30APR96	55	07MAY96	62	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	62	250	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
CIGARETTE SMOKER	TOBACCO USE	MENTAL DISORD	CUR	
DYSMENORRHEA	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1991
NEAR-SIGHTED	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	CUR	
SCARS LEFT AND RIGHT FOREARM	SCARRING	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-1892, .	01JAN91	.		HEADACHE
			3, .	09MAR96	09MAR96	200 MG	HEADACHE
			38, .	13APR96	15APR96	400 MG BID	MENSTRUAL CRAMPS
RESPIRATORY	Chlorphenamine Maleate	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD
	Dextromethorphan Hydrobromide	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD
	Paracetamol	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD
	Phenylpropanolamine Hydrochloride	Comtrex	48, .	23APR96	23APR96	800 MG X1	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	1, .	3 Days	50	2	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	40, .	1 Mins	300	1	MIL	NO	PSR	No	No
		DIZZINESS (ORTHOSTATIC)	41, .	2 Mins	300		MIL	NO	PSR	No	No
		LIGHT HEADEDNESS	14, .	14 Days	150	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	48, .	8 Days	300		MIL	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	38, .	3 Days	300		MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	01MAR96	-6, .	0	90	60	78	90	58	76	176.00	63.3
BL	07MAR96	1, .	0	86	60	88	86	60	88	176.00	
1	12MAR96	6, .	100	90	60	84	90	60	84	176.00	
2	19MAR96	13, .	150	100	70	96	100	70	96	177.00	
3	26MAR96	20, .	200	92	56	84	90	56	84	175.00	
4	02APR96	27, .	250	100	60	84	90	60	88	176.00	
5	09APR96	34, .	300	106	70	84	100	66	84	178.00	
6	16APR96	41, .	300	106	72	96	100	66	96	180.00	
7	23APR96	48, .	300	98	78	88	90	74	88	176.00	
8	30APR96	55, .	250	100	70	96	96	70	96	177.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	320000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.3	.	.	.	30 - 70	%
				Lymphocytes	37.5	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	376000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00249 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	14MAR96	1	18MAR96	5	5
00250	Oral	2	20 MG	19MAR96	6	25MAR96	12	7
00250	Oral	3	20 MG	26MAR96	13	01APR96	19	7
00250	Oral	4	20 MG	02APR96	20	11APR96	29	10
00250	Oral	5	30 MG	12APR96	30	18APR96	36	7
00250	Oral	6	40 MG	19APR96	37	22APR96	40	4
00250	Oral	6	40 MG	23APR96	41	29APR96	47	7
00250	Oral	5	30 MG	30APR96	48	09MAY96	57	10
00250	Oral	6	40 MG	10MAY96	58	12MAY96	60	3
00250	Oral	5	30 MG	13MAY96	61	27MAY96	75	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	75	30	Adverse event, including intercurrent illness	PT TOOK OVERDOSE & WAS HOSPITALIZED

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	47, -11	29APR96	29APR96	25 MG	ALLERGY
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	47, -11	29APR96	29APR96	25 MG	ALLERGY

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	ALLERGIES	47, -11	24:00 Hrs	40		MIL	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEOUS	2, -56	12 Days	20	CON	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	2, -56	5 Mins	20	2	MIL	NO	PBU	No	No
	Emotional Lability	OVERDOSE {INTENTIONAL}	37, -21	21 Days	40	CON	MOD	NO	UNR	No	Yes
			75, 18	01:00 Hrs	30	1	SEV	STP	UNR	No	Yes
	Somnolence	SLEEPINESS	37, -21	Not Stated	40	CON	MOD	DCR	PSR	No	No
		SLEEPY	2, -56	12 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05MAR96	-9, -66	0	110	70	60	100	65	64	180.00	64.0
BL	14MAR96	1, -57	0	100	60	96	100	60	96	186.00	
1	19MAR96	6, -52	20	120	66	88	110	60	88	181.00	
2	26MAR96	13, -45	20	100	60	84	100	60	84	179.00	
3	02APR96	20, -38	20	110	62	96	100	60	96	180.00	
4	12APR96	30, -28	30	118	76	96	110	70	96	181.00	
5	16APR96	34, -24	30	114	72	88	110	70	88	183.00	
6	23APR96	41, -17	40	112	68	96	110	68	96	181.00	
7	30APR96	48, -10	30	110	70	88	110	70	88	182.00	
8	09MAY96	57, -1	30	110	70	96	110	70	96	184.00	
12	28MAY96	76, 19	30	94	58	88	90	60	88	182.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	3	L	.	.	4 - 12	%
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	340000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	25.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	77	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00250 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	6	Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00251 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28MAR96	1	04APR96	8	8
00251	Oral	2	0 MG	05APR96	9	08APR96	12	4
00251	Oral	3	0 MG	09APR96	13	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	13	0	Lost to follow-up	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00251 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MYRINGOTOMY {TUBE PLACEMENT}	OPERATION, EAR	OPERATIONS	.	
DIZZINESS	DIZZINESS AND GIDDINESS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SHORTNESS OF BREATH	DYSPNEA, OTHER	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19MAR96	-9, .	0	120	80	60	120	90	61	124.50	61.0
1	04APR96	8, .	0	110	70	96	100	66	96	130.00	
2	09APR96	13, .	0	112	64	96	106	56	96	131.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00251 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.5	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00251 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	10APR96	1	16APR96	7	7
00252	Oral	2	0 MG	17APR96	8	23APR96	14	7
00252	Oral	3	0 MG	24APR96	15	30APR96	21	7
00252	Oral	4	0 MG	01MAY96	22	09MAY96	30	9
00252	Oral	4	0 MG	10MAY96	31	14MAY96	35	5
00252	Oral	5	0 MG	15MAY96	36	20MAY96	41	6
00252	Oral	4	0 MG	21MAY96	42	27MAY96	48	7
00252	Oral	4	0 MG	28MAY96	49	10JUN96	62	14
	Oral	3	0 MG	11JUN96	63	18JUN96	70	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	70	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIC TO SULFA DRUGS	ADVERSE EFF/ANTI-INFECT	EXT CAUSES OF INJURY/POISONING	CUR	
ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	
FACIAL CYSTIC ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	
MURMUR {I/VI SYSTOLIC EJECTION MURMUR}	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	39, .	18MAY96	18MAY96	2 TAB	HEADACHE
	Caffeine	Midol	39, .	18MAY96	18MAY96	2 TAB	HEADACHE
	Cinnamedrine Hydrochloride	Midol	39, .	18MAY96	18MAY96	2 TAB	HEADACHE
	Paracetamol	Tylenol	., .		.	500 MG	HEADACHE
DERMATOLOGICALS	Tretinoin	Retin-A	., .		.		CYSTIC ACNE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	16, .	20 Days	0	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE	21, .	30 Mins	0	5	MIL	NO	PSR	No	No
			39, .	02:00 Hrs	0	1	MOD	DCR	PSR	Yes	No
Digestive System	Nausea	NAUSEA	21, .	30 Mins	0	5	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	20, .	1 Mins	0	1	MIL	NO	PSR	No	No
	Nervousness	IRRITABILITY	37, .	13 Days	0	CON	MOD	DCR	PSR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	42, .	30 Mins	0	1	MIL	DCR	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19MAR96	-22, .	0	100	68	68	100	64	66	106.00	66.5
BL	09APR96	-1, .	0	100	60	88	100	60	88	109.00	
1	16APR96	7, .	0	102	58	96	100	58	96	113.00	
2	23APR96	14, .	0	90	56	.	100	56	104	113.00	
3	30APR96	21, .	0	102	54	100	100	54	100	113.00	
4	09MAY96	30, .	0	98	54	96	96	54	96	114.00	
5	14MAY96	35, .	0	100	56	96	100	56	96	114.00	
6	21MAY96	42, .	0	102	56	84	102	56	84	113.00	
7	28MAY96	49, .	0	100	60	84	100	60	84	113.00	
8	04JUN96	56, .	0	100	60	96	100	60	96	112.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
				Hematocrit	34	L	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.4	H	.	.	30 - 70	%
				Lymphocytes	22	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	103	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00252 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	30.7	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28FEB96	1	05MAR96	7	7
00289	Oral	2	100 MG	06MAR96	8	12MAR96	14	7
00289	Oral	3	150 MG	13MAR96	15	19MAR96	21	7
00289	Oral	4	200 MG	20MAR96	22	26MAR96	28	7
00289	Oral	4	200 MG	27MAR96	29	02APR96	35	7
00289	Oral	4	200 MG	03APR96	36	09APR96	42	7
00289	Oral	4	200 MG	10APR96	43	16APR96	49	7
00289	Oral	4	200 MG	17APR96	50	23APR96	56	7
00131	Oral	4	200 MG	24APR96	57	21MAY96	84	28
00131	Oral	4	200 MG	22MAY96	85	19JUN96	113	29
00131	Oral	4	200 MG	20JUN96	114	18JUL96	142	29
00131	Oral	4	200 MG	19JUL96	143	15AUG96	170	28
00131	Oral	4	200 MG	16AUG96	171	12SEP96	198	28
00131	Oral	4	200 MG	13SEP96	199	10OCT96	226	28
00289	Oral	3	150 MG	11OCT96	227	12OCT96	228	2
00289	Oral	2	100 MG	13OCT96	229	15OCT96	231	3
00289	Oral	1	50 MG	16OCT96	232	22OCT96	238	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	238	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES {TO POLLEN, TREES, DUST}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
DYSMENORRHEA	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
ASTHMA {AS YOUNG CHILD}	ASTHMA	RESPIRATORY SYST DIS	PRV	1981

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Mepyramine Maleate	Pamprin	.,	.	.	2 TABS	MENSTRUAL CRAMPS
	Pamabrom	Pamprin	.,	.	.	2 TABS	MENSTRUAL CRAMPS
	Paracetamol	Pamprin	.,	.	.	2 TABS	MENSTRUAL CRAMPS
		Tylenol	.,	.	.	1000MG	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	1, -56	85 Days	50		MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	13, -44	31 Days	100		MIL	NO	PSR	No	No
Hemic and Lymphatic System	Anemia	ANEMIA	227, 171	Not Stated	150	CON	MIL	NO	UNR	No	No
Nervous System	Insomnia	INSOMNIA	15, -42	129 Days	150		MIL	NO	PBU	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	57, 1	Not Stated	200	6	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12FEB96	-16, -72	0	110	56	76	104	62	76	118.63	63.0
1	06MAR96	8, -49	100	114	82	84	102	72	84	119.07	
2	13MAR96	15, -42	150	94	70	108	88	68	120	118.41	
3	20MAR96	22, -35	200	102	70	96	98	70	112	117.53	
4	27MAR96	29, -28	200	104	70	94	94	76	112	114.66	
5	03APR96	36, -21	200	94	64	96	84	66	112	113.12	
6	10APR96	43, -14	200	98	70	82	86	66	96	114.66	
7	17APR96	50, -7	200	100	66	98	92	62	112	116.87	
8	24APR96	57, 1	200	106	74	84	98	68	82	118.41	
12	22MAY96	85, 29	200	104	74	102	90	70	108	113.78	
16	20JUN96	114, 58	200	90	62	92	84	64	100	115.10	
20	19JUL96	143, 87	200	99	65	86	93	66	90	105.80 L	
24	16AUG96	171, 115	200	80 L	60	100	84	60	104	102.09 L	
28	13SEP96	199, 143	200	92	58	80	82	64	90	106.06 L	
32	11OCT96	227, 171	150	88	60	68	86	64	70	108.93 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.9	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	2.6	.	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-16	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	10.3	L	.	.	12 - 15.6	G/DL
				Hematocrit	30.4	L	.	-	35 - 46	%
				Red Blood Cell Count	3.4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.4	.	.	.	30 - 70	%
				Lymphocytes	33.1	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.6	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	143	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	36	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50	.	.	.	30 - 70	%
				Lymphocytes	40.6	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	143	Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	227	Hemoglobin	10.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	30.5	L	.	-	35 - 46	%
				Red Blood Cell Count	3.4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.4	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00289 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	227	Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	19	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	47	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11MAR96	1	19MAR96	9	9
00290	Oral	2	100 MG	20MAR96	10	22MAR96	12	3

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	No	No	12	100	Adverse event, including intercurrent illness	HIGH BLOOD PRESSURE

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
NEARSIGHTED	VISUAL DISTURB	NERVOUS SYST/SENSE ORGAN DIS	CUR	
SORE THROATS {FREQUENT}	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1994
TONSILLECTOMY AND ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1994

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Hypertension	HIGH BLOOD PRESSURE	10, .	15 Days	100	CON	MIL	STP	PSR	No	No
	Tachycardia	TACHYCARDIA	10, .	Not Stated	100	CON	MIL	STP	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	2, .	24:00 Hrs	50	1	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06MAR96	-5, .	0	122	70	90	128	72	112	176.18	66.1
1	20MAR96	10, .	100	150	76	112	160	86	124	175.08	
2	22MAR96	12, .	100	136	70	104	160	88	118		

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	38.9	.	.	.	30 - 70	%
				Lymphocytes	44.3	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	68	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00290 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03JUL96	1	14JUL96	12	12
00291	Oral	2	0 MG	15JUL96	13	23JUL96	21	9
00291	Oral	3	0 MG	24JUL96	22	30JUL96	28	7
00291	Oral	4	0 MG	31JUL96	29	06AUG96	35	7
00291	Oral	4	0 MG	07AUG96	36	13AUG96	42	7
00291	Oral	4	0 MG	14AUG96	43	20AUG96	49	7
00291	Oral	4	0 MG	21AUG96	50	27AUG96	56	7
00291	Oral	5	0 MG	28AUG96	57	05SEP96	65	9
00135	Oral	5	0 MG	06SEP96	66	01OCT96	91	26
00135	Oral	5	0 MG	02OCT96	92	29OCT96	119	28
00135	Oral	5	0 MG	30OCT96	120	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	120	0	Lost to follow-up	

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH PAINS	7, -59	01:00 Hrs	0	2	MIL	NO	PSR	No	No
	Headache	HEADACHE	12, -54	01:00 Hrs	0	1	MOD	NO	PSR	No	No
Carciovascular System	Arrhythmia	SINUS-ARRHYTHMIA	92, 27	29 Days	0	1	MIL	NO	PBU	No	No
Digestive System	Constipation	CONSTIPATION	50, -16	Not Stated	0	1	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	57, -9	8 Days	0	CON	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZINESS	36, -30	8 Days	0	1	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	01JUL96	-2, -67	0	100	58	84	102	60	84	101.65	62.2
BL	03JUL96	1, -65	0	97	75	66	97	64	70		
2	15JUL96	13, -53	0	109	68	84	105	64	96	102.53	
3	24JUL96	22, -44	0	110	62	80	102	64	88	101.43	
4	31JUL96	29, -37	0	108	56	92	104	58	92	103.19	
5	07AUG96	36, -30	0	112	64	78	108	66	86	102.75	
6	14AUG96	43, -23	0	108	60	86	100	62	104	102.09	
7	21AUG96	50, -16	0	110	70	78	110	65	92	102.53	
8	28AUG96	57, -9	0	102	62	84	108	58	90	102.75	
8	04SEP96	64, -2	0	104	58	92	104	62	98	103.19	
12	02OCT96	92, 27	0	104	60	92	108	62	98	100.99	
16	30OCT96	120, 55	0	106	60	90	108	70	90	102.31	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-2	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	290000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-2	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00291 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	MONGOLOID (KOREAN)

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07AUG96	1	16AUG96	10	10
00292	Oral	2	20 MG	17AUG96	11	21AUG96	15	5
00292	Oral	3	20 MG	22AUG96	16	30AUG96	24	9
00292	Oral	4	20 MG	31AUG96	25	04SEP96	29	5
00292	Oral	4	20 MG	05SEP96	30	17SEP96	42	13
00292	Oral	4	20 MG	18SEP96	43	25SEP96	50	8
00292	Oral	4	20 MG	26SEP96	51	03OCT96	58	8
00179	Oral	4	20 MG	04OCT96	59	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	59	20	Lost to follow-up	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	07AUG96	1, -58	0	126	56	80	130	56	80	143.10	60.6
1	16AUG96	10, -49	20	138	74	86	142	62	88	141.56	
2	21AUG96	15, -44	20	112	80	80	118	76	45 L	139.36	
3	30AUG96	24, -35	20	122	50	80	128	54	82	139.80	
4	04SEP96	29, -30	20	126	50	92	116	46	106	141.12	
7	25SEP96	50, -9	20	128	58	95	132	48	98	142.88	
8	04OCT96	59, 1	20	120	65	100	120	70	96	144.43	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	4.3	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	134	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70 (12)	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	76.1	H	.	.	30 - 70	%
				Lymphocytes	18.9	L	.	.	21 - 51	%
				Monocytes	2.4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	325000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	101	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00292 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	70 (12)	Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	17MAY96	1	20MAY96	4	4
00313	Oral	2	20 MG	21MAY96	5	28MAY96	12	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	No	No	12	20	Adverse event, including intercurrent illness	PT. WAS DROPPED DUE TO HOSPITALIZATION I.E. ADVERSE EXPERIENCE

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OVERWEIGHT	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	
TUBERCULOSIS	TUBERCULOSIS	INFECTIOUS/PARASITIC DIS	PRV	

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	2, .	Not Stated	20	CON	MIL	NO	PSR	No	No
Nervous System	Emotional Lability	SUPERFICIAL CUTS RISK TO SELF	12, .	6 Days	20	CON	SEV	STP	PBU	No	Yes
	Hallucinations	AUDITORY HALLUCINATIONS	12, .	6 Days	20	CON	SEV	STP	PBU	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08MAY96	-9, .	0	116	70	60	118	80	60	175.00	63.0
BL	17MAY96	1, .	0	90	60	72	82	56	72	191.00	
1	21MAY96	5, .	20	90	60	72	90	60	72	194.00	
2	28MAY96	12, .	20	112	74	84	112	74	84	182.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	57.9	.	.	.	40 - 75	%
				Lymphocytes	32.5	.	.	.	16 - 46	%
				Monocytes	6.5	.	.	.	0 - 12	%
				Eosinophils	2.7	.	.	.	0 - 7	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	205000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	69	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00313 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22OCT96	1	28OCT96	7	7
00314	Oral	2	100 MG	29OCT96	8	04NOV96	14	7
00314	Oral	3	150 MG	05NOV96	15	13NOV96	23	9
00314	Oral	4	200 MG	14NOV96	24	25NOV96	35	12
00314	Oral	4	200 MG	26NOV96	36	02DEC96	42	7
00314	Oral	4	200 MG	03DEC96	43	09DEC96	49	7
00314	Oral	4	200 MG	10DEC96	50	17DEC96	57	8
00314	Oral	5	250 MG	18DEC96	58	22DEC96	62	5
00314	Oral	5	250 MG	23DEC96	63	06JAN97	77	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	77	250	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
PHARYNGITIS	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid Ac	44, .	04DEC96	06DEC96	ONE CAP	HEARTBURN
ANTIINFECTIVES,SYSTEMIC	Phenoxymethylpenicillin Potassium	Pen-Vee-K	-111, .	03JUL96	13JUL96#	TABS 2X DAY	PHARYNGITIS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	60, .	20DEC96	20DEC96	500 GRM	EARACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	25, .	15NOV96	17NOV96	200 MG TID	FLU

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU	25, .	3 Days	200	1	MIL	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	24, .	Not Stated	200	1	MIL	NO	PSR	No	No
	Dyspepsia	HEARTBURN	44, .	48:00 Hrs	200	1	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZINESS	57, .	Not Stated	200	CON	MIL	NO	PSR	No	No
		LIGHT HEADED	3, .	13 Days	50	CON	MIL	NO	PSR	No	No
	Insomnia	INSOMNIA	2, .	3 Days	50	3	MOD	NO	PSR	No	No
Special Senses	Ear Pain	EARACHE	60, .	24:00 Hrs	250	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15OCT96	-7, .	0	100	60	70	.	.	.	145.00	65.5
BL	22OCT96	1, .	0	106	64	84	106	64	84	148.00	
1	29OCT96	8, .	100	90	60	96	90	60	96	147.00	
2	05NOV96	15, .	150	100	60	96	100	60	96	147.00	
3	14NOV96	24, .	200	104	64	84	104	64	84	151.00	
5	26NOV96	36, .	200	110	70	84	110	70	84	150.00	
6	03DEC96	43, .	200	106	70	96	100	70	96	152.00	
7	10DEC96	50, .	200	112	74	84	112	74	84	152.00	
8	17DEC96	57, .	200	110	76	84	110	76	84	153.00	
8	23DEC96	63, .	250	110	60	80	105	60	80	150.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.8	.	.	.	30 - 70	%
				Lymphocytes	23.2	.	.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	301000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	50	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 8/ACUTE PHASE-WEEK 6	50	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.3	.	.	.	30 - 70	%
				Lymphocytes	21.1	.	.	.	21 - 51	%
				Monocytes	11.7	H	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00314 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	12NOV96	1	21NOV96	10	10
00315	Oral	2	0 MG	22NOV96	11	25NOV96	14	4
00315	Oral	3	0 MG	26NOV96	15	02DEC96	21	7
00315	Oral	4	0 MG	03DEC96	22	11DEC96	30	9
00315	Oral	4	0 MG	12DEC96	31	17DEC96	36	6
00315	Oral	4	0 MG	18DEC96	37	22DEC96	41	5
00315	Oral	4	0 MG	23DEC96	42	29DEC96	48	7
00315	Oral	4	0 MG	30DEC96	49	06JAN97	56	8
	Oral	4	0 MG	07JAN97	57	10JAN97	60	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	60	0		PT. DID NOT WANT TO CONTINUE

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Sinutab	7, .	18NOV96	20NOV96	2	COLD
	Phenacetin	Sinutab	7, .	18NOV96	20NOV96	2	COLD
	Phenylpropanolamine Hydrochloride	Sinutab	7, .	18NOV96	20NOV96	2	COLD
	Phenyltoloxamine Citrate	Sinutab	7, .	18NOV96	20NOV96	2	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	7, .	3 Days	0	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	05NOV96	-7, .	0	110	70	84	110	70	84	177.00	
SC	12NOV96	1, .	0	112	62	80	110	68	84	173.00	65.0
1	21NOV96	10, .	0	120	80	96	120	80	96	178.00	
2	26NOV96	15, .	0	116	80	96	116	80	96	178.00	
3	03DEC96	22, .	0	130	84	84	130	84	84	181.00	
4	12DEC96	31, .	0	120	84	84	120	84	84	182.00	
5	17DEC96	36, .	0	120	76	84	120	76	84	182.00	
6	23DEC96	42, .	0	126	80	80	120	80	80	185.00	
8	07JAN97	57, .	0	120	80	78	100	80	78	187.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.6	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	7.1	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.8	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	1.8	.	.	.	0 - 2	%
				Platelets	320000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00315 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	17DEC96	1	23DEC96	7	7
00316	Oral	2	0 MG	24DEC96	8	30DEC96	14	7
00316	Oral	3	0 MG	31DEC96	15	07JAN97	22	8
00316	Oral	4	0 MG	08JAN97	23	14JAN97	29	7
00316	Oral	5	0 MG	15JAN97	30	21JAN97	36	7
00316	Oral	6	0 MG	22JAN97	37	28JAN97	43	7
00316	Oral	6	0 MG	29JAN97	44	03FEB97	49	6
00316	Oral	6	0 MG	04FEB97	50	09FEB97	55	6
	Oral	5	0 MG	10FEB97	56	18FEB97	64	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	64	0	Lack of Efficacy	

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Hemic and Lymphatic System	Thrombocythemia	ELEVATED PLATELETS	57, .	Not Stated	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	05DEC96	-12, .	0	110	70	.	.	.	.	135.00	65.8
BL	17DEC96	1, .	0	96	62	96	96	62	96	135.00	
1	23DEC96	7, .	0	110	70	80	110	70	90	138.00	
3	07JAN97	22, .	0	100	70	80	100	70	88	136.50	
4	14JAN97	29, .	0	104	64	96	104	64	96	138.00	
5	21JAN97	36, .	0	100	66	96	100	66	96	140.00	
6	28JAN97	43, .	0	96	66	84	96	66	84	140.00	
7	04FEB97	50, .	0	106	70	84	106	70	84	138.00	
8	11FEB97	57, .	0	110	70	84	100	70	84	140.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	14.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.5	H	.	.	30 - 70	%
				Lymphocytes	17.3	L	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	606000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	142	H	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	3	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.6	. . .	12 - 15.6	G/DL
				Hematocrit	40.6	. . .	35 - 46	%
				Red Blood Cell Count	4.5	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.2	. . .	30 - 70	%
				Lymphocytes	21.1	. . .	21 - 51	%
				Monocytes	6.2	. . .	0 - 10	%
				Eosinophils	2.6	. . .	0 - 5	%
				Basophils	0.8	. . .	0 - 2	%
				Platelets	771000	H . +	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	. . .	25 - 35	PG
				Mean Corpuscle Volume	89	. . .	80 - 100	FL
				Blood Urea Nitrogen	14	. . .	7 - 25	MG/DL
				Creatinine	0.7	L . .	0.8 - 1.5	MG/DL
				Uric Acid	3.8	. . .	2.3 - 7	MG/DL
				Alkaline Phosphatase	115	. . .	22 - 130	U/L
				Aspartate Aminotransferase	15	. . .	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00316 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19DEC96	1	23DEC96	5	5
00317	Oral	2	100 MG	24DEC96	6	30DEC96	12	7
00317	Oral	3	150 MG	31DEC96	13	07JAN97	20	8
00317	Oral	4	200 MG	08JAN97	21	14JAN97	27	7
00317	Oral	4	200 MG	15JAN97	28	21JAN97	34	7
00317	Oral	5	250 MG	22JAN97	35	28JAN97	41	7
00317	Oral	6	300 MG	29JAN97	42	04FEB97	48	7
00317	Oral	6	300 MG	05FEB97	49	11FEB97	55	7
	Oral	5	250 MG	11FEB97	55	26FEB97	70	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	70	250	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIC RHINITIS	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	1, .	19DEC96	04FEB97	500 MG	HEADACHES
			34, .	21JAN97	21JAN97	500 MG	BACKACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	27, .	14JAN97	14JAN97	25 GM	ALLERGIES
RESPIRATORY	Antiasthmatic, Nos	Over The Counter {Asthma Nos}	., .		.		ASTHMA
	Diphenhydramine Hydrochloride	Benadryl	27, .	14JAN97	14JAN97	25 GM	ALLERGIES
VARIOUS	Allergenic Extract, Nos	Over The Counter {Allergenic Extract Nos}	., .		.		ALLERGIC

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	ALLERGY	27, .	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
	Back Pain	BACKACHE	20, .	27 Days	150	3	MIL	NO	PSR	No	No
	Headache	HEADACHES	1, .	48 Days	50	7	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS ORTHOSTATIC	20, .	29 Days	150	4	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {COMMON}	27, .	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12DEC96	-7, .	0	110	70	80	108	64	88	120.00	62.3
BL	17DEC96	-2, .	0	110	70	96	110	70	96	122.00	
1	23DEC96	5, .	50	90	60	96	90	60	110	119.00	
3	07JAN97	20, .	150	115	80	88	115	70	96	118.50	
4	14JAN97	27, .	200	110	80	96	100	80	96	118.00	
5	21JAN97	34, .	200	110	80	88	100	80	88	118.50	
6	28JAN97	41, .	250	110	80	92	100	80	92	118.00	
7	04FEB97	48, .	300	110	74	84	110	74	84	118.00	
8	11FEB97	55, .	250	120	70	84	120	70	84	116.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	34.6	L	.	.	35 - 46	%
				Red Blood Cell Count	3.8	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60	.	.	.	30 - 70	%
				Lymphocytes	24.3	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	2.6	H	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.3	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66	.	.	.	30 - 70	%
				Lymphocytes	24.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.003.00317 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19JUL94	1	25JUL94	7	7
00013	Oral	2	100 MG	26JUL94	8	01AUG94	14	7
00013	Oral	3	150 MG	02AUG94	15	08AUG94	21	7
00013	Oral	4	200 MG	09AUG94	22	14AUG94	27	6
00013	Oral	4	200 MG	15AUG94	28	22AUG94	35	8
00013	Oral	4	200 MG	23AUG94	36	30AUG94	43	8
00013	Oral	4	200 MG	31AUG94	44	07SEP94	51	8
00013	Oral	4	200 MG	08SEP94	52	15SEP94	59	8
00074	Oral	4	200 MG	16SEP94	60	10OCT94	84	25
00074	Oral	4	200 MG	11OCT94	85	26OCT94	100	16
00074	Oral	5	250 MG	27OCT94	101	07NOV94	112	12
00074	Oral	5	250 MG	08NOV94	113	05DEC94	140	28
00074	Oral	5	250 MG	06DEC94	141	09JAN95	175	35
00074	Oral	5	250 MG	10JAN95	176	06FEB95	203	28
00074	Oral	5	250 MG	07FEB95	204	09MAR95	234	31
00013	Oral	4	200 MG	10MAR95	235	11MAR95	236	2
00013	Oral	3	150 MG	12MAR95	237	13MAR95	238	2
00013	Oral	2	100 MG	14MAR95	239	16MAR95	241	3
00013	Oral	1	50 MG	17MAR95	242	23MAR95	248	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	Yes	248	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Minocycline	Minocin	-48, -107	01JUN94	01FEB95	200MG	ACNE
DERMATOLOGICALS	Isotretinoin	Accutane	59, -1	15SEP94	16SEP94	40-80MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	2, -58	5 Days	50	CON	SEV	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	12, -48	Not Stated	100	CON	MOD	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	2, -58	5 Days	50	CON	MOD	NO	REL	No	No
	Somnolence	SLEEPINESS	2, -58	3 Days	50	2	MIL	NO	REL	No	No
	Tremor	TREMBLING OF HANDS	20, -40	4 Days	150	2	MIL	NO	REL	No	No
Skin and Appendages	Sweating	SWEATING	2, -58	3 Days	50	CON	MIL	NO	REL	No	No
Special Senses	Abnormal Vision	VISUAL BRIGHT SPOTS	2, -58	5 Days	50	8	MIL	NO	REL	No	No
	Tinnitus	RINGING IN EARS-5-10 MINUTES IN A.M.	16, -44	8 Days	150	7	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05JUL94	-14, -73	0	90	60	78	100	60	84	132.30	68.5
BL	19JUL94	1, -59	0	108	70	60	104	70	64	131.86	
1	26JUL94	8, -52	100	104	56	84	104	58	88	133.62	
2	02AUG94	15, -45	150	104	78	74	96	76	88	132.30	
3	09AUG94	22, -38	200	110	84	80	108	80	96	134.06	
4	15AUG94	28, -32	200	115	80	78	100	75	100	136.71	
5	23AUG94	36, -24	200	112	82	88	112	80	116	136.93	
6	31AUG94	44, -16	200	120	82	92	100	72	104	136.71	
7	08SEP94	52, -8	200	100	80	100	98	80	100	136.27	
8	16SEP94	60, 1	200	102	82	92	104	82	108	138.92	
12	11OCT94	85, 26	200	114	82	84	112	80	96	141.12 H	
16	08NOV94	113, 54	250	110	80	90	120	90	100	144.43 H	
20	06DEC94	141, 82	250	110	80	80	110	80	88	148.84 H	
24	10JAN95	176, 117	250	110	70	80	110	70	100	151.04 H	
28	07FEB95	204, 145	250	112	84	88	110	82	96	153.25 H	
32	10MAR95	235, 176	200	112	84	92	116	86	92	153.03 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.5	.	.	.	30 - 70	%
				Lymphocytes	31.1	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	118	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.3	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	60	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	85	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.1	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	172000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106	.	.	.	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	141	Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	176	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	26.9	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	9.8	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	177000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 14/CONTINUATION-WEEK 24	176	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 15/CONTINUATION-WEEK 28	204	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9	.	.	.	30 - 70	%
				Lymphocytes	25.9	.	.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 15/CONTINUATION-WEEK 28	204	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	235	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.7	.	.	.	30 - 70	%
				Lymphocytes	31.3	.	.	.	21 - 51	%
				Monocytes	12.1	H	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	64	L	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00013 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 16/CONTINUATION-WEEK 32	235	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	29NOV94	1	04DEC94	6	6
00014	Oral	2	100 MG	05DEC94	7	13DEC94	15	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	15	100	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ascorbic Acid	Vitamin C	-5, .	24NOV94	.	UNKNOWN	COMMON COLD

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Constipation	CONSTIPATED	4, .	Not Stated	50	CON	MOD	NO	REL	No	No
	Dysphagia	LUMP IN THE THROAT	1, .	11 Days	50	7	MOD	NO	REL	No	No
	Nausea	NAUSEA	7, .	3 Days	100	1	MOD	NO	PSR	No	No
			9, .	Not Stated	100	18	SEV	NO	PSR	No	No
		RETCHING	7, .	Not Stated	100	21	MOD	STP	PSR	No	No
Respiratory System	Respiratory Disorder	COMMON COLD	-5, .	6 Days	0	1	MIL	NO	UNR	Yes	No
Urogenital System	Polyuria	POLYURIA	7, .	1 Days	100		MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22NOV94	-7, .	0	100	68	70	110	80	80	145.31	72.8
BL	29NOV94	1, .	0	100	60	78	100	60	80	147.51	
1	05DEC94	7, .	100	130	70	84	120	70	88	142.44	
2	13DEC94	15, .	100	100	60	80	100	70	88	138.03	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	174	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.9	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.6	.	.	.	30 - 70	%
				Lymphocytes	36.4	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	8.5	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	163000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
		VISIT 4/ACUTE PHASE-WEEK 2	15	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	32.5	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 4/ACUTE PHASE-WEEK 2	15	Platelets	174000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	179	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00014 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 4/ACUTE PHASE-WEEK 2	15	Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08DEC94	1	13DEC94	6	6
00015	Oral	2	20 MG	14DEC94	7	20DEC94	13	7
00015	Oral	3	20 MG	21DEC94	14	27DEC94	20	7
00015	Oral	4	20 MG	28DEC94	21	03JAN95	27	7
00015	Oral	4	20 MG	04JAN95	28	10JAN95	34	7
00015	Oral	4	20 MG	11JAN95	35	17JAN95	41	7
00015	Oral	4	20 MG	18JAN95	42	24JAN95	48	7
00015	Oral	4	20 MG	25JAN95	49	02FEB95	57	9
00073	Oral	4	20 MG	03FEB95	58	27FEB95	82	25
00073	Oral	4	20 MG	28FEB95	83	21MAR95	104	22
00073	Oral	4	20 MG	22MAR95	105	18APR95	132	28
00073	Oral	4	20 MG	19APR95	133	16MAY95	160	28
00073	Oral	4	20 MG	17MAY95	161	13JUN95	188	28
00015	Oral	4	20 MG	14JUN95	189	14JUN95	189	1
00015	Oral	3	20 MG	15JUN95	190	15JUN95	190	1
00015	Oral	2	20 MG	16JUN95	191	18JUN95	193	3
00015	Oral	1	20 MG	19JUN95	194	28JUN95	203	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	203	20	Other reason	CONFLICT BETWEEN SCHOOL AND STUDY

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ENURESIS	INCONTINENCE, URINARY	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1990
URETERS BILATERALLY REEMBEDDED	OPERATION, OTHER URINARY	OPERATIONS	PRV	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ascorbic Acid	Vitamin C	5, -53	12DEC94	13DEC94	1	COLD,NASAL CONGESTION
	Minerals Nos	Centrum	5, -53	12DEC94	13DEC94	1	COLD-NASAL CONGESTION
	Vitamins Nos	Centrum	5, -53	12DEC94	13DEC94	1	COLD-NASAL CONGESTION
ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole	Septra Double Strength	82, 25	27FEB95	05MAR95	2TABS	COLD
	Trimethoprim	Septra Double Strength	82, 25	27FEB95	05MAR95	2TABS	COLD
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	13, -45	20DEC94	20DEC94	500MG	HEADACHE
			69, 12	14FEB95	14FEB95	2TAB	HEADACHE
			79, 22	24FEB95	24FEB95	2TAB	HEADACHE
		Tylenol Extra Strength	4, -54	11DEC94	11DEC94	2000MG	HEADACHE
			34, -24	10JAN95	10JAN95	500MG	HEADACHE
			41, -17	17JAN95	17JAN95	2000MG	HEADACHE
			53, -5	29JAN95	29JAN95	2000MG	MENSTRUAL CRAMPS
			131, 74	17APR95	17APR95	2TAB	MENSTRUAL CRAMPS
RESPIRATORY	Dexbrompheniramine Maleate	Drixoral Pills	5, -53	12DEC94	13DEC94	1	COLD NASAL CONGESTION
	Pseudoephedrine Sulfate	Drixoral Pills	5, -53	12DEC94	13DEC94	1	COLD NASAL CONGESTION
SENSORY ORGANS	Gramicidin	Polysporin Eye Drops	-1, -58	07DEC94	18DEC94	6DROPS	BILATERAL EYE INFECTION
			27, -31	03JAN95	14JAN95	4DROPS	BILATERAL EYE INFECTION
	Polymyxin B Sulfate	Polysporin Eye Drops	-1, -58	07DEC94	18DEC94	6DROPS	BILATERAL EYE INFECTION
			27, -31	03JAN95	14JAN95	4DROPS	BILATERAL EYE INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES INTERMITTENT AM AND LUNCH	1, -57	12 Days	20	6	MIL	NO	REL	No	No
	Allergic Reaction	CONGESTION-NASAL DUE TO ALLERGIES	184, 127	Not Stated	20	CON	MOD	NO	UNR	No	No
		ITCHY EYES-DUE TO ALLERGIES	184, 127	Not Stated	20	CON	MOD	NO	UNR	No	No
	Asthenia	FATIGUE	1, -57	15 Days	20	CON	MIL	NO	REL	No	No
			15, -43	11 Days	20	CON	MOD	NO	REL	No	No
		FATIGUE NEW	57, -1	43 Days	20	CON	MOD	NO	PBU	No	No
	Headache	HEADACHE	13, -45	03:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			34, -24	01:00 Hrs	20	1	SEV	NO	PBU	Yes	No
			41, -17	02:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			69, 12	01:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			79, 22	01:00 Hrs	20	1	MOD	NO	PBU	Yes	No
			180, 123	2 Days	20	CON	MOD	NO	UNR	No	No
		HEADACHES 1 DAILY	4, -54	7 Days	20	3	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	73, 16	31 Days	20	CON	MIL	NO	PBU	No	No
			180, 123	2 Days	20	CON	MOD	NO	UNR	No	No
	Emotional Lability	SELF-MUTILATION	31, -27	30 Mins	20	1	MIL	NO	UNR	No	No
		SUICIDAL IDEATION	73, 16	03:00 Hrs	20	1	MIL	NO	UNR	No	No
	Tremor	HANDS TREMBLING INTERMITTENT	3, -55	14 Days	20	4	MOD	NO	REL	No	No
Respiratory System	Cough Increased	COUGH	5, -53	5 Days	20	CON	MIL	NO	UNR	Yes	No
			57, -1	34 Days	20	CON	MOD	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	57, -1	34 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	4, -54	10 Days	20	CON	MIL	NO	UNR	Yes	No
			57, -1	34 Days	20	CON	MOD	NO	UNR	Yes	No
Special Senses	Conjunctivitis	CONJUNCTIVITIS BILATERAL	1, -57	11 Days	20	CON	MOD	NO	UNR	Yes	No
			27, -31	12 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	131, 74	30 Mins	20	1	MOD	NO	UNR	Yes	No
		PREMENSTRUAL CRAMPS	53, -5	02:00 Hrs	20	1	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	30NOV94	-8, -65	0	100	68	80	110	70	84	109.37	62.6
BL	07DEC94	-1, -58	0	100	68	60	96	70	80	116.87	
1	14DEC94	7, -51	20	90	60	96	90	64	104	107.16 L	
2	21DEC94	14, -44	20	100	60	88	100	64	100	106.06 L	
3	28DEC94	21, -37	20	100	70	82	100	70	90	104.96 L	
4	04JAN95	28, -30	20	90	60	74	90	60	80	102.53 L	
5	11JAN95	35, -23	20	110	70	76	110	78	100	102.97 L	
6	18JAN95	42, -16	20	98	60	80	90	68	96	105.18 L	
7	25JAN95	49, -9	20	110	78	94	100	66	100	105.18 L	
8	03FEB95	58, 1	20	104	68	80	100	66	84	105.84 L	
12	27FEB95	82, 25	20	102	64	80	98	64	104	99.67 L	
16	22MAR95	105, 48	20	108	76	72	106	72	72	102.97 L	
20	19APR95	133, 76	20	90	60	68	90	60	70	103.64 L	
24	17MAY95	161, 104	20	90	60	64	100	60	64	105.84 L	
28	14JUN95	189, 132	20	100	60	60	100	64	64	106.94 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.3	.	.	.	30 - 70	%
				Lymphocytes	27	.	.	.	21 - 51	%
				Monocytes	2.6	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	206000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	28.1	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	-1	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.2	H	.	.	30 - 70	%
				Lymphocytes	19.7	L	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	258000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 6/ACUTE PHASE-WEEK 4	28	Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	35	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.6	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	White Blood Cell Count	9.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.9	.	.	.	30 - 70	%
				Lymphocytes	21.8	.	.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	222000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	82	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.9	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 11/CONTINUATION-WEEK 12	82	Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	16.8	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.9	H	.	.	30 - 70	%
				Lymphocytes	15.6	L	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	344000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	133	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	215000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	133	Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 14/UNSCHEDULED LAB 1	182	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.6	.	.	.	30 - 70	%
				Lymphocytes	21	.	.	.	21 - 51	%
				Monocytes	9.2	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00015 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 14/UNSCHEDULED LAB 1	182	Basophils	0.7	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	13MAR95	1	19MAR95	7	7
00016	Oral	2	0 MG	20MAR95	8	28MAR95	16	9
00016	Oral	3	0 MG	29MAR95	17	04APR95	23	7
00016	Oral	4	0 MG	05APR95	24	11APR95	30	7
00016	Oral	4	0 MG	12APR95	31	19APR95	38	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	No	No	38	0	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES-ANIMAL HAIR & POLLENS	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1988

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Hyoscine Butylbromide	Buscopan	16, .	28MAR95	30MAR95	10MG	STOMACH CRAMPS
RESPIRATORY	Cetirizine Hydrochloride	Reactine	13, .	25MAR95	.	10MG	ALLERGIES/HAYFEVER
	Salbutamol Sulfate	Ventodisk	-2628, .	01JAN88	.	1XWK	ALLERGIES
			-2628, .	01JAN88	.	1XWK	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH CRAMPS	16, .	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Allergic Reaction	COUGHING DUE TO ALLERGIES	18, .	Not Stated	0	CON	MIL	NO	UNR	Yes	No
		HEADACHES DUE TO ALLERGIES	12, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No
		SNEEZING DUE TO ALLERGIES	12, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No
		STUFFED SINUSES DUE TO ALLERGIES	12, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01MAR95	-12, .	0	104	60	64	98	74	68	155.45	68.5
BL	13MAR95	1, .	0	104	80	72	108	84	80	155.45	
1	20MAR95	8, .	0	108	72	72	108	76	72	157.66	
2	29MAR95	17, .	0	110	60	78	120	70	84	158.76	
3	05APR95	24, .	0	112	72	80	114	84	80	157.66	
4	12APR95	31, .	0	100	60	70	110	78	78	158.98	
5	19APR95	38, .	0	110	68	84	110	70	84	159.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	33.1	.	.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	131	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-3	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEC	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	1	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	31	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.6	.	.	.	30 - 70	%
				Lymphocytes	36.1	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
		VISIT 7/ACUTE PHASE-WEEK 5	38	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.9	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.9	.	.	.	0 - 2	%
				Platelets	315000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00016 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 7/ACUTE PHASE-WEEK 5	38	Alkaline Phosphatase	117	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	EAST INDIAN

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	22MAR95	1	26MAR95	5	5
00017	Oral	0	0 MG	27MAR95	6	27MAR95	6	1
00017	Oral	1	20 MG	28MAR95	7	29MAR95	8	2
00017	Oral	2	20 MG	30MAR95	9	05APR95	15	7
00017	Oral	3	20 MG	06APR95	16	12APR95	22	7
00017	Oral	4	20 MG	13APR95	23	19APR95	29	7
00017	Oral	4	20 MG	20APR95	30	25APR95	35	6
	Oral	5	30 MG	26APR95	36	02MAY95	42	7
00017	Oral	5	30 MG	03MAY95	43	09MAY95	49	7
00017	Oral	5	30 MG	10MAY95	50	16MAY95	56	7
00075	Oral	5	30 MG	17MAY95	57	13JUN95	84	28
00075	Oral	5	30 MG	14JUN95	85	12JUL95	113	29
00075	Oral	5	30 MG	13JUL95	114	09AUG95	141	28
00075	Oral	5	30 MG	10AUG95	142	05SEP95	168	27
00075	Oral	5	30 MG	06SEP95	169	03OCT95	196	28
00075	Oral	5	30 MG	04OCT95	197	31OCT95	224	28
00017	Oral	4	20 MG	01NOV95	225	02NOV95	226	2
00017	Oral	3	20 MG	03NOV95	227	04NOV95	228	2
00017	Oral	2	20 MG	05NOV95	229	07NOV95	231	3
00017	Oral	1	20 MG	08NOV95	232	14NOV95	238	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	238	20		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Maalox	232, 176	08NOV95	08NOV95	5CC	NAUSEA
	Calcium Pantothenate	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
	Magnesium Hydroxide	Maalox	232, 176	08NOV95	08NOV95	5CC	NAUSEA
	Nicotinamide	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
	Pyridoxine Hydrochloride	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
	Riboflavin	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
	Thiamine Hydrochloride	Vitamin B Complex	48, -9	08MAY95	.	ONE TAB	SHIVERING(>
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	161, 105	29AUG95	30AUG95	650MG	FEVER
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benylin	177, 121	14SEP95	16SEP95	1TSP	COLD
RESPIRATORY	Diphenhydramine Hydrochloride	Benylin	177, 121	14SEP95	16SEP95	1TSP	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH PAIN	235, 179	Not Stated	20	CON	MIL	NO	UNR	No	No
	Chills	SHIVERING AND SHAKING	7, -50	12 Days	20	CON	MIL	NO	PSR	No	No
	Fever	FEVER	161, 105	18:00 Hrs	30		MOD	NO	UNR	Yes	No
Digestive System	Constipation	CONSTIPATION	23, -34	12 Days	20	CON	MOD	NO	REL	No	No
			35, -22	28 Days	20	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	2, -55	4 Days	20	CON	SEV	DCR	REL	No	No
			6, -51	5 Days	0	CON	MIL	NO	REL	No	No
			230, 174	7 Days	20	CON	MOD	NO	UNR	Yes	No
	Vomiting	VOMITING	232, 176	5 Days	20	3	MOD	NO	UNR	No	No
Nervous System	Anxiety	ANXIETY	2, -55	4 Days	20	CON	SEV	DCR	REL	No	No
	Dizziness	DIZZINESS	230, 174	5 Days	20	CON	MIL	NO	UNR	No	No
	Insomnia	INSOMNIA	6, -51	5 Days	0	CON	MIL	NO	PSR	No	No
		INSOMNIA(NO SLEEP)	3, -54	3 Days	20	CON	SEV	DCR	REL	No	No
	Manic Reaction	HOSPITALIZATION RULE-OUT HYPOMANIA	163, 107	3 Days	30	CON	MIL	NO	UNR	No	Yes
	Tremor	TREMORS	31, -26	11 Days	20	CON	MOD	NO	REL	No	No
			42, -15	87 Days	30	CON	SEV	NO	REL	Yes	No
			129, 73	40 Days	30	CON	MOD	NO	REL	No	No
			169, 113	57 Days	30	CON	MIL	NO	REL	No	No
Respiratory System	Cough Increased	COUGHING	63, 7	15 Days	30	CON	MOD	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	233, 177	5 Days	20	CON	MOD	NO	UNR	No	No
	Respiratory Disorder	RHINITIS-COLD	177, 121	3 Days	30	CON	MIL	NO	UNR	Yes	No
	Rhinitis	RHINITIS	233, 177	5 Days	20	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15MAR95	-7, -63	0	112	70	56	112	74	60	137.15	63.4
BL	22MAR95	1, -56	0	90	60	64	100	68	70	135.17	
1	30MAR95	9, -48	20	80	60	64	90	60	64	135.39	
2	06APR95	16, -41	20	90	60	68	100	70	70	133.84	
3	13APR95	23, -34	20	100	60	70	100	60	74	134.95	
4	20APR95	30, -27	20	100	60	72	110	60	78	137.59	
5	26APR95	36, -21	30	100	60	64	110	70	68	135.39	
6	03MAY95	43, -14	30	90	60	60	90	70	72	133.62	
7	10MAY95	50, -7	30	90	60	64	100	60	68	132.96	
8	17MAY95	57, 1	30	90	60	68	90	60	70	133.40	
12	14JUN95	85, 29	30	100	60	70	110	80	70	131.64	
16	13JUL95	114, 58	30	110	70	72	110	70	80	131.42	
20	10AUG95	142, 86	30	110	70	60	105	70	68	135.61	
24	06SEP95	169, 113	30	90	60	60	100	70	64	135.17	
28	04OCT95	197, 141	30	90	60	64	100	68	68	138.92	
32	01NOV95	225, 169	20	100	70	78	100	68	68	140.02	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.7	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	30	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 6/ACUTE PHASE-WEEK 4	30	Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	32.3	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	277000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	24	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	42	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	142	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	169	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	313000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
		VISIT 16/CONTINUATION-WEEK 32	225	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	225	Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	28.3	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	290000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00017 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	225	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells		4	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03MAY95	1	10MAY95	8	8
00018	Oral	2	0 MG	11MAY95	9	17MAY95	15	7
00018	Oral	3	0 MG	18MAY95	16	24MAY95	22	7
00018	Oral	4	0 MG	25MAY95	23	31MAY95	29	7
00018	Oral	5	0 MG	01JUN95	30	07JUN95	36	7
00018	Oral	5	0 MG	08JUN95	37	18JUN95	47	11
00018	Oral	6	0 MG	19JUN95	48	21JUN95	50	3
00018	Oral	6	0 MG	22JUN95	51	28JUN95	57	7
00018	Oral	5	0 MG	29JUN95	58	14JUL95	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	73	0	Other reason	PATIENT WANTED TO TERMINATE,DID NOT WISH TO BE ON MEDICATION

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991
UPPER RESPIRATORY TRACT INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1995

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	-9,	.	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION
ANTINEOPLASTIC & IMMUNOSUP	Diethylstilbestrol Dipropionate	Cyclen	-1583,	.	01JAN91	24MAY95	1TAB	BIRTH CONTROL
CENTRAL NERVOUS SYSTEM	Diazepam	Valium	26,	.	28MAY95	28MAY95	15MG	TENSION
	Paracetamol	Tylenol	-1583,	.	01JAN91	03MAY95	650TO 1300MG	HEADACHES
			22,	.	24MAY95	.	325-650	HEADACHE
DERMATOLOGICALS	Erythromycin	Erythromycin	-9,	.	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION
GU SYSTEM/SEX HORMONES	Diethylstilbestrol Dipropionate	Cyclen	-1583,	.	01JAN91	24MAY95	1TAB	BIRTH CONTROL
	Ethinylestradiol	Ortho Tri-Cyclen	30,	.	01JUN95	.	1TAB	BIRTH CONTROL
	Norgestimate	Ortho Tri-Cyclen	30,	.	01JUN95	.	1TAB	BIRTH CONTROL
RESPIRATORY	Brompheniramine Maleate	Dimetapp	-12,	.	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
		Dimetapp-C	-12,	.	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION
	Codeine Phosphate	Dimetapp-C	-12,	.	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION
	Loratadine	Claritin	13,	.	15MAY95	18MAY95	1TAB	POLLEN ALLERGY
	Paracetamol	Neo Citran	-12,	.	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
	Pheniramine Maleate	Neo Citran	-12,	.	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
	Phenylephrine Hydrochloride	Dimetapp	-12,	.	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
		Dimetapp-C	-12,	.	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION
		Neo Citran	-12,	.	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
	Phenylpropanolamine Hydrochloride	Dimetapp	-12,	.	21APR95	21APR95#	X1	UPPER RESPIRATORY TRACT INFECTION
		Dimetapp-C	-12,	.	21APR95	28APR95#	4TEASPOONS	UPPER RESPIRATORY TRACT INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
SENSORY ORGANS	Erythromycin	Erythromycin	-9, .	24APR95	02MAY95#	333MG	UPPER RESPIRATORY TRACT INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	RHINITIS, SNEEZING, ITCHY EYES {POLLEN ALLERGY}	10, .	7 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	22, .	02:00 Hrs	0	1	SEV	NO	UNR	Yes	No
		HEADACHES	51, .	Not Stated	0	CON	MOD	NO	PSR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	49, .	21 Days	0	CON	SEV	NO	PSR	No	No
	Nausea	NAUSEA	7, .	5 Days	0	CON	MOD	NO	REL	No	No
	Vomiting	NAUSEA-VOMITING	30, .	38 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Anxiety	TENSION {ANXIOUS FEELING POST CONFRONTATION NON-MEDICATION RELATED}	26, .	1 Days	0	1	SEV	NO	UNR	Yes	No
	Insomnia	INSOMNIA{WORSENING}	5, .	20 Days	0	CON	SEV	NO	REL	No	No
Special Senses	Abnormal Vision	BLURRY VISION	49, .	21 Days	0	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	19APR95	-14, .	0	125	75	88	125	75	88	126.79	64.2
BL	03MAY95	1, .	0	120	70	70	120	70	72	126.79	
1	11MAY95	9, .	0	100	60	70	100	60	84	127.89	
2	18MAY95	16, .	0	100	60	80	100	60	84	127.89	
3	25MAY95	23, .	0	110	70	90	110	70	98	127.23	
4	01JUN95	30, .	0	120	70	104	118	70	108	126.35	
5	08JUN95	37, .	0	100	60	72	110	70	84	126.79	
7	19JUN95	48, .	0	118	70	68	120	70	78	126.13	
7	22JUN95	51, .	0	100	70	84	120	70	96	124.14	
8	29JUN95	58, .	0	140	84	90	145	90	100	127.01	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	POS	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-7	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	36.8	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	278000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/UNSCHEDULED LAB 1	-7	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		1010.ZZ2	-2	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	POS	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEC	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	28.4	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	119	H	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		ACUTE PHASE/DOWN TITRATION	72	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00018 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	ACUTE PHASE/DOWN TITRATION	72	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	31MAY95	1	06JUN95	7	7
00019	Oral	2	20 MG	07JUN95	8	13JUN95	14	7
00019	Oral	3	20 MG	14JUN95	15	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	15	20	Lost to follow-up	

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	7, .	06JUN95	06JUN95	3TABS	HEADACHE
	Caffeine	Excedrin	7, .	06JUN95	06JUN95	3TABS	HEADACHE
	Paracetamol	Excedrin	7, .	06JUN95	06JUN95	3TABS	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	7, .	09:00 Hrs	20	1	MOD	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZY GETTING OUT OF BED OR AFTER LYING DOWN A LONG TIME	4, .	Not Stated	20		MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24MAY95	-7, .	0	90	60	60	100	70	78	120.17	66.1
BL	31MAY95	1, .	0	100	60	64	110	70	80	117.31	
1	07JUN95	8, .	20	90	60	80	110	70	84	119.51	
2	14JUN95	15, .	20	100	60	70	110	80	90	120.61	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.1	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	5.9	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	209000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	2.2	L	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00019 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	09NOV95	1	15NOV95	7	7
00020	Oral	2	0 MG	16NOV95	8	24NOV95	16	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	16	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANXIETY	ANXIETY	MENTAL DISORD	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Diazepam	Valium	-21, .	19OCT95	19OCT95#	5MG	ANXIETY

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	4, .	3 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02NOV95	-7, .	0	90	60	72	100	60	80	110.47	62.6
BL	09NOV95	1, .	0	90	60	70	90	60	74	110.25	
1	16NOV95	8, .	0	90	64	78	98	70	80	109.15	
2	24NOV95	16, .	0	90	60	60	90	60	78	109.15	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.5	.	.	.	30 - 70	%
				Lymphocytes	35.3	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	199000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	16	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.8	.	.	.	30 - 70	%
				Lymphocytes	37.9	.	.	.	21 - 51	%
				Monocytes	2.5	.	.	.	0 - 10	%
				Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	219000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 4/ACUTE PHASE-WEEK 2	16	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEC		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00020 TREATMENT GROUP: PLACEBO

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	02FEB96	1	08FEB96	7	7
00211	Oral	2	100 MG	09FEB96	8	15FEB96	14	7
00211	Oral	3	150 MG	16FEB96	15	22FEB96	21	7
00211	Oral	4	200 MG	23FEB96	22	28FEB96	27	6
00211	Oral	4	200 MG	29FEB96	28	06MAR96	34	7
00211	Oral	4	200 MG	07MAR96	35	13MAR96	41	7
00211	Oral	4	200 MG	14MAR96	42	21MAR96	49	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	No	No	49	200	Adverse event, including intercurrent illness	DEHYDTRATION POST NAUSEA AND VOMITTING/DIARRHEA DUE TO BACTERIA GASTROENTERITIS RESULTED IN SEVERE DEHYDRATION AND MOUTH SORES/CUTS UNABLE TO TOLERATE SIDE EFFECTS OF DRY MOUTH.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Antiemetics & Antinauseants Nos	Antiemetic {Nos}	49, .	21MAR96	22MAR96		NAUSEA&VOMITING
	Ascorbic Acid	Vitamin C	., .		.	500MG	HEALTH MAINTENANCE
	Calcium Pantothenate	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
	Nicotinamide	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
	Pyridoxine Hydrochloride	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
	Riboflavin	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
	Thiamine Hydrochloride	Jamieson B Complex Vitamins	., .		.	ONE CAP	HEALTH MAINTENANCE
BLOOD/BLOOD FORM ORGANS	I.V. Fluids	Intravenous Fluids	49, .	21MAR96	22MAR96		DEHYDRATION
CENTRAL NERVOUS SYSTEM	Analgesics	Analgesic {Nos}	49, .	21MAR96	22MAR96		MOUTH SORES
	Paracetamol	Tylenol	38, .	10MAR96	.	2TABS	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	22, .	Not Stated	200	CON	MOD	NO	PBU	Yes	No
	Trauma	MOUTH CUTS	48, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	11, .	7 Days	100	CON	MIL	NO	PSR	No	No
			18, .	15 Days	150	CON	MOD	NO	REL	No	No
			33, .	Not Stated	200	CON	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	4, .	14 Days	50	CON	MIL	NO	PSR	No	No
			18, .	15 Days	150	CON	SEV	NO	REL	No	No
			33, .	14 Days	200	CON	MOD	NO	REL	No	No
			47, .	Not Stated	200	CON	SEV	STP	REL	No	No
	Gastroenteritis	BACTERIAL GASTROENTERITIS	49, .	3 Days	200	CON	SEV	STP	UNR	Yes	No
	Ulcerative Stomatitis	MOUTH SORES	48, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
Nervous System	Dizziness	DIZZINESS	18, .	18 Days	150	CON	MIL	NO	REL	No	No
	Hypertonia	STIFF NECK	22, .	18 Days	200	CON	MIL	NO	PBU	No	No
	Tremor	TREMORS	18, .	22 Days	150	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JAN96	-9, .	0	80	60	60	90	60	68	102.53	63.0
BL	01FEB96	-1, .	0	100	60	64	100	60	72	102.53	
1	08FEB96	7, .	50	100	60	60	100	60	70	100.33	
2	16FEB96	15, .	150	100	70	78	90	70	80	102.53	
3	23FEB96	22, .	200	100	70	70	100	70	74	101.87	
4	29FEB96	28, .	200	100	72	80	100	70	80	103.64	
5	07MAR96	35, .	200	100	60	78	110	80	88	104.96	
6	14MAR96	42, .	200	90	60	70	100	60	90	104.08	
7	25MAR96	53, .	200	90	60	80	90	60	84	98.12	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	37.3	L	.	.	40 - 75	%
				Lymphocytes	48.4	H	.	.	16 - 46	%
				Monocytes	10.4	.	.	.	0 - 12	%
				Eosinophils	3.1	.	.	.	0 - 7	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-9		Urine Squamous Epithelial Cells	4	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	53	(4)	Hemoglobin	15.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	44.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.9	.	.	.	3.9 - 5.2	MILL/MCL
					White Blood Cell Count	5.1	.	.	.	3.8 - 10.8	THOU/MCL
					Segmented Neutrophils	72.4	.	.	.	40 - 75	%
					Lymphocytes	14.1	L	.	.	16 - 46	%
					Monocytes	9.4	.	.	.	0 - 12	%
					Eosinophils	2.4	.	.	.	0 - 7	%
					Basophils	1.8	.	.	.	0 - 2	%
					Platelets	244000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.1	.	.	.	27 - 33	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	96	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	67	H	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00211 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 9/ACUTE PHASE-WEEK 7	53 (4)	Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	03JUN96	1	09JUN96	7	7
00212	Oral	2	20 MG	10JUN96	8	20JUN96	18	11
00212	Oral	3	20 MG	21JUN96	19	25JUN96	23	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	23	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES{ENVIRONMENTAL}	ALLERGY, NEC	INJURY/POISONING	CUR	1995
AMENORRHEA	AMENORRHEA	GENITOURINARY SYST DIS	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Sinutabs	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
	Phenacetin	Sinutabs	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
	Phenylpropanolamine Hydrochloride	Sinutabs	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
	Phenyltoloxamine Citrate	Sinutabs	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Ortho 777	-215, .	01NOV95	.	1 TABLET	BIRTH CONTROL
	Norethisterone	Ortho 777	-215, .	01NOV95	.	1 TABLET	BIRTH CONTROL
RESPIRATORY	Loratadine	Claritin	-215, .	01NOV95	09JUN96	0-2 TABS	ENVIRONMENTAL ALLERGIES
	Pseudoephedrine Hydrochloride	Sudafed	-215, .	01NOV95	.	1-2 TAB/DAY PRN	ENVIRONMENTAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Somnolence	SEDATION	7, .	12:00 Hrs	20	1	SEV	NO	PSR	No	No
			8, .	2 Days	20	CON	MIL	NO	PSR	No	No
			10, .	14 Days	20	CON	SEV	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24MAY96	-10, .	0	100	60	60	90	60	72	143.33	65.7
BL	03JUN96	1, .	0	90	60	72	90	60	78	139.80	
1	10JUN96	8, .	20	110	60	78	110	78	84	137.81	
3	21JUN96	19, .	20	116	78	80	108	80	92	139.58	
4	28JUN96	26, .	20	118	78	90	110	80	98	137.81	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.3	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-10		Urine Squamous Epithelial Cells	4	.	.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	26	(3)	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.2	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	46.1	.	.	.	30 - 70	%
					Lymphocytes	43.1	.	.	.	21 - 51	%
					Monocytes	6.6	.	.	.	0 - 10	%
					Eosinophils	3.9	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	211000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
					Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	52	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 5/ACUTE PHASE-WEEK 3	26 (3)	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEC		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00212 TREATMENT GROUP: PAROXETINE

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	02AUG96	1	07AUG96	6	6
00213	Oral	2	0 MG	08AUG96	7	14AUG96	13	7
00213	Oral	3	0 MG	15AUG96	14	20AUG96	19	6
00213	Oral	4	0 MG	21AUG96	20	28AUG96	27	8
00213	Oral	4	0 MG	29AUG96	28	02SEP96	32	5
00213	Oral	4	0 MG	03SEP96	33	09SEP96	39	7
00213	Oral	4	0 MG	10SEP96	40	16SEP96	46	7
00213	Oral	4	0 MG	17SEP96	47	24SEP96	54	8
00122	Oral	4	0 MG	25SEP96	55	21OCT96	81	27
00122	Oral	4	0 MG	22OCT96	82	18NOV96	109	28
00122	Oral	4	0 MG	19NOV96	110	19DEC96	140	31
00122	Oral	4	0 MG	20DEC96	141	20JAN97	172	32
00122	Oral	4	0 MG	21JAN97	173	17FEB97	200	28
00122	Oral	4	0 MG	18FEB97	201	18MAR97	229	29
00213	Oral	3	0 MG	19MAR97	230	20MAR97	231	2
00213	Oral	2	0 MG	21MAR97	232	23MAR97	234	3
00213	Oral	1	0 MG	24MAR97	235	30MAR97	241	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	Yes	241	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACKACHES	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	222	65, 11	05OCT96	05OCT96	375 MGS	HEADACHE
		Bufferin	3, -52	04AUG96	04AUG96	325 MGS	HEADACHE
	Aluminium Glycinate	Bufferin	3, -52	04AUG96	04AUG96	325 MGS	HEADACHE
	Caffeine Citrate	222	65, 11	05OCT96	05OCT96	375 MGS	HEADACHE
	Codeine Phosphate	222	65, 11	05OCT96	05OCT96	375 MGS	HEADACHE
	Magnesium Carbonate	Bufferin	3, -52	04AUG96	04AUG96	325 MGS	HEADACHE
	Paracetamol	Acetaminophen	65, 11	05OCT96	05OCT96	1000 MG	HEADACHE
			110, 56	19NOV96	19NOV96	1000 MG	HEADACHE
			122, 68	01DEC96	01DEC96	375 MG	HEADACHE
			150, 96	29DEC96	29DEC96	1000 MG	HEADACHE
			224, 170	13MAR97	13MAR97	1000 MG	HEADACHE
		Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD
	Phenacetin	Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD
	Phenylpropanolamine Hydrochloride	Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD
	Phenyltoloxamine Citrate	Sinutab	11, -44	12AUG96	12AUG96	1 TAB	COLD
			134, 80	13DEC96	13DEC96	1 TAB	COLD

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES	2, -53	8 Days	0	CON	MIL	NO	PSR	No	No
			10, -45	192 Days	0	CON	MOD	NO	UNR	Yes	No
	Back Pain	BACKACHE	1, -54	8 Days	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHES	3, -52	227 Days	0	CON	MIL	NO	UNR	Yes	No
	Trauma	HEAD INJURY WITH LACERATION TO SCALP (4 STITCHES) NO LOSS OF CONSCIOUSNESS (PUSHED ONTO SUBWAY TRACK)	65, 11	5 Mins	0	1	MOD	NO	UNR	No	No
Digestive System	Constipation	CONSTIPATION	7, -48	5 Days	0	2	MIL	NO	PSR	No	No
			9, -46	13 Days	0	CON	MIL	NO	UNR	No	No
	Diarrhea	DIARRHEA	6, -49	4 Days	0	4	MIL	NO	PSR	No	No
			192, 138	31 Days	0	CON	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	44, -11	Not Stated	0	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	UPPER RESPIRATORY INFECTION (COLD)	11, -44	19 Days	0	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Rash	RASH	141, 87	8 Days	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JUL96	-15, -69	0	98	78	90	110	98	100	191.17	63.8
BL	01AUG96	-1, -55	0	100	70	74	110	78	80	190.73	
1	08AUG96	7, -48	0	100	70	88	110	78	90	192.94	
2	15AUG96	14, -41	0	100	60	84	110	78	90	194.04	
3	21AUG96	20, -35	0	110	70	64	110	80	88	193.60	
4	29AUG96	28, -27	0	124	64	92	110	68	100	196.25	
5	03SEP96	33, -22	0	110	80	90	120	88	104	197.79	
6	10SEP96	40, -15	0	120	88	80	110	70	90	195.36	
7	17SEP96	47, -8	0	110	70	104	120	80	120	195.80	
8	24SEP96	54, -1	0	120	70	84	120	80	100	196.25	
12	22OCT96	82, 28	0	110	70	120	100	60	120	191.84	
16	19NOV96	110, 56	0	120	70	80	110	70	84	196.25	
20	20DEC96	141, 87	0	130	70	84	120	70	90	193.82	
24	21JAN97	173, 119	0	120	66	84	116	70	88	198.01	
28	18FEB97	201, 147	0	120	58	84	110	60	80	196.69	
32	19MAR97	230, 176	0	115	60	68	114	58	76	195.58	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74.3	H	.	.	30 - 70	%
				Lymphocytes	17.4	L	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	308000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.7	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	318000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	43	.	.	.	35 - 46	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 6/ACUTE PHASE-WEEK 4	28	Segmented Neutrophils	70.8	H	.	.	30 - 70	%
				Lymphocytes	21.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.5	.	.	.	30 - 70	%
				Lymphocytes	21.2	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	319000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	8	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 14/CONTINUATION-WEEK 24	174	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74.9	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 14/CONTINUATION-WEEK 24	174	Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	79	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	230	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/CONTINUATION-WEEK 32	230	Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75.7	H	.	.	30 - 70	%
				Lymphocytes	17.8	L	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.2	L	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00213 TREATMENT GROUP: PLACEBO

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	04OCT96	1	08OCT96	5	5
00214	Oral	2	20 MG	09OCT96	6	14OCT96	11	6
00214	Oral	3	20 MG	15OCT96	12	20OCT96	17	6
00214	Oral	4	20 MG	21OCT96	18	30OCT96	27	10
00214	Oral	5	30 MG	01NOV96	29	10NOV96	38	10
00214	Oral	5	30 MG	11NOV96	39	17NOV96	45	7
00214	Oral	4	20 MG	18NOV96	46	24NOV96	52	7
00214	Oral	4	20 MG	25NOV96	53	02DEC96	60	8
00119	Oral	4	20 MG	03DEC96	61	30DEC96	88	28

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	88	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
JOINT PAIN - FLEXIBLE JOINTS	PAIN, JOINT	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996
HEAD LACERATION	OPEN WOUND	INJURY/POISONING	PRV	1987

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Hepatitis B Vaccine	Hepatitis B Shot {Vaccine}	60,	-1	02DEC96	02DEC96		PROPHYLAXIS
		Hepatitis B {Vaccine}	-1,	-61	03OCT96	03OCT96#		PROPHYLAXIS
	Tetracycline Hydrochloride	Apo-Tetra	-16,	-76	18SEP96	18SEP96#		COLD
			10,	-51	13OCT96	13OCT96	500 MG	COLD
			14,	-47	17OCT96	20OCT96	500 MG	COLD
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	36,	-25	08NOV96	09NOV96	700 MG	HEADACHE
			44,	-17	16NOV96	16NOV96	700 MG	HEADACHE
			83,	23	25DEC96	25DEC96	1000 MG	DIZZINESS
			84,	24	26DEC96	26DEC96	1000 MG	DIZZINESS
			85,	25	27DEC96	27DEC96	1000 MG	DIZZINESS
			87,	27	29DEC96	29DEC96	1000 MG	DIZZINESS
		Tylenol Extra Strength	-8,	-68	26SEP96	26SEP96#	700 MG	KNEE PAIN
DERMATOLOGICALS	Tetracycline Hydrochloride	Apo-Tetra	-16,	-76	18SEP96	18SEP96#		COLD
			10,	-51	13OCT96	13OCT96	500 MG	COLD
			14,	-47	17OCT96	20OCT96	500 MG	COLD
GU SYSTEM/SEX HORMONES	Oral Contraceptive	Birth Control Pill	-32,	-92	02SEP96	.	1	TO REGULATE PERIODS
RESPIRATORY	Dimenhydrinate	Gravol	37,	-24	09NOV96	10NOV96	100 MG	UPSET STOMACH
			44,	-17	16NOV96	17NOV96	50 MG	NAUSEA
SENSORY ORGANS	Tetracycline Hydrochloride	Apo-Tetra	-16,	-76	18SEP96	18SEP96#		COLD
			10,	-51	13OCT96	13OCT96	500 MG	COLD
			14,	-47	17OCT96	20OCT96	500 MG	COLD
			-16,	-76	18SEP96	18SEP96#		COLD
			10,	-51	13OCT96	13OCT96	500 MG	COLD
			14,	-47	17OCT96	20OCT96	500 MG	COLD

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	36, -25	2 Days	30	CON	MIL	DCR	REL	Yes	No
			43, -18	1 Days	30	CON	MOD	DCR	PSR	Yes	No
Digestive System	Dyspepsia	UPSET STOMACH	37, -24	2 Days	30	CON	MIL	DCR	REL	Yes	No
	Nausea	NAUSEA	43, -18	1 Days	30	CON	MOD	DCR	PSR	Yes	No
			81, 21	06:00 Hrs	20	3	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	43, -18	1 Days	30	CON	MOD	DCR	PSR	No	No
			81, 21	06:00 Hrs	20	3	MOD	NO	PSR	No	No
	Hyperkinesia	HYPERACTIVE	5, -56	01:00 Hrs	20	5	MIL	NO	PSR	No	No
	Insomnia	AWAKENING (MIDDLE OF NIGHT)	9, -52	15 Mins	20	2	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	14, -47	4 Days	20	CON	MIL	NO	UNR	No	No
Skin and Appendages	Rash	RASH ON ARMS (RED, DRY, ITCHY)	59, -2	10:00 Hrs	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	27SEP96	-7, -67	0	120	90	68	120	90	80	128.99	60.6
BL	04OCT96	1, -60	0	110	70	78	110	70	80	129.43	
1	09OCT96	6, -55	20	125	70	84	120	80	84	128.11	
2	15OCT96	12, -49	20	120	80	84	120	90	88	127.89	
2	21OCT96	18, -43	20	110	70	78	110	90	98	127.89	
4	01NOV96	29, -32	30	100	60	60	100	60	120	128.99	
5	11NOV96	39, -22	30	110	70	98	100	70	120	126.35	
6	18NOV96	46, -15	20	110	60	100	135	85	120	128.11	
7	25NOV96	53, -8	20	110	60	78	110	70	84	126.79	
8	03DEC96	61, 1	20	125	75	84	125	75	95	129.43	
12	30DEC96	88, 28	20	110	60	88	110	76	96	128.99	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2	.	.	.	30 - 70	%
				Lymphocytes	31.2	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	318000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	4.3	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.8	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEC		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	88	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	88	Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	27.4	.	.	.	21 - 51	%
				Monocytes	11.3	H	.	.	0 - 10	%
				Eosinophils	7.4	H	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	266000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Amphetamines	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00214 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	88	Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells		4	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	20MAR97	1	26MAR97	7	7
00215	Oral	2	100 MG	27MAR97	8	02APR97	14	7
00215	Oral	3	150 MG	03APR97	15	09APR97	21	7
00215	Oral	4	200 MG	10APR97	22	14APR97	26	5
00215	Oral	4	200 MG	15APR97	27	23APR97	35	9
00215	Oral	4	200 MG	24APR97	36	28APR97	40	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	40	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
LOW ENERGY	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
VARIOUS	Herbal Medication	Unknown Chinese Herbal Med	-139, .	01NOV96	11MAR97#		LOW ENERGY
	Homeopathic Preparations	Yinchia0 Tablet {Chiehtupien} {Homeopathic}	7, .	26MAR97	26MAR97	ONE TABLET	RHINITIS AND SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	WEAKNESS	42, .	Not Stated	200	CON	MOD	STP	REL	No	No
	Headache	HEADACHE	6, .	2 Days	50	1	MIL	NO	UNR	No	No
			13, .	30 Days	100	CON	MIL	NO	PSR	No	No
		HEADACHES	43, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	13, .	21 Days	100	CON	MOD	NO	REL	No	No
			34, .	11 Days	200	CON	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	9, .	Not Stated	100	CON	MOD	NO	REL	No	No
	Esophagitis	ESOPHAGEAL IRRITATION	21, .	3 Days	150	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	42, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
	Vomiting	VOMITING	42, .	Not Stated	200	CON	SEV	STP	REL	Yes	No
Musculoskeletal System	Arthralgia	JOINT PAINS	42, .	Not Stated	200	CON	MIL	STP	REL	Yes	No
Nervous System	Abnormal Dreams	NIGHTMARES	37, .	7 Days	200	CON	MOD	STP	REL	No	Yes
	Dizziness	DIZZINESS	16, .	2 Days	150	CON	MIL	NO	REL	No	No
			37, .	Not Stated	200	CON	MOD	STP	REL	No	Yes
	Hallucinations	VISUAL HALLUCINATIONS	37, .	7 Days	200	CON	SEV	STP	REL	No	Yes
	Nervousness	IRRITABILITY	37, .	7 Days	200	CON	SEV	STP	REL	No	Yes
Respiratory System	Pharyngitis	SORE THROAT	6, .	5 Days	50	CON	MIL	NO	UNR	Yes	No
	Rhinitis	RHINITIS	7, .	4 Days	50	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12MAR97	-8, .	0	98	64	60	98	70	64	103.19	58.3
BL	20MAR97	1, .	0	98	50	76	98	45	76	102.31	
1	27MAR97	8, .	100	105	60	84	100	60	88	99.23	
2	03APR97	15, .	150	100	65	92	95	50	100	99.23	
3	10APR97	22, .	200	100	60	100	95	50	108	98.78	
4	15APR97	27, .	200	110	70	104	98	65	112	98.12	
5	24APR97	36, .	200	108	70	104	100	68	108	99.89	
6	29APR97	41, .	200	108	65	96	104	70	104	97.68	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	30.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	9.4	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	97	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.004.00215 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 8/ACUTE PHASE-WEEK 6	41 (1)	Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	39	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	20APR94	1	26APR94	7	7
00001	Oral	2	0 MG	27APR94	8	03MAY94	14	7
00001	Oral	3	0 MG	04MAY94	15	10MAY94	21	7
00001	Oral	4	0 MG	11MAY94	22	17MAY94	28	7
00001	Oral	5	0 MG	18MAY94	29	24MAY94	35	7
00001	Oral	6	0 MG	25MAY94	36	31MAY94	42	7
00001	Oral	6	0 MG	01JUN94	43	07JUN94	49	7
00001	Oral	6	0 MG	08JUN94	50	14JUN94	56	7
	Oral	6	0 MG	15JUN94	57	28JUN94	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	70	0	Lack of Efficacy	-MINIMAL IMPROVEMENT OF DEPRESSION SYMPTOMS

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11APR94	-9, .	0	110	70	105	108	72	108	125.00	67.0
BL	20APR94	1, .	0	114	80	92	110	78	96	125.91	
1	27APR94	8, .	0	100	60	96	92	60	106	122.82	
2	04MAY94	15, .	0	108	60	90	108	80	94	123.92	
3	11MAY94	22, .	0	126	78	92	124	88	96	123.92	
4	18MAY94	29, .	0	120	80	96	118	80	90	124.80	
5	25MAY94	36, .	0	124	78	84	124	78	96	124.80	
6	01JUN94	43, .	0	122	62	98	118	70	92	124.80	
7	08JUN94	50, .	0	118	68	80	110	68	92	126.35	
8	15JUN94	57, .	0	102	60	92	118	78	98	125.02	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.6	.	.	.	30 - 70	%
				Lymphocytes	26.2	.	.	.	21 - 51	%
				Monocytes	4.3	.	.	.	0 - 10	%
				Eosinophils	0.4	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-2	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	67	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00001 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		ACUTE PHASE/DOWN TITRATION	70	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	25MAY94	1	31MAY94	7	7
00002	Oral	2	20 MG	01JUN94	8	07JUN94	14	7
00002	Oral	3	20 MG	08JUN94	15	14JUN94	21	7
00002	Oral	4	20 MG	15JUN94	22	22JUN94	29	8
00002	Oral	5	30 MG	23JUN94	30	29JUN94	36	7
00002	Oral	6	40 MG	30JUN94	37	06JUL94	43	7
00002	Oral	6	40 MG	07JUL94	44	12JUL94	49	6
00002	Oral	6	40 MG	13JUL94	50	19JUL94	56	7
00091	Oral	6	40 MG	20JUL94	57	16AUG94	84	28
00091	Oral	6	40 MG	17AUG94	85	14SEP94	113	29
00091	Oral	6	40 MG	15SEP94	114	17OCT94	146	33
00091	Oral	6	40 MG	18OCT94	147	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	147	40	Other reason	PT.STOPPED TAKING MEDICATION BECAUSE SHE DIDN'T WANT TO TAKE PILLS ANYMORE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
CANNABIS USE	DRUG ABUSE	MENTAL DISORD	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-5, -61	20MAY94	20MAY94#	500MG	HEADACHE
			54, -3	17JUL94	20JUL94	500MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN	26, -31	06:30 Hrs	20	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	-5, -61	03:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
			54, -3	4 Days	40	3	MOD	NO	PSR	Yes	No
Cardiovascular System	Palpitation	CHEST PALPITATIONS	26, -31	06:30 Hrs	20	CON	MOD	NO	PSR	No	No
Nervous System	Drug Dependence	POSITIVE CANNABIS	-5, -61	1 Days	0	1	MIL	NO	UNR	No	No
Skin and Appendages	Urticaria	HIVES - BOTH ARMS BOTH LEGS AND STOMACH AREA (QUESTIONABLE)	20, -37	2 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20MAY94	-5, -61	0	80	60	92	80	60	92	115.76	62.0
BL	25MAY94	1, -56	0	100	70	88	90	70	88	112.90	
1	01JUN94	8, -49	20	90	60	92	90	64	92	114.88	
2	08JUN94	15, -42	20	98	60	80	90	60	80	113.78	
3	15JUN94	22, -35	20	90	60	80	88	60	80	111.79	
4	23JUN94	30, -27	30	90	60	72	88	60	60	115.54	
5	30JUN94	37, -20	40	90	60	72	80	60	76	113.12	
6	07JUL94	44, -13	40	90	60	88	88	60	88	115.10	
7	14JUL94	51, -6	40	84	60	80	80	60	80	115.10	
8	20JUL94	57, 1	40	90	60	88	80	60	88	110.47	
12	17AUG94	85, 29	40	94	68	88	94	70	88	115.10	
16	15SEP94	114, 58	40	90	70	92	90	60	92	113.56	
20	18OCT94	147, 91	40	94	70	94	90	70	86	112.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.4	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	31	L	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	22	Glucose - Random	87	.	.	.	70 - 115	MG/DL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.9	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57		Segmented Neutrophils	75.3	H	.	.	30 - 70	%
					Lymphocytes	13.4	L	.	.	21 - 51	%
					Monocytes	5.8	.	.	.	0 - 10	%
					Eosinophils	5.3	H	.	.	0 - 5	%
					Basophils	0.2	.	.	.	0 - 2	%
					Platelets	245000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	88	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	109	.	.	.	70 - 115	MG/DL
					Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	(1)	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.9	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	58.2	.	.	.	30 - 70	%
					Lymphocytes	33.2	.	.	.	21 - 51	%
					Monocytes	6.2	.	.	.	0 - 10	%
					Eosinophils	1.9	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	271000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	147 (1)	Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	96	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	POS		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00002 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	147 (1)	Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	20SEP94	1	26SEP94	7	7
00003	Oral	2	100 MG	27SEP94	8	30SEP94	11	4
00003	Oral	2	100 MG	01OCT94	12	04OCT94	15	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	15	100	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EAR INFECTION	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1994
ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1988
HISTORY OF HEART MURMUR	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	-19, .	01SEP94	14SEP94#	750MG	EAR INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Acetaminophen	-5, .	15SEP94	15SEP94#	650MG	HEADACHE
DERMATOLOGICALS	Erythromycin	Erythromycin	-19, .	01SEP94	14SEP94#	750MG	EAR INFECTION
RESPIRATORY	Carbinoxamine Maleate	Naldecon	., .		.	20ML	FOR RELIEF OF ALLERGIES
	Codeine Phosphate	Tussi-Organidin	., .		.	120MG	FOR RELIEF OF ALLERGIES
	Iodinated Glycerol	Tussi-Organidin	., .		.	120MG	FOR RELIEF OF ALLERGIES
	Phenylephrine Hydrochloride	Naldecon	., .		.	20ML	FOR RELIEF OF ALLERGIES
	Phenylpropanolamine Hydrochloride	Naldecon	., .		.	20ML	FOR RELIEF OF ALLERGIES
	Phenyltoloxamine Citrate	Naldecon	., .		.	20ML	FOR RELIEF OF ALLERGIES
SENSORY ORGANS	Erythromycin	Erythromycin	-19, .	01SEP94	14SEP94#	750MG	EAR INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	4, .	03:00 Hrs	50	1	MOD	NO	PSR	No	No
Cardiovascular System	Tachycardia	"RACING HEART"	4, .	12 Days	50	4	MOD	NO	PBU	No	No
		RACING HEARTBEAT	11, .	5 Days	100	2	MOD	STP	REL	No	No
Nervous System	Dizziness	DIZZINESS	8, .	10 Days	100	CON	MOD	NO	PSR	No	No
	Tremor	SHAKINESS	8, .	10 Days	100	CON	MOD	NO	PSR	No	No
Skin and Appendages	Sweating	SWEATINESS	3, .	6 Days	50	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12SEP94	-8, .	0	106	70	80	108	70	84	116.50	60.0
BL	20SEP94	1, .	0	110	78	82	110	80	90	116.70	
1	27SEP94	8, .	100	112	72	106	102	80	116	114.60	
2	04OCT94	15, .	100	106	70	106	102	70	110	112.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.8	.	.	.	30 - 70	%
				Lymphocytes	37.7	.	.	.	21 - 51	%
				Monocytes	3.6	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	108	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	116	H	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00003 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	10OCT94	1	19OCT94	10	10
00004	Oral	2	20 MG	20OCT94	11	26OCT94	17	7
00004	Oral	3	20 MG	27OCT94	18	02NOV94	24	7
00004	Oral	4	20 MG	03NOV94	25	09NOV94	31	7
00004	Oral	5	30 MG	10NOV94	32	16NOV94	38	7
00004	Oral	6	40 MG	17NOV94	39	22NOV94	44	6
00004	Oral	6	40 MG	23NOV94	45	30NOV94	52	8
00004	Oral	6	40 MG	01DEC94	53	07DEC94	59	7
00093	Oral	6	40 MG	08DEC94	60	04JAN95	87	28
00004	Oral	5	30 MG	05JAN95	88	20JAN95	103	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	103	30	Other reason	PT. CHOSE TO WITHDRAW.

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	81, 22	29DEC94	30DEC94	500MG	SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	15, -45	02:30 Hrs	20	CON	MIL	NO	PBU	No	No
			81, 22	2 Days	40	CON	MOD	NO	PBU	No	No
Respiratory System	Pharyngitis	SORE THROAT	81, 22	2 Days	40	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22SEP94	-18, -77	0	130	70	62	124	70	62	143.00	68.0
BL	10OCT94	1, -59	0	134	74	68	130	70	68	141.50	
1	20OCT94	11, -49	20	130	70	62	124	70	62	142.00	
2	27OCT94	18, -42	20	118	74	64	110	70	62	144.80	
3	03NOV94	25, -35	20	120	70	60	90	70	60	145.40	
4	10NOV94	32, -28	30	120	70	68	100	60	64	148.00	
5	17NOV94	39, -21	40	124	80	84	120	80	80	150.50	
6	23NOV94	45, -15	40	124	80	64	120	80	64	148.00	
7	01DEC94	53, -7	40	112	70	60	100	60	64	152.90 H	
8	08DEC94	60, 1	40	110	60	60	118	60	62	149.60	
12	05JAN95	88, 29	30	118	62	76	110	60	90	153.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-4	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.5	.	.	.	30 - 70	%
				Lymphocytes	24.1	.	.	.	21 - 51	%
				Monocytes	10.5	H	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	2.1	H	.	+	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-4	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.2	.	.	.	30 - 70	%
				Lymphocytes	22.3	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	1.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	148	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00004 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	1	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	37.5	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	264000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	122	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00005 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	01NOV94	1	09NOV94	9	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	9	0	Adverse event, including intercurrent illness	ELEVATED HEART RATE ON LEVEL ONE

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00005 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	SLIGHTLY TIRED	3, .	14 Days	0	5	MIL	NO	PSR	No	No
Carciovascular System	Tachycardia	ELEVATED HEART RATE	8, .	2 Days	0	2	MOD	STP	PSR	No	No
Nervous System	Dizziness	SLIGHTLY DIZZY	3, .	14 Days	0	4	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24OCT94	-8, .	0	100	64	80	100	60	88	111.57	60.5
BL	01NOV94	1, .	0	98	58	88	104	68	88	114.66	
1	08NOV94	8, .	0	104	66	98	108	62	136 H	114.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00005 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	34.2	.	.	.	21 - 51	%
				Monocytes	3.3	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	340	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00005 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	04NOV94	1	13NOV94	10	10
00006	Oral	2	100 MG	14NOV94	11	20NOV94	17	7
00006	Oral	3	150 MG	21NOV94	18	27NOV94	24	7
00006	Oral	4	200 MG	28NOV94	25	04DEC94	31	7
00006	Oral	5	250 MG	05DEC94	32	11DEC94	38	7
00006	Oral	6	300 MG	12DEC94	39	18DEC94	45	7
00006	Oral	6	300 MG	19DEC94	46	26DEC94	53	8
00006	Oral	6	300 MG	27DEC94	54	02JAN95	60	7
00089	Oral	6	300 MG	03JAN95	61	01FEB95	90	30
00089	Oral	6	300 MG	02FEB95	91	26FEB95	115	25
00089	Oral	6	300 MG	27FEB95	116	04APR95	152	37
00089	Oral	6	300 MG	05APR95	153	11APR95	159	7
00006	Oral	5	250 MG	12APR95	160	13APR95	161	2
00006	Oral	4	200 MG	14APR95	162	15APR95	163	2
00006	Oral	3	150 MG	16APR95	164	17APR95	165	2
00006	Oral	2	100 MG	18APR95	166	20APR95	168	3
00006	Oral	1	50 MG	21APR95	169	27APR95	175	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	175	50	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HISTORY OF ENVIRONMENTAL ALLERGIES-DUST	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	
HISTORY OF ENVIRONMENTAL ALLERGIES-POLLEN	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	
HISTORY OF RECURRENT TONSILLITIS	TONSILS/ADENOIDS DIS	RESPIRATORY SYST DIS	PRV	
STATUS POST MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Calcium Carbonate	Tums	23, -38	26NOV94	.	2DAILY	UPSET STOMACH
			23, -38	26NOV94	.	2DAILY	UPSET STOMACH
ANTIINFECTIVES,SYSTEMIC	Cefaclor	Ceclor	21, -40	24NOV94	28NOV94	750MG	TONSILLITIS/STREP THROAT
			25, -36	28NOV94	09DEC94	1000MG	TONSILLITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT/FEVER/SORE THROAT	23, -38	5 Days	150	CON	SEV	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	6, -55	Not Stated	50	CON	MOD	NO	REL	No	No
	Dyspepsia	UPSET STOMACH	23, -38	64 Days	150	CON	MOD	NO	UNR	Yes	No
	Increased Appetite	CRAVINGS:CEREALS,PASTAS, CARBOHYDRATES	21, -40	41 Days	150	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	23, -38	64 Days	150	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS WHEN GETTING OUT OF BED IN AM	8, -53	25 Days	50	CON	MIL	NO	REL	No	No
	Neurosis	OBSESSIVE THOUGHTS	116, 56	Not Stated	300	CON	MOD	STP	PBU	No	No
Urogenital System	Pyuria	URINALYSIS - WBC'S {INCREASED}	176, 116	Not Stated	50		MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	27OCT94	-8, -68	0	110	70	72	108	68	72	145.00	68.0
BL	03NOV94	-1, -61	0	100	70	60	90	70	62	141.90	
1	14NOV94	11, -50	100	110	70	76	100	68	78	141.00	
2	21NOV94	18, -43	150	110	70	64	100	70	64	141.00	
3	28NOV94	25, -36	200	118	74	76	110	70	76	140.24	
4	05DEC94	32, -29	250	100	60	70	90	60	72	142.00	
5	12DEC94	39, -22	300	110	60	64	110	70	68	141.50	
6	19DEC94	46, -15	300	100	64	80	90	60	94	139.00	
8	27DEC94	54, -7	300	106	68	92	94	70	104	138.92	
8	03JAN95	61, 1	300	104	70	90	90	60	94	139.14	
12	02FEB95	91, 31	300	108	70	88	110	60	92	140.00	
16	27FEB95	116, 56	300	104	70	84	100	70	88	145.31	
20	05APR95	153, 93	300	120	70	92	104	70	96	147.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	30 - 70	%
				Lymphocytes	33.2	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEC		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55	.	.	.	30 - 70	%
				Lymphocytes	36	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	61		Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	3	.	.	.	0 - 5	%
					Basophils	0	.	.	.	0 - 2	%
					Platelets	114000	L	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.7	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	76	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	93	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
		VISIT 17/DOWN TITRATION	176	(1)	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	48.4	.	.	.	41 - 50	%
					Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.3	.	.	.	30 - 70	%
					Lymphocytes	34	.	.	.	21 - 51	%
					Monocytes	9.3	.	.	.	0 - 10	%
					Eosinophils	4.1	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	292000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 17/DOWN TITRATION	176 (1)	Blood Urea Nitrogen	20	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEC		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00006 TREATMENT GROUP: IMIPRAMINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	09NOV94	1	09NOV94	1	1
00007	Oral	1	50 MG	10NOV94	2	15NOV94	7	6
00007	Oral	1	50 MG	16NOV94	8	22NOV94	14	7
00007	Oral	2	100 MG	23NOV94	15	29NOV94	21	7
00007	Oral	3	150 MG	30NOV94	22	06DEC94	28	7
00007	Oral	4	200 MG	07DEC94	29	13DEC94	35	7
00007	Oral	5	250 MG	14DEC94	36	20DEC94	42	7
00007	Oral	6	300 MG	21DEC94	43	27DEC94	49	7
00007	Oral	5	250 MG	28DEC94	50	03JAN95	56	7
00007	Oral	5	250 MG	04JAN95	57	10JAN95	63	7
00092	Oral	5	250 MG	11JAN95	64	14FEB95	98	35
00092	Oral	5	250 MG	15FEB95	99	21MAR95	133	35
00092	Oral	5	250 MG	22MAR95	134	18APR95	161	28
00092	Oral	5	250 MG	19APR95	162	16MAY95	189	28
00092	Oral	5	250 MG	17MAY95	190	19MAY95	192	3

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	192	250	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
QUESTIONABLE OVARIAN CYST	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	81, 18	28JAN95	.	500MG(PRN)	LEG CRAMPS
			180, 117	07MAY95	07MAY95	500MG	HEADACHE
	Prochlorperazine	Compazine	195, 132	22MAY95	22MAY95		DEHYDRATION NAUSEA,VOMITING,DIARRHEA
		Compazine Suppositories	196, 133	23MAY95	24MAY95		DEHYDRATION NAUSEA,VOMITING,DIARRHEA
DERMATOLOGICALS	Calamine	Caladryl Lotion	2, -62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
	Camphor	Caladryl Lotion	2, -62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
	Diphenhydramine Hydrochloride	Benadryl	197, 134	24MAY95	24MAY95		SEIZURE
		Caladryl Lotion	2, -62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
	Glycerol	Caladryl Lotion	2, -62	10NOV94	14NOV94	TOPICAL LOTION	HIVES-RASH ON ARMS
GU SYSTEM/SEX HORMONES	Oral Contraceptive	Birth Control Pills	-219, -282	04APR94	.	1A DAY	IRREGULAR MENSTRUAL CYCLES
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	197, 134	24MAY95	24MAY95		SEIZURE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	180, 117	03:30 Hrs	250	CON	MOD	NO	UNR	Yes	No
	Infection	GI VIRUS-NAUSEA,VOMITING AND DIARRHEA	32, -32	4 Days	200	CON	SEV	NO	UNR	No	No
		NAUSEA,VOMITING,DIARRHEA ,FLU	52, -12	2 Days	250	CON	SEV	NO	UNR	No	No
Carciovascular System	Postural Hypotension	DIZZINESS-POSTURAL HYPOTENSION(ONLY IN GYM CLASSES)	23, -41	14 Days	150	1	MOD	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	42, -22	151 Days	250	CON	MOD	NO	REL	No	No
Metabolic and Nutritional Disorders	Dehydration	DEHYDRATION	191, 128	8 Days	250	CON	SEV	STP	PBU	Yes	No
Musculoskeletal System	Myalgia	LEG CRAMPS AND ACHES	81, 18	Not Stated	250	CON	MOD	NO	PSR	Yes	No
Nervous System	Abnormal Dreams	NIGHTMARES	145, 82	15 Days	250	10	SEV	NO	UNR	No	No
	Convulsion	SEIZURE	197, 134	5 Mins	250	CON	SEV	STP	UNR	Yes	No
	Tremor	HAND TREMORS	42, -22	6 Days	250	CON	MIL	NO	REL	No	No
			48, -16	3 Days	300	CON	MOD	DCR	REL	No	No
			51, -13	142 Days	250	CON	MIL	NO	REL	No	No
Skin and Appendages	Rash	RASH-BILATERAL FOREARMS	2, -62	5 Days	50	CON	MOD	STP	PBU	Yes	No
	Urticaria	HIVES-BILATERAL FOREARMS	2, -62	5 Days	50	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02NOV94	-7, -70	0	110	70	64	104	68	74	135.00	64.0
BL	09NOV94	1, -63	0	110	70	74	100	70	72	132.30	
2	23NOV94	15, -49	100	110	70	72	100	68	72	132.95	
3	30NOV94	22, -42	150	100	70	74	94	68	74	132.52	
4	07DEC94	29, -35	200	100	68	90	90	60	92	129.00	
5	14DEC94	36, -28	250	110	80	80	94	70	80	127.80	
6	21DEC94	43, -21	300	114	70	100	88	64	100	128.20	
7	28DEC94	50, -14	250	110	80	100	100	70	104	129.50	
8	04JAN95	57, -7	250	100	70	104	104	68	108	128.00	
8	11JAN95	64, 1	250	104	74	86	90	70	92	128.10	
12	15FEB95	99, 36	250	120	80	104	110	80	108	126.00	
20	22MAR95	134, 71	250	120	70	80	98	60	88		
24	19APR95	162, 99	250	104	70	100	100	60	104	127.00	
28	17MAY95	190, 127	250	104	70	100	90	60	104	129.00	
32	09AUG95	274, 211#	0	104	74	92	100	70	98	129.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.1	.	.	.	30 - 70	%
				Lymphocytes	27.4	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	307000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	87	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.3	.	.	.	30 - 70	%
				Lymphocytes	22.7	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	0.6	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	44000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	107	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	99	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	17.4	H	.	.	12 - 15.6	G/DL
				Hematocrit	51.5	H	.	.	35 - 46	%
				Red Blood Cell Count	6.1	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	28.4	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	0.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	28000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	162		Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	99	.	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	NEG		.	.	.	
					Urine Red Blood Cells/HPF	NEG		.	.	.	
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.	.	
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 15/CONTINUATION-WEEK 28	274	(82)	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	41.1	.	.	.	35 - 46	%
					Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	63	.	.	.	30 - 70	%
					Lymphocytes	28.3	.	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	1.2	.	.	.	0 - 5	%
					Basophils	1.6	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00007 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 15/CONTINUATION-WEEK 28	274	(82)	Platelets	238000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.8	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	71	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
					Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	82	.	.	.	70 - 115	MG/DL
					Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	16NOV94	1	22NOV94	7	7
00008	Oral	2	20 MG	23NOV94	8	29NOV94	14	7
00008	Oral	3	20 MG	30NOV94	15	06DEC94	21	7
00008	Oral	4	20 MG	07DEC94	22	13DEC94	28	7
00008	Oral	5	30 MG	14DEC94	29	20DEC94	35	7
00008	Oral	6	40 MG	21DEC94	36	27DEC94	42	7
00008	Oral	6	40 MG	28DEC94	43	03JAN95	49	7
00008	Oral	6	40 MG	04JAN95	50	09JAN95	55	6
00095	Oral	5	30 MG	10JAN95	56	05FEB95	82	27
00095	Oral	5	30 MG	06FEB95	83	07MAR95	112	30
00095	Oral	5	30 MG	08MAR95	113	06APR95	142	30

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	142	30	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	25, -31	3 Days	20	CON	MOD	NO	UNR	No	No
	Asthenia	EXTREME SLEEPINESS/FATIGUE	44, -12	11 Days	40	CON	SEV	DCR	REL	No	No
	Headache	HEADACHE	25, -31	3 Days	20	CON	MOD	NO	UNR	No	No
	Infection	STOMACH FLU WITH NAUSEA,VOMITING AND DIARRHEA	12, -44	3 Days	20	CON	SEV	NO	UNR	No	No
		STOMACH FLU-NAUSEA,VOMITING AND DIARRHEA	31, -25	4 Days	30	CON	SEV	NO	UNR	No	No
Carciovascular System	Postural Hypotension	POSTURAL HYPOTENSION	-4, -59	2 Mins	0	2	MIL	NO	PSR	No	No
Digestive System	Diarrhea	DIARRHEA	25, -31	3 Days	20	CON	MOD	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	5, -51	140 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Personality Disorder	BEHAVIOR PROBLEMS-->STOLE MOM'S CAR AND WRECKED IT.	77, 22	02:00 Hrs	30	1	SEV	NO	PSR	No	No
		SKIPPING SCHOOL TALKING BACK TO MOM {BEHAVIOR PROBLEMS}	37, -19	47 Days	40	CON	SEV	NO	PSR	No	No
	Somnolence	DROWSINESS-SLEEPINESS	1, -55	17 Days	20	7	MIL	NO	PSR	No	No
			17, -39	160 Days	20	CON	MOD	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	10NOV94	-6, -61	0	100	70	70	100	68	70	88.50	60.0
BL	16NOV94	1, -55	0	100	70	80	110	70	80	91.00	
1	23NOV94	8, -48	20	100	70	72	108	70	72	89.00	
2	30NOV94	15, -41	20	98	70	76	110	70	80	89.50	
3	07DEC94	22, -34	20	80	60	84	84	60	88	88.00	
4	14DEC94	29, -27	30	100	60	80	100	60	88	89.00	
5	21DEC94	36, -20	40	104	70	76	110	70	76	90.85	
6	28DEC94	43, -13	40	90	60	84	90	60	88	91.29	
7	03JAN95	49, -7	40	100	60	80	100	64	84	90.00	
8	10JAN95	56, 1	30	90	60	72	94	64	80	92.00	
12	06FEB95	83, 28	30	100	70	80	96	60	80	95.50	
16	08MAR95	113, 58	30	100	60	80	100	60	88	98.20 H	
24	10MAY95	176, 121#	0	94	64	88	90	60	88	101.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	38.6	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	222000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	281	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	32	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.4	.	.	.	30 - 70	%
				Lymphocytes	41.8	.	.	.	21 - 51	%
				Monocytes	10.3	H	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	8 - 21	MG/DL
				Creatinine	1.1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.4	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	244	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	56		Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	103	.	.	.	60 - 110	MG/DL
					Globulin	2.7	.	.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	176	(34)	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	37.4	L	.	.	41 - 50	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	44.2	.	.	.	30 - 70	%
					Lymphocytes	44.4	.	.	.	21 - 51	%
					Monocytes	7.8	.	.	.	0 - 10	%
					Eosinophils	3.2	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	211000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	19	.	.	.	8 - 21	MG/DL
					Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
					Alkaline Phosphatase	320	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	30	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.8	.	.	.	5.7 - 8.2	G/DL
					Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	103	.	.	.	60 - 110	MG/DL
					Globulin	2.4	.	.	.	2.1 - 3.8	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00008 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	176	(34)	Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF	NEG	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	1/2SPANISH 1/2WHITE

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	12DEC94	1	18DEC94	7	7
00009	Oral	2	100 MG	19DEC94	8	26DEC94	15	8
00009	Oral	3	150 MG	27DEC94	16	02JAN95	22	7
00009	Oral	4	200 MG	03JAN95	23	10JAN95	30	8
00009	Oral	5	250 MG	11JAN95	31	17JAN95	37	7
00009	Oral	6	300 MG	18JAN95	38	24JAN95	44	7
00009	Oral	5	250 MG	25JAN95	45	30JAN95	50	6
00009	Oral	5	250 MG	31JAN95	51	06FEB95	57	7
	Oral	5	250 MG	07FEB95	58	22FEB95	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	73	250	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
HAY FEVER	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	PRV	1984

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-11, .	01DEC94	07DEC94#	500MG	HEADACHE
			5, .	16DEC94	19DEC94	500MG	HEADACHE
			11, .	22DEC94	27DEC94	500MG	HEADACHES
			21, .	01JAN95	01JAN95	500MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	5,	.	4 Days	50	3	MOD	NO	PSR	Yes	No
			21,	.	04:00 Hrs	150	1	SEV	NO	PSR	Yes	No
		HEADACHES	11,	.	6 Days	100	3	SEV	NO	PSR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	5,	.	Not Stated	50	CON	MOD	NO	REL	No	No
			29,	.	Not Stated	200	CON	MOD	NO	REL	No	No
	Dyspepsia	HEARTBURN	29,	.	03:00 Hrs	200	1	MOD	NO	PBU	No	No
		UPSET STOMACH/INDIGESTION	6,	.	Not Stated	50	6	MIL	NO	PSR	No	No
Hemic and Lymphatic System	Leukocytosis	NEUTROPHILS, SEGS {INCREASED}	-5,	.	1 Days	0	1	MIL	NO	UNR	No	No
	Leukopenia	LYMPHOCYTES {DECREASED}	-5,	.	1 Days	0	1	MIL	NO	UNR	No	No
Metabolic and Nutritional Disorders	Hyperglycemia	GLUCOSE ELEVATED	59,	.	1 Days	250	1	SEV	NO	UNR	No	No
Nervous System	Tremor	HAND TREMORS	32,	.	Not Stated	250	CON	MIL	NO	REL	No	No
			35,	.	10 Days	250	CON	MIL	NO	REL	No	No
			44,	.	8 Days	300	CON	SEV	DCR	REL	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	40,	.	5 Days	300	CON	SEV	NO	UNR	No	No
	Haematuria	[URINE OCCULT BLOOD]	-5,	.	1 Days	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07DEC94	-5, .	0	110	70	76	104	70	80	146.00	63.0
BL	12DEC94	1, .	0	100	70	80	100	60	88	145.00	
1	19DEC94	8, .	100	110	70	84	116	70	96	143.00	
2	27DEC94	16, .	150	110	70	100	100	70	100	143.00	
3	03JAN95	23, .	200	110	70	92	104	74	92	143.00	
4	11JAN95	31, .	250	110	70	90	94	60	94	145.00	
5	18JAN95	38, .	300	108	62	80	100	62	100	144.65	
6	25JAN95	45, .	250	100	70	84	94	70	88	144.43	
7	31JAN95	51, .	250	110	80	80	100	80	80	144.21	
8	07FEB95	58, .	250	100	88	96	94	70	104	145.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.5	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.5	H	.	.	30 - 70	%
				Lymphocytes	20.3	L	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	45.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	71.4	H	.	.	30 - 70	%
				Lymphocytes	20.5	L	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	54000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	45	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00009 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	49	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	13DEC94	1	19DEC94	7	7
00010	Oral	2	0 MG	20DEC94	8	26DEC94	14	7
00010	Oral	3	0 MG	27DEC94	15	03JAN95	22	8
00010	Oral	4	0 MG	04JAN95	23	10JAN95	29	7
00010	Oral	5	0 MG	11JAN95	30	17JAN95	36	7
00010	Oral	6	0 MG	18JAN95	37	24JAN95	43	7
00010	Oral	6	0 MG	25JAN95	44	01FEB95	51	8
00010	Oral	6	0 MG	02FEB95	52	07FEB95	57	6
00090	Oral	6	0 MG	08FEB95	58	09MAR95	87	30
00090	Oral	6	0 MG	10MAR95	88	12APR95	121	34
00090	Oral	6	0 MG	13APR95	122	09MAY95	148	27
00090	Oral	6	0 MG	10MAY95	149	05JUN95	175	27
00090	Oral	6	0 MG	06JUN95	176	11JUL95	211	36
00090	Oral	6	0 MG	12JUL95	212	08AUG95	239	28
00010	Oral	5	0 MG	09AUG95	240	10AUG95	241	2
00010	Oral	4	0 MG	11AUG95	242	12AUG95	243	2
00010	Oral	3	0 MG	13AUG95	244	14AUG95	245	2
00010	Oral	2	0 MG	15AUG95	246	17AUG95	248	3
00010	Oral	1	0 MG	18AUG95	249	24AUG95	255	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	255	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DISLOCATED RIGHT HIP AT BIRTH	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1978
HERNIA REPAIR AT AGE 7	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1987
RUPTURED RIGHT EAR DRUM AT BIRTH	CONGEN ANOM, HEAD/NECK	ANOMALIES	PRV	1978

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	122, 65	13APR95	15APR95	1GM	FOOT/ANKLE INJURY
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	81, 24	03MAR95	05MAR95		HIVES
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	81, 24	03MAR95	05MAR95		HIVES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU-NAUSEA,CRAMPS DIARRHEA,STOMACH ACHE	37, -21	3 Days	0	CON	SEV	NO	UNR	No	No
	Trauma	FOOT/ANKLE (RUN OVER BY CAR INJURY-PAIN)	488, 431	3 Days	0	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS	10, -48	6 Days	0	4	MIL	NO	PSR	No	No
			39, -19	24:00 Hrs	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Urticaria	HIVES	80, 23	6 Days	0	CON	MOD	NO	UNR	Yes	No
Urogenital System	Menstrual Disorder	2 MENSTRUAL CYCLES IN JULY-2 WEEKS APART	203, 146	6 Days	0	CON	MOD	NO	PBU	No	No
			218, 161	7 Days	0	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07DEC94	-6, -63	0	100	72	68	94	60	72	121.00	69.0
BL	13DEC94	1, -57	0	100	60	68	110	68	70	121.00	
1	20DEC94	8, -50	0	100	70	78	100	70	78	120.00	
2	27DEC94	15, -43	0	100	68	88	110	70	88	119.00	
3	04JAN95	23, -35	0	100	60	76	90	60	78	122.16	
4	11JAN95	30, -28	0	104	70	76	100	60	80	123.04	
5	18JAN95	37, -21	0	102	70	72	110	70	72	123.70	
6	25JAN95	44, -14	0	90	60	70	100	70	74	120.39	
7	02FEB95	52, -6	0	104	60	74	90	60	76	121.00	
8	08FEB95	58, 1	0	100	70	76	90	60	76	121.50	
12	10MAR95	88, 31	0	90	60	76	94	60	78	123.00	
16	13APR95	122, 65	0	100	70	80	90	64	84	120.70	
20	10MAY95	149, 92	0	90	60	72	88	58	74	123.00	
24	06JUN95	176, 119	0	100	60	70	100	58	76	120.39	
32	12JUL95	212, 155	0	100	60	70	90	60	76	118.63	
32	09AUG95	240, 183	0	80	60	72	80 L	60	78	120.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.8	.	.	.	30 - 70	%
				Lymphocytes	24.4	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	208000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.2	H	.	.	30 - 70	%
				Lymphocytes	15.8	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	1.2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.9	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	24000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	149	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	240	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	29.7	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	204000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00010 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	240	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	13DEC94	1	19DEC94	7	7
00011	Oral	2	20 MG	20DEC94	8	26DEC94	14	7
00011	Oral	3	20 MG	27DEC94	15	02JAN95	21	7
00011	Oral	4	20 MG	03JAN95	22	08JAN95	27	6
00011	Oral	5	30 MG	09JAN95	28	16JAN95	35	8
00011	Oral	6	40 MG	17JAN95	36	22JAN95	41	6
00011	Oral	6	40 MG	23JAN95	42	30JAN95	49	8
00011	Oral	6	40 MG	31JAN95	50	06FEB95	56	7
00021	Oral	6	40 MG	07FEB95	57	08MAR95	86	30
00021	Oral	6	40 MG	09MAR95	87	05APR95	114	28
00021	Oral	6	40 MG	06APR95	115	02MAY95	141	27
00021	Oral	5	30 MG	03MAY95	142	17MAY95	156	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	156	30	Adverse event, including intercurrent illness	OVERDOSE WITH BAYER EXTRA STRENGTH {INTENTIONAL}

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Charcoal, Activated	Charcoal	156, 100	17MAY95	17MAY95	UNKNOWN	OVERDOSE WITH BAYER EXTRA STRENGTH
	Sodium Chloride	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
BLOOD/BLOOD FORM ORGANS	Sodium Chloride	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
			156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Bayer Aspirin Extra Strength	156, 100	17MAY95	17MAY95	UNKNOWN	OVERDOSE
	Paracetamol	Tylenol	8, -49	20DEC94	03JAN95	500MG	HEADACHE
RESPIRATORY	Sodium Chloride	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE
SENSORY ORGANS	Sodium Chloride	Normal Saline Solution	156, 100	17MAY95	19MAY95	UNKNOWN	OVERDOSE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE WITH DIZZINESS AND DROWSINESS [FATIGUE WITH DROWSINESS]	47, -10	Not Stated	40	CON	MIL	NO	PSR	No	No
		TIREDNESS INCREASED FATIGUE	7, -50	10 Days	20	4	MIL	NO	PSR	No	No
	Headache	HEADACHES	8, -49	15 Days	20	14	MOD	NO	PSR	Yes	No
Nervous System	Dizziness	DIZZINESS	21, -36	34 Days	20		MIL	NO	REL	No	No
		FATIGUE WITH DIZZINESS AND DROWSINESS [DIZZINESS]	47, -10	Not Stated	40	CON	MIL	NO	PSR	No	No
	Emotional Lability	[OVERDOSE{WITH BAYER EXTRA STRENGTH}[INTENTIONAL]	156, 100	1 Days	30	1	SEV	STP	UNR	Yes	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06DEC94	-7, -63	0	112	70	84	100	70	88	122.00	69.0
BL	13DEC94	1, -56	0	100	70	80	100	70	84	122.00	
1	20DEC94	8, -49	20	100	70	84	104	70	84	122.00	
2	27DEC94	15, -42	20	90	60	84	90	60	84	119.00	
3	03JAN95	22, -35	20	90	60	76	90	60	76	121.50	
4	09JAN95	28, -29	30	92	60	88	88	60	88	119.50	
5	17JAN95	36, -21	40	90	60	84	100	70	88	120.50	
6	23JAN95	42, -15	40	90	60	100	90	60	100	121.00	
7	31JAN95	50, -7	40	90	60	72	94	60	76	118.10	
8	07FEB95	57, 1	40	104	70	84	100	60	88	118.50	
12	09MAR95	87, 31	40	110	70	96	112	64	114	117.50	
16	06APR95	115, 59	40	110	70	90	100	62	96	118.20	
20	03MAY95	142, 86	30	100	64	88	98	60	92	119.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	24.7	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	235000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	35	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	56.6	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	51000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alkaline Phosphatase	58	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Segmented Neutrophils	64	.	.	.	30 - 70	%
				Lymphocytes	26	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00011 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	142	Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	19DEC94	1	26DEC94	8	8
00012	Oral	2	0 MG	27DEC94	9	04JAN95	17	9
00012	Oral	3	0 MG	05JAN95	18	11JAN95	24	7
00012	Oral	4	0 MG	12JAN95	25	17JAN95	30	6
00012	Oral	5	0 MG	18JAN95	31	24JAN95	37	7
00012	Oral	6	0 MG	25JAN95	38	30JAN95	43	6
00012	Oral	6	0 MG	31JAN95	44	07FEB95	51	8
00012	Oral	6	0 MG	08FEB95	52	15FEB95	59	8
00096	Oral	6	0 MG	16FEB95	60	26MAR95	98	39
00096	Oral	6	0 MG	27MAR95	99	03MAY95	136	38
00096	Oral	6	0 MG	04MAY95	137	30MAY95	163	27
00096	Oral	6	0 MG	31MAY95	164	01JUN95	165	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	165	0	Adverse event, including intercurrent illness	RECURRENCE OF OCULAR TAXOPLASMOSIS

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
TOXOPLASMOSIS{RIGHT EYE}	INFECT/PARASIT DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	37, -23	24JAN95	24JAN95	500MG	HEADACHE
SENSORY ORGANS	Steroid Eye Drops, Nos	Steroid Eye Drops {Nos}	165, 106	01JUN95	.		OCULAR TOXOPLASMOSIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	37, -23	04:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
	Infection	STOMACH FLU-(HEADACHE,NAUSEA/VOMITING AND DIARRHEA)	13, -47	4 Days	0	CON	SEV	NO	UNR	No	No
		TOXOPLASMOSIS	165, 106	Not Stated	0	CON	MOD	STP	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH (1/2 HOUR AFTER TAKING MEDICATION)	4, -56	13 Days	0	CON	MIL	NO	REL	No	No
	Dyspepsia	UPSET STOMACH (1/2 HOUR AFTER TAKING MEDICATION)	4, -56	13 Days	0	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12DEC94	-7, -66	0	110	74	80	110	70	84	145.50	69.0
BL	19DEC94	1, -59	0	100	70	84	110	70	88	145.00	
1	27DEC94	9, -51	0	110	70	88	112	72	92	144.00	
2	05JAN95	18, -42	0	120	80	92	118	70	94	143.50	
3	12JAN95	25, -35	0	94	68	68	100	70	72	143.50	
4	18JAN95	31, -29	0	118	74	72	100	70	74	144.00	
5	25JAN95	38, -22	0	110	70	60	108	72	64	142.50	
6	31JAN95	44, -16	0	112	70	60	120	82	64	140.10	
7	08FEB95	52, -8	0	112	70	68	112	80	72	140.00	
8	16FEB95	60, 1	0	110	60	78	100	60	80	145.00	
12	27MAR95	99, 40	0	120	80	80	110	78	84	146.00	
20	04MAY95	137, 78	0	110	64	64	100	70	68	149.30	
24	31MAY95	164, 105	0	110	80	60	100	82	64	147.74	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.2	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.6	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	32	L	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.7	.	.	.	30 - 70	%
				Lymphocytes	46.5	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	2.1	H	.	.	0 - 2	%
				Platelets	298000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	36	L	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	60	Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	164	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5	.	.	.	30 - 70	%
				Lymphocytes	43.9	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	36	L	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00012 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	164	Aspartate Aminotransferase	8	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	30DEC94	1	04JAN95	6	6
00109	Oral	2	20 MG	05JAN95	7	11JAN95	13	7
00109	Oral	3	20 MG	12JAN95	14	18JAN95	20	7
00109	Oral	4	20 MG	19JAN95	21	25JAN95	27	7
00109	Oral	4	20 MG	26JAN95	28	01FEB95	34	7
00109	Oral	4	20 MG	02FEB95	35	07FEB95	40	6
00109	Oral	4	20 MG	08FEB95	41	15FEB95	48	8
00109	Oral	4	20 MG	16FEB95	49	20FEB95	53	5
00023	Oral	4	20 MG	21FEB95	54	22MAR95	83	30
00023	Oral	4	20 MG	23MAR95	84	23APR95	115	32
00023	Oral	4	20 MG	24APR95	116	16MAY95	138	23

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	138	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
POSTPARTUM - NOT BREAST FEEDING	POSTPARTUM CARE	FAMILY/PERSONAL HISTORY	CUR	1994
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1979
BLEEDING ULCER {NOS}	CONDITIONS, OTHER, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ranitidine Hydrochloride	Zantac	123, 70	01MAY95	08MAY95		QUESTIONABLE BLEEDING ULCER
	Vitamins Nos	Prenatal Vitamin	-395, -448	30NOV93	.	1 4X DAILY	PREGNANCY/LACTATION
BLOOD/BLOOD FORM ORGANS	Ferrous Sulfate	Ferrous Sulfate	-133, -186	19AUG94	.	320 MG	LOW IRON
	I.V. Fluids	Iv Fluids	129, 76	07MAY95	10MAY95		QUESTIONABLE BLEEDING ULCER
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	81, 28	20MAR95	22MAR95	1 GM	HEADACHE
GU SYSTEM/SEX HORMONES	Desogestrel	Desogen 28	14, -40	12JAN95	.	1 4X DAILY	BIRTH CONTROL
	Ethinylestradiol	Desogen 28	14, -40	12JAN95	.	1 4X DAILY	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	81, 28	3 Days	20	4	MOD	NO	UNR	Yes	No
	Infection	COLD AND FLU STUFFY NOSE/NAUSEA/VOMITING DIARRHEA	42, -12	4 Days	20	CON	MOD	NO	UNR	No	No
Digestive System	Peptic Ulcer Hemorrhage	BLEEDING ULCER {PEPTIC}	129, 76	4 Days	20	CON	SEV	NO	UNR	Yes	Yes
	Vomiting	NAUSEA AND VOMITING	132, 79	2 Days	20	CON	SEV	NO	PSR	No	No
Nervous System	Drug Dependence	POSITIVE URINE DRUG SCREEN CANNABINOIDS	147, 94	1 Days	20	1	SEV	NO	UNR	No	No
	Tremor	HAND TREMORS	22, -32	12 Days	20	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22DEC94	-8, -61	0	112	70	60	100	70	60	137.00	67.0
BL	30DEC94	1, -53	0	98	60	76	90	60	76	137.50	
1	05JAN95	7, -47	20	110	70	72	120	70	72	138.50	
2	12JAN95	14, -40	20	100	60	76	108	60	72	137.50	
3	19JAN95	21, -33	20	112	70	72	112	70	76	136.20	
4	26JAN95	28, -26	20	120	80	80	110	76	84	136.00	
5	02FEB95	35, -19	20	100	70	76	98	68	80	132.10	
6	08FEB95	41, -13	20	90	60	68	100	60	72	135.50	
7	16FEB95	49, -5	20	128	76	72	128	78	76	135.61	
8	21FEB95	54, 1	20	118	74	72	110	72	74	134.00	
12	23MAR95	84, 31	20	90	70	72	104	70	76	134.00	
16	24APR95	116, 63	20	120	88	60	120	78	68	140.00	
20	25MAY95	147, 94	20	120	80	68	120	78	72	137.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.5	.	.	.	30 - 70	%
				Lymphocytes	47.5	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	1.2	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	304000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.5	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	23	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.2	L	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8		Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54		Neutrophil Bands	0	L	.	.	4 - 12	%
					Segmented Neutrophils	41	.	.	.	30 - 70	%
					Lymphocytes	48	.	.	.	21 - 51	%
					Monocytes	7	.	.	.	0 - 10	%
					Eosinophils	3	.	.	.	0 - 5	%
					Basophils	1	.	.	.	0 - 2	%
					Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	39	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
					Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	100	.	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	147	(9)	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.8	.	.	.	35 - 46	%
					Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.8	.	.	.	30 - 70	%
					Lymphocytes	38.3	.	.	.	21 - 51	%
					Monocytes	7.1	.	.	.	0 - 10	%
					Eosinophils	1.1	.	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	319000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	147 (9)	Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	32	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids POS		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00109 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	147 (9)	Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11JAN95	1	17JAN95	7	7
00110	Oral	2	100 MG	18JAN95	8	19JAN95	9	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	9	100	Adverse event, including intercurrent illness	POSITIVE PREGNANCY TEST

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1984

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Dizziness	DIZZINESS	5, .	5 Mins	50	CON	MIL	NO	PSR	No	No
Urogenital System	Unintended Pregnancy	POSITIVE PREGNANCY TEST RESULT	11, .	1 Days	100	CON	SEV	STP	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	04JAN95	-7, .	0	98	54	80	106	66	88	124.36	67.0
BL	11JAN95	1, .	0	100	70	72	100	60	80	123.00	
1	18JAN95	8, .	100	110	72	70	98	64	90	120.00	
2	25JAN95	15, .	100	110	70	74	100	70	78	122.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	22.5	.	.	.	21 - 51	%
				Monocytes	16.2	H	.	+	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEG		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	46	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	42	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00110 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 2/ELIGIBILITY	1	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	BORDERLINE	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	10 (1)	Serum BHCG pregnancy test	POSITIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11JAN95	1	17JAN95	7	7
00111	Oral	2	0 MG	18JAN95	8	24JAN95	14	7
00111	Oral	3	0 MG	25JAN95	15	31JAN95	21	7
00111	Oral	4	0 MG	01FEB95	22	07FEB95	28	7
00111	Oral	4	0 MG	08FEB95	29	14FEB95	35	7
00111	Oral	4	0 MG	15FEB95	36	21FEB95	42	7
00111	Oral	4	0 MG	22FEB95	43	28FEB95	49	7
00111	Oral	4	0 MG	01MAR95	50	07MAR95	56	7
00018	Oral	4	0 MG	08MAR95	57	04APR95	84	28
00018	Oral	4	0 MG	05APR95	85	18APR95	98	14
00111	Oral	3	0 MG	19APR95	99	20APR95	100	2
00111	Oral	2	0 MG	21APR95	101	23APR95	103	3
00111	Oral	1	0 MG	24APR95	104	30APR95	110	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	110	0	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	37, -20	16FEB95	20FEB95	750MG	SORE THROAT-STREP THROAT?
	Amoxicillin Trihydrate	Augmentin	97, 41	17APR95	27APR95	750MG	SINUS INFECTION
	Clavulanic Acid	Augmentin	97, 41	17APR95	27APR95	750MG	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Codeine Phosphate	Tylenol#3	96, 40	16APR95	17APR95	60MG	H/A/SORE THROAT
	Paracetamol	Tylenol	-4, -60	07JAN95	14FEB95	500MG	HEADACHE/BACKACHE
			36, -21	15FEB95	20FEB95	1GM	SORE THROAT/FEVER
			65, 9	16MAR95	17MAR95	1GM	SORE THROAT
			94, 38	14APR95	15APR95	2GM	H/A,PAIN-FACE,NOSE,TEETH
			96, 40	16APR95	17APR95	2GM	H/A/SORE THROAT
		Tylenol#3	96, 40	16APR95	17APR95	60MG	H/A/SORE THROAT
RESPIRATORY	Beclometasone Dipropionate	Beconase Nasal Spray .042%	85, 29	05APR95	.	4 SPRAYS	ALLERGIES/ASTHMA
			85, 29	05APR95	.	4 SPRAYS	ALLERGIES/ASTHMA
		Vancenase	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
			37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
	Cromoglicate Sodium	Nasalcrom	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
			37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
	Salbutamol	Proventil	85, 29	05APR95	07APR95	2PUFFS PRN 4XHOUR	ALLERGIES/ASTHMA
			85, 29	05APR95	07APR95	2PUFFS PRN 4XHOUR	ALLERGIES/ASTHMA
SENSORY ORGANS	Cromoglicate Sodium	Nasalcrom	37, -20	16FEB95	.	2XADAY PUFFS PRN	SINUS STUFFINESS
SYSTEMIC HORMONAL	Corticosteroids	Steroidal Nasal Preps. {Nos}	97, 41	17APR95	.		ALLERGIES/SINUS INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	"PUFFY",ITCHY,WATERY EYES {ALLERGIES}	53, -4	9 Days	0	CON	SEV	NO	PBU	No	No
	Asthenia	FATIGUE	21, -36	8 Days	0	CON	MIL	NO	PSR	No	No
	Back Pain	BACKACHE	-4, -60	39 Days	0	12	MOD	NO	PBU	Yes	No
	Fever	FEVER	36, -21	6 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	-4, -60	39 Days	0	12	MOD	NO	PBU	Yes	No
			94, 38	2 Days	0	CON	SEV	NO	UNR	Yes	No
			96, 40	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Pain	FACE PAIN	94, 38	2 Days	0	CON	SEV	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	36, -21	4 Days	0	CON	MIL	NO	PSR	No	No
			65, 9	2 Days	0	CON	MIL	NO	PBU	No	No
	Tooth Disorder	TEETH PAIN	94, 38	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Vomiting	VOMITING DRY HEAVES	97, 41	20:00 Hrs	0	CON	SEV	NO	UNR	No	No
Respiratory System	Pharyngitis	SORE THROAT	36, -21	6 Days	0	CON	MOD	NO	UNR	Yes	No
			65, 9	2 Days	0	CON	SEV	NO	UNR	Yes	No
			96, 40	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Rhinitis	NASAL STUFFINESS	37, -20	49 Days	0	CON	SEV	NO	PBU	Yes	No
		NOSE PAIN	94, 38	2 Days	0	CON	SEV	NO	UNR	Yes	No
	Sinusitis	SINUS INFECTION	97, 41	Not Stated	0	CON	SEV	STP	UNR	Yes	No
		SINUS STUFFINESS	37, -20	49 Days	0	CON	SEV	NO	PBU	Yes	No
Skin and Appendages	Rash	RASH ON BOTH FOREARMS	20, -37	6 Days	0	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	05JAN95	-6, -62	0	94	64	84	100	70	88	132.50	65.0
BL	11JAN95	1, -56	0	90	60	88	94	60	92	132.00	
1	18JAN95	8, -49	0	100	68	92	120	70	98	132.00	
2	25JAN95	15, -42	0	98	60	76	110	80	80	134.70	
3	01FEB95	22, -35	0	90	60	72	98	70	74	132.20	
4	08FEB95	29, -28	0	108	70	88	90	68	88	130.50	
5	15FEB95	36, -21	0	90	60	72	84	60	72	133.50	
6	22FEB95	43, -14	0	100	70	76	94	70	76	132.00	
7	01MAR95	50, -7	0	110	70	70	90	60	90	132.50	
8	08MAR95	57, 1	0	110	70	80	100	70	84	129.00	
12	05APR95	85, 29	0	90	60	80	104	64	76	129.87	
12	19APR95	99, 43	0	94	68	80	90	60	80	128.00	
16	03MAY95	113, 57	0	90	68	80	90	60	84	128.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.6	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	323000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 12/CONTINUATION-WEEK 16	99	Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00111 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 12/CONTINUATION-WEEK 16	99	Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	26JAN95	1	31JAN95	6	6
00112	Oral	2	20 MG	01FEB95	7	07FEB95	13	7
00112	Oral	3	20 MG	08FEB95	14	14FEB95	20	7
00112	Oral	4	20 MG	15FEB95	21	22FEB95	28	8
00112	Oral	4	20 MG	23FEB95	29	28FEB95	34	6
00112	Oral	4	20 MG	01MAR95	35	07MAR95	41	7
00112	Oral	4	20 MG	08MAR95	42	14MAR95	48	7
00112	Oral	4	20 MG	15MAR95	49	21MAR95	55	7
00024	Oral	4	20 MG	22MAR95	56	18APR95	83	28
00112	Oral	2	20 MG	19APR95	84	21APR95	86	3
00112	Oral	1	20 MG	22APR95	87	28APR95	93	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	93	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BURNING STOMACH	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-2, -57	24JAN95	26JAN95	1000MG	HEADACHE,FEVER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Fever	FEVER	-2, -57	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	-2, -57	3 Days	0	CON	MOD	NO	UNR	Yes	No
	Infection	NAUSEA VOMITING DIARRHEA (FLU)	47, -9	2 Days	20	CON	SEV	NO	UNR	No	No
Digestive System	Tooth Disorder	TOOTHACHE	32, -24	10:30 Hrs	20	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	17JAN95	-9, -64	0	104	70	66	100	70	72	119.00	61.0
BL	26JAN95	1, -55	0	100	70	68	98	70	68	115.00	
1	01FEB95	7, -49	20	100	70	80	90	60	84	119.00	
2	08FEB95	14, -42	20	100	70	76	104	70	76	119.50	
3	15FEB95	21, -35	20	90	60	84	84	56	88	118.00	
4	23FEB95	29, -27	20	98	60	84	100	70	84	118.00	
5	01MAR95	35, -21	20	100	70	80	110	74	80	118.50	
6	08MAR95	42, -14	20	120	78	100	120	82	110	122.00	
7	15MAR95	49, -7	20	90	60	92	90	60	96	122.00	
8	22MAR95	56, 1	20	94	64	76	92	60	80	123.00	
12	19APR95	84, 29	20	110	74	80	104	70	88	124.00 H	
20	21JUN95	147, 92#	0	100	70	80	104	72	84	124.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32	.	.	.	30 - 70	%
				Lymphocytes	60	H	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	300	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	32	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	31	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	34.3	.	.	.	30 - 70	%
				Lymphocytes	55.2	H	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	10000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	280	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	37	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	40	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	56		Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	104	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
		VISIT 17/DOWN TITRATION	147	(54)	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	43.2	.	.	.	41 - 50	%
					Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	30.5	.	.	.	30 - 70	%
					Lymphocytes	58.7	H	.	.	21 - 51	%
					Monocytes	6	.	.	.	0 - 10	%
					Eosinophils	4.3	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	270000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.7	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	326	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	32	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
					Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00112 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 17/DOWN TITRATION	147 (54)	Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	130	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	30JAN95	1	07FEB95	9	9
00113	Oral	2	100 MG	08FEB95	10	15FEB95	17	8
00113	Oral	3	150 MG	16FEB95	18	22FEB95	24	7
00113	Oral	4	200 MG	23FEB95	25	02MAR95	32	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	32	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1985
ABORTION	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	2,	.	31JAN95	31JAN95	500 MG	H/A
RESPIRATORY	Salbutamol	Ventolin	-3591,	.	01APR85	.	2 PUFFS PRN	ASTHMA
			-3591,	.	01APR85	.	2 PUFFS PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, .	03:45 Hrs	50	1	SEV	NO	UNR	Yes	No
Cardiovascular System	Palpitation	HEART WAS POUNDING	21, .	30 Mins	150	1	MOD	NO	REL	No	No
	Tachycardia	QUESTIONABLE INCREASED HEART RATE QUESTIONABLE TACHYCARDIA	21, .	30 Mins	150	1	MOD	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	7, .	Not Stated	50	CON	MOD	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	8, .	Not Stated	50	9	MIL	NO	REL	No	No
	Emotional Lability	SUICIDAL IDEATION	32, .	1 Days	200	CON	MOD	STP	UNR	No	No
	Tremor	HAND TREMORS	8, .	Not Stated	50	CON	MIL	NO	REL	No	No
Special Senses	Abnormal Vision	BLURRED VISION	8, .	Not Stated	50	10	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20JAN95	-10, .	0	110	70	68	100	70	72	145.00	67.0
BL	30JAN95	1, .	0	90	60	80	100	70	84	143.33	
1	08FEB95	10, .	100	110	70	72	100	60	74	145.20	
2	16FEB95	18, .	150	104	70	88	104	68	100	141.34	
3	23FEB95	25, .	200	110	70	72	100	70	80	140.00	
4	02MAR95	32, .	200	100	70	80	84	60	80	140.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	33	.	.	.	30 - 70	%
				Lymphocytes	58	H	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	54000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00113 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	31JAN95	1	06FEB95	7	7
00114	Oral	2	0 MG	07FEB95	8	13FEB95	14	7
00114	Oral	3	0 MG	14FEB95	15	20FEB95	21	7
00114	Oral	4	0 MG	21FEB95	22	27FEB95	28	7
00114	Oral	4	0 MG	28FEB95	29	08MAR95	37	9
00114	Oral	4	0 MG	09MAR95	38	14MAR95	43	6
00114	Oral	4	0 MG	15MAR95	44	21MAR95	50	7
00114	Oral	4	0 MG	22MAR95	51	28MAR95	57	7
00020	Oral	4	0 MG	29MAR95	58	25APR95	85	28
00114	Oral	4	0 MG	26APR95	86	26APR95	86	1
00114	Oral	3	0 MG	27APR95	87	28APR95	88	2
00114	Oral	2	0 MG	29APR95	89	01MAY95	91	3
00114	Oral	1	0 MG	02MAY95	92	08MAY95	98	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	98	0	Lack of Efficacy	DEPRESSIVE SYMPTOMS RETURNED AFTER GIRLFRIEND BROKE UP WITH HIM.RETURN MAJOR DEPRESSIVE DISORDER SYMPTOMS.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	7, -51	06FEB95	16FEB95	750MG	STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	5, -53	04FEB95	08FEB95	500MG	STREP THROAT-PAIN
RESPIRATORY	Salbutamol	Ventolin Inhaler	-565, -622	15JUL93	18OCT94#	2PUFFS	ASTHMA
			-565, -622	15JUL93	18OCT94#	2PUFFS	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT SORE THROAT AND FEVER	5, -53	11 Days	0	CON	SEV	NO	UNR	Yes	No
Nervous System	Tremor	HAND TREMORS	30, -28	22 Days	0	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23JAN95	-8, -65	0	112	70	68	108	72	72	145.20	70.0
BL	31JAN95	1, -57	0	80	60	72	70	50	72	145.00	
1	07FEB95	8, -50	0	108	62	80	102	62	88	153.50	
2	14FEB95	15, -43	0	110	80	60	90	70	64	154.50	
3	21FEB95	22, -36	0	100	70	58	104	70	60	155.89 H	
4	28FEB95	29, -29	0	110	70	70	90	60	72	157.00 H	
5	09MAR95	38, -20	0	100	70	80	90	64	80	157.00 H	
6	15MAR95	44, -14	0	104	80	80	100	70	84	155.00	
7	22MAR95	51, -7	0	104	70	60	90	70	64	154.50	
8	29MAR95	58, 1	0	100	70	68	92	70	72	153.00	
12	26APR95	86, 29	0	90	60	70	98	68	74	155.10	
16	17MAY95	107, 50	0	104	70	72	100	70	74	155.50 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.6	.	.	.	30 - 70	%
				Lymphocytes	21.1	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	99	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	.	.	.	30 - 70	%
				Lymphocytes	49	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	103000	L	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.4	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	91	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	58		Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	NEG		.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 17/DOWN TITRATION	107	(9)	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	46	.	.	.	41 - 50	%
					Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	60	.	.	.	30 - 70	%
					Lymphocytes	35	.	.	.	21 - 51	%
					Monocytes	1	.	.	.	0 - 10	%
					Eosinophils	4	.	.	.	0 - 5	%
					Basophils	0	.	.	.	0 - 2	%
					Platelets	225000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	6.3	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	89	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	89	.	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00114 TREATMENT GROUP: PLACEBO

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	06FEB95	1	12FEB95	7	7
00115	Oral	2	0 MG	13FEB95	8	19FEB95	14	7
00115	Oral	3	0 MG	20FEB95	15	01MAR95	24	10
00115	Oral	4	0 MG	02MAR95	25	09MAR95	32	8
00115	Oral	4	0 MG	10MAR95	33	16MAR95	39	7
00115	Oral	4	0 MG	17MAR95	40	27MAR95	50	11
00115	Oral	4	0 MG	28MAR95	51	09APR95	63	13
00115	Oral	4	0 MG	10APR95	64	17APR95	71	8
00003	Oral	4	0 MG	18APR95	72	21APR95	75	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	Yes	No	75	0	Other reason	PT. REPORTS FEELING BETTER AND DOES NOT WANT TO TAKE MEDICATION ANY LONGER.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1984

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	19, -53	24FEB95	15MAR95	750 MG	TOOTH ACHE/SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Hydrocodone Bitartrate	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
	Paracetamol	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
GU SYSTEM/SEX HORMONES	Oral Contraceptive	Birth Control Pills	-31, -102	06JAN95	.	1X	PREVENT PREGNANCY
RESPIRATORY	Hydrocodone Bitartrate	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
	Paracetamol	Vicodin	19, -53	24FEB95	10MAR95	750 MG PRN	TOOTH ACHE/SINUS INFECTION
	Salbutamol	Ventolin Inhaler	-27, -98	10JAN95	10JAN95#	2 PUFFS PRN	ASTHMA
			-27, -98	10JAN95	10JAN95#	2 PUFFS PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	7, -65	02:30 Hrs	0	CON	MIL	NO	PSR	No	No
		HEADACHES	37, -35	02:00 Hrs	0	7	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	3, -69	6 Days	0	CON	MIL	NO	REL	No	No
Hemic and Lymphatic System	Wbc Abnormality	ATYPICAL LYMPHS	72, 1	1 Days	0	1	MIL	NO	PBU	No	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS (12 POUNDS)	64, -8	9 Days	0	CON	SEV	NO	UNR	No	No
Respiratory System	Sinusitis	TOOTHACHE/QUESTIONABLE SINUS INFECTION	18, -54	26 Days	0	CON	SEV	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	27JAN95	-10, -81	0	118	76	78	110	74	82	144.00	64.0
BL	06FEB95	1, -71	0	120	70	84	118	60	88	143.50	
1	13FEB95	8, -64	0	104	70	80	110	70	84	143.70	
2	20FEB95	15, -57	0	120	70	88	110	68	92	142.22	
3	02MAR95	25, -47	0	124	80	88	118	70	88	146.00	
5	10MAR95	33, -39	0	120	76	80	112	70	84	144.00	
6	17MAR95	40, -32	0	112	70	76	110	64	80	144.70	
7	28MAR95	51, -21	0	106	70	84	118	80	94	145.00	
8	10APR95	64, -8	0	116	78	60	120	70	60	152.00	
8	18APR95	72, 1	0	110	54	76	110	60	82	140.00	
12	27APR95	81, 10	0	114	70	68	110	68	74	141.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	53.7	.	.	.	40 - 75	%
				Lymphocytes	41.6	.	.	.	16 - 46	%
				Monocytes	3.5	.	.	.	0 - 12	%
				Eosinophils	1	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	72	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7	.	.	.	3.8 - 10.8	THOU/MCL
				Neutrophil Bands	0	.	.	.	0 - 8	%
				Segmented Neutrophils	44	.	.	.	40 - 75	%
				Lymphocytes	35	.	.	.	16 - 46	%
				Monocytes	3	.	.	.	0 - 12	%
				Eosinophils	0	.	.	.	0 - 7	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	221000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	72	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	118	H	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	81 (6)	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	51.8	.	.	.	40 - 75	%
				Lymphocytes	40.7	.	.	.	16 - 46	%
				Monocytes	5.8	.	.	.	0 - 12	%
				Eosinophils	1.5	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	215000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00115 TREATMENT GROUP: PLACEBO

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07FEB95	1	12FEB95	6	6
00116	Oral	2	20 MG	13FEB95	7	19FEB95	13	7
00116	Oral	3	20 MG	20FEB95	14	26FEB95	20	7
00116	Oral	4	20 MG	27FEB95	21	08MAR95	30	10
	Oral	4	20 MG	09MAR95	31	15MAR95	37	7
00116	Oral	4	20 MG	16MAR95	38	22MAR95	44	7
00116	Oral	4	20 MG	23MAR95	45	29MAR95	51	7
00116	Oral	4	20 MG	30MAR95	52	05APR95	58	7
00002	Oral	4	20 MG	06APR95	59	03MAY95	86	28
00002	Oral	4	20 MG	04MAY95	87	30MAY95	113	27
00002	Oral	5	30 MG	31MAY95	114	27JUN95	141	28
00116	Oral	4	20 MG	28JUN95	142	29JUN95	143	2
00116	Oral	3	20 MG	30JUN95	144	01JUL95	145	2
00116	Oral	2	20 MG	02JUL95	146	04JUL95	148	3
00116	Oral	1	20 MG	05JUL95	149	11JUL95	155	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	155	20	Adverse event, including intercurrent illness	SEVERE POISON IVY-TAKING PREDNISONE

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	26, -33	04MAR95	14MAR95	750MG	BRONCHITIS
	Amoxicillin Trihydrate	Augmentin	25, -34	03MAR95	13MAR95	UNKNOWN,THRE E TIMES DAILY	EAR INFECTION
	Cefuroxime Axetil	Ceftin	141, 83	27JUN95	07JUL95	UNKNOWN MG(2PILLS)	TONSILLITIS
	Clavulanic Acid	Augmentin	25, -34	03MAR95	13MAR95	UNKNOWN,THRE E TIMES DAILY	EAR INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	25, -34	03MAR95	04APR95	500MG	EARACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	65, 7	12APR95	12APR95	UNKNOWN	HEADACHE
			111, 53	28MAY95	30MAY95	UNKNOWN PRN	MENSTRUAL CRAMPS
RESPIRATORY	Cough Syrup/Med	Smith Brothers Cough Drop	75, 17	22APR95	07MAY95	1DAILY	COUGH
	Guaifenesin	Robitussin	75, 17	22APR95	07MAY95	2TSP	COUGH
	Prednisone	Prednisone	135, 77	21JUN95	28JUN95	30MG	POISON IVY
			143, 85	29JUN95	02JUL95	20MG	POISON IVY
			147, 89	03JUL95	07JUL95	10MG	POISON IVY
			152, 94	08JUL95	12JUL95	10MG EVERY OTHER DAY	POISON IVY
	Salbutamol	Ventolin Inhaler	26, -33	04MAR95	14MAR95	2PUFFS 4TIME A DAY	BRONCHITIS
			26, -33	04MAR95	14MAR95	2PUFFS 4TIME A DAY	BRONCHITIS
SENSORY ORGANS	Ear Medication, Nos	Ear Drops {Nos}	25, -34	03MAR95	04APR95	THREE TIMES DAILY	EARACHE
SYSTEMIC HORMONAL	Prednisone	Prednisone	135, 77	21JUN95	28JUN95	30MG	POISON IVY
			143, 85	29JUN95	02JUL95	20MG	POISON IVY
			147, 89	03JUL95	07JUL95	10MG	POISON IVY
			152, 94	08JUL95	12JUL95	10MG EVERY OTHER DAY	POISON IVY

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	65, 7	1 Days	20	3	MOD	NO	PBU	Yes	No
	Infection	NAUSEA,VOMITING,DIARRHEA (STOMACH FLU)	28, -31	24:00 Hrs	20	CON	SEV	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	4, -55	152 Days	20	CON	MOD	NO	REL	No	No
	Dyspepsia	UPSET STOMACH	2, -57	6 Days	20	10	MOD	NO	PBU	No	No
		UPSET STOMACH {WHEN TAKES MEDICATIONS AT BEDTIME}	57, -2	99 Days	20	CON	MIL	NO	PSR	No	No
	Increased Appetite	INCREASED APPETITE	9, -50	162 Days	20	CON	MOD	NO	PSR	No	No
Musculoskeletal System	Myalgia	CRAMPS IN LEFT LEG	30, -29	2 Days	20	CON	MOD	NO	UNR	No	No
Nervous System	Tremor	HAND TREMORS	26, -33	29 Days	20	CON	MIL	NO	REL	No	No
Respiratory System	Bronchitis	BRONCHITIS WITH COUGH	26, -33	25 Days	20	CON	SEV	NO	UNR	Yes	No
	Cough Increased	COUGH	75, 17	16 Days	20	5	MOD	NO	UNR	Yes	No
	Pharyngitis	TONSILLITIS	138, 80	14 Days	30	CON	SEV	NO	UNR	Yes	No
Skin and Appendages	Contact Dermatitis	POISON IVY	131, 73	26 Days	30	CON	SEV	STP	UNR	Yes	No
Special Senses	Otitis Media	EAR INFECTION/ACHE	26, -33	25 Days	20	CON	SEV	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	111, 53	3 Days	20	CON	SEV	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	30JAN95	-8, -66	0	118	80	54	110	80	56	206.80	71.0
BL	07FEB95	1, -58	0	112	80	68	90	72	64	206.50	
1	13FEB95	7, -52	20	110	80	72	90	60	74	206.70	
2	20FEB95	14, -45	20	110	70	72	104	60	74	204.10	
3	27FEB95	21, -38	20	118	62	70	112	70	74	203.30	
4	09MAR95	31, -28	20	104	78	84	100	74	88	201.00	
5	16MAR95	38, -21	20	120	78	84	110	80	88	201.00	
6	23MAR95	45, -14	20	118	70	76	110	70	80	201.50	
7	30MAR95	52, -7	20	120	84	96	112	80	98	206.00	
8	06APR95	59, 1	20	120	80	88	112	70	92	208.00	
12	04MAY95	87, 29	20	100	74	72	98	70	80	211.00	
16	31MAY95	114, 56	30	104	80	80	98	70	84	214.00	
20	28JUN95	142, 84	20	90	60	68	88	60	64	212.20	
24	26JUL95	170, 112#	0	118	80	80	110	74	84	212.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	34.9	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	52	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.4	.	.	.	30 - 70	%
				Lymphocytes	33.7	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Platelets	71000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	78	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
		VISIT 17/DOWN TITRATION	170 (15)	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	30 - 70	%
				Lymphocytes	32.1	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00116 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 17/DOWN TITRATION	170	(15)	Platelets	218000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	7	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	95	.	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	18MAR95	1	26MAR95	9	9
00117	Oral	2	100 MG	27MAR95	10	02APR95	16	7
00117	Oral	3	150 MG	03APR95	17	09APR95	23	7
00117	Oral	4	200 MG	10APR95	24	16APR95	30	7
00117	Oral	4	200 MG	17APR95	31	23APR95	37	7
00117	Oral	4	200 MG	24APR95	38	30APR95	44	7
00117	Oral	4	200 MG	01MAY95	45	07MAY95	51	7
00117	Oral	4	200 MG	08MAY95	52	14MAY95	58	7
	Oral	4	200 MG	15MAY95	59	26MAY95	70	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	70	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HISTORY OF CHRONIC OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1979
MILD HEARING LOSS	HEARING LOSS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1979
STATUS POST HIP SURGERY	OPERATION, BONE/JOINT	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Cimetidine	Cimetidine	41, .	27APR95	.	1200MG	GASTRITIS
	Cisapride	Propulsid	41, .	27APR95	.	40MG	GASTRITIS
CENTRAL NERVOUS SYSTEM	Oxycodone Hydrochloride	Percocet	52, .	08MAY95	15MAY95	1X DAILY EVERY 4HRS.AS NE	PAIN
	Oxycodone Terephthalate	Percocet	52, .	08MAY95	15MAY95	1X DAILY EVERY 4HRS.AS NE	PAIN
	Paracetamol	Percocet	52, .	08MAY95	15MAY95	1X DAILY EVERY 4HRS.AS NE	PAIN

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chills	CHILLS-INCREASED AND DECREASED BACK AND ARMS-NO FEVER	1, .	31 Days	50	11	MOD	NO	PSR	No	No
	Headache	HEADACHE	39, .	Not Stated	200	CON	SEV	NO	PBU	No	No
Carciovascular System	Tachycardia	INCREASED HEART RATE	24, .	22 Days	200	CON	MOD	NO	PSR	No	No
	Vasodilatation	FLUSHED FACE-NO HIVES	1, .	4 Days	50	3	MIL	NO	PSR	No	No
Digestive System	Diarrhea	DIARRHEA	2, .	3 Days	50	1	MOD	NO	PSR	No	No
	Gastritis	GASTRITIS	41, .	Not Stated	200	CON	MOD	NO	PBU	Yes	No
	Tooth Disorder	PAIN DUE TO WISDOM TOOTH EXTRACTION	52, .	8 Days	200	CON	MOD	NO	UNR	Yes	No
	Vomiting	NAUSEATED AND VOMITING	21, .	Not Stated	150	CON	SEV	NO	PBU	No	No
Nervous System	Nervousness	INCREASED IRRITABILITY	29, .	Not Stated	200	CON	MOD	NO	PBU	No	No
Respiratory System	Epistaxis	NOSEBLEEDS	28, .	15 Mins	200	2	MIL	NO	PBU	No	No
Skin and Appendages	Pruritus	ITCHING-WITHOUT HIVES	2, .	3 Days	50	1	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06MAR95	-12, .	0	120	84	82	116	80	86	245.64	52.0
BL	16MAR95	-2, .	0	124	84	84	100	80	88	246.96	
1	27MAR95	10, .	100	108	80	98	122	90	98	245.86	
2	03APR95	17, .	150	114	68	98	118	70	108	249.20	
3	10APR95	24, .	200	120	70	102	110	70	110	248.40	
4	17APR95	31, .	200	110	70	100	114	70	108	246.50	
5	24APR95	38, .	200	100	58	96	98	50	104	246.20	
6	01MAY95	45, .	200	114	68	98	120	76	108	243.87	
7	08MAY95	52, .	200	100	72	92	90	60	106	239.46	
8	15MAY95	59, .	200	98	68	90	90	60	96	237.26	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	28.9	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	364000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	119	H	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00117 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells		4	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	17MAY95	1	23MAY95	7	7
00118	Oral	2	100 MG	24MAY95	8	29MAY95	13	6
00118	Oral	3	150 MG	30MAY95	14	05JUN95	20	7
00118	Oral	4	200 MG	06JUN95	21	13JUN95	28	8
00118	Oral	5	250 MG	14JUN95	29	19JUN95	34	6
00118	Oral	6	300 MG	20JUN95	35	26JUN95	41	7
	Oral	5	250 MG	27JUN95	42	05JUL95	50	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	50	250	Protocol violation, including non-compliance	POSITIVE DRUG SCREEN

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
GYNECOMASTIA	GYNECOMASTIA	GENITOURINARY SYST DIS	CUR	
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	4, .	20MAY95	23MAY95	500 MG	SORE THROAT
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-20, .	27APR95	27APR95#	400MG	HEADACHE
RESPIRATORY	Guaifenesin	Robitussin	3, .	19MAY95	.	4 TSP.	COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	24, .	02:00 Hrs	200	2	MOD	NO	PBU	No	No
Carciovascular System	Migraine	MIGRAINE HEADACHE	4, .	04:00 Hrs	50	CON	SEV	NO	UNR	No	No
Nervous System	Dizziness	LIGHT-HEADEDNESS	7, .	23 Days	50	5	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	4, .	4 Days	50	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	CHEST CONGESTION AND COUGH	3, .	6 Days	50	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	09MAY95	-8, .	0	116	70	64	112	72	70	151.00	65.0
BL	17MAY95	1, .	0	110	68	60	108	70	66	151.90	
1	24MAY95	8, .	100	100	70	80	98	64	84	152.20	
2	30MAY95	14, .	150	116	70	86	108	70	96	152.59	
3	06JUN95	21, .	200	108	74	98	98	60	98	151.92	
4	14JUN95	29, .	250	114	78	84	116	80	94	153.47	
5	20JUN95	35, .	300	110	70	94	98	64	110	154.00	
6	27JUN95	42, .	250	112	76	98	104	70	108	153.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.7	.	.	.	30 - 70	%
				Lymphocytes	35.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEC	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	35	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00118 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 7/ACUTE PHASE-WEEK 5	35	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11JUL95	1	17JUL95	7	7
00119	Oral	2	20 MG	18JUL95	8	25JUL95	15	8
00119	Oral	3	20 MG	26JUL95	16	01AUG95	22	7
00119	Oral	4	20 MG	02AUG95	23	07AUG95	28	6
00119	Oral	5	30 MG	08AUG95	29	14AUG95	35	7
00119	Oral	6	40 MG	15AUG95	36	22AUG95	43	8
00119	Oral	6	40 MG	23AUG95	44	28AUG95	49	6
00119	Oral	6	40 MG	29AUG95	50	07SEP95	59	10
00056	Oral	6	40 MG	08SEP95	60	02OCT95	84	25
00056	Oral	6	40 MG	03OCT95	85	29OCT95	111	27
00056	Oral	6	40 MG	30OCT95	112	27NOV95	140	29
00119	Oral	5	30 MG	28NOV95	141	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	141	30	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	7, -53	17JUL95	17JUL95	650MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	47, -13	26AUG95	26AUG95	1TAB DAILY	ORTHODONTIC DISCOMFORT
RESPIRATORY	Dextromethorphan Hydrobromide	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS
	Doxylamine Succinate	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS
	Guaifenesin	Robitussin	80, 21	28SEP95	28SEP95	1 DOSE	COLD SYMPTOMS
	Paracetamol	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS
	Pseudoephedrine Hydrochloride	Nyquil	79, 20	27SEP95	27SEP95		COLD SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	"STOMACH ACHE"	105, 46	5 Days	40	5	MOD	NO	PBU	No	No
		STOMACH ACHE	10, -50	4 Days	20	2	MIL	NO	PBU	No	No
	Asthenia	FATIGUE	1, -59	4 Days	20	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	7, -53	02:00 Hrs	20		MOD	NO	PSR	Yes	No
			41, -19	01:00 Hrs	40	2	MOD	NO	PBU	No	No
Digestive System	Vomiting	NAUSEA AND VOMITING	105, 46	5 Days	40	5	MOD	NO	PBU	No	No
Nervous System	Hostility	PHYSICAL FIGHT {AGGRESSION}	18, -42	10 Mins	20	1	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS	79, 20	4 Days	40	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	27JUN95	-14, -73	0	118	80	70	110	82	70	150.10	65.0
BL	11JUL95	1, -59	0	128	80	70	120	80	88	153.20	
1	18JUL95	8, -52	20	120	80	74	110	72	76	153.50	
2	26JUL95	16, -44	20	120	82	80	118	88	80	152.60	
3	02AUG95	23, -37	20	124	74	70	120	80	80	152.00	
4	08AUG95	29, -31	30	110	64	72	110	64	86	151.00	
5	15AUG95	36, -24	40	100	60	88	104	60	96	155.20	
6	23AUG95	44, -16	40	128	80	94	120	80	106	156.80	
7	29AUG95	50, -10	40	118	78	86	106	74	92	159.00	
8	08SEP95	60, 1	40	122	80	88	120	72	96	158.00	
12	03OCT95	85, 26	40	128	80	84	118	86	98	156.00	
16	30OCT95	112, 53	40	120	80	92	118	68	108	155.00	
20	28NOV95	141, 82	30	90	60	94	90	50	106	159.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.5	.	.	.	30 - 70	%
				Lymphocytes	38.3	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	249000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	94	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEC		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.8	.	.	.	30 - 70	%
				Lymphocytes	39.7	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	60	Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141 (1)	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	141 (1)	Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.9	.	.	.	30 - 70	%
				Lymphocytes	38.4	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	300000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00119 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	141 (1)	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	30AUG95	1	06SEP95	8	8
00120	Oral	2	0 MG	07SEP95	9	13SEP95	15	7
00120	Oral	3	0 MG	14SEP95	16	20SEP95	22	7
00120	Oral	4	0 MG	21SEP95	23	27SEP95	29	7
00120	Oral	5	0 MG	28SEP95	30	04OCT95	36	7
00120	Oral	5	0 MG	05OCT95	37	11OCT95	43	7
00120	Oral	6	0 MG	12OCT95	44	18OCT95	50	7
00120	Oral	6	0 MG	19OCT95	51	26OCT95	58	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	58	0	Lack of Efficacy	DIDN'T RETURN TAPER PACK ALTHOUGH MOM REPORTED THAT HE COMPLETED TAPER PACK DURING A PHONE CONVERSATION.THEY THEN MOVED OUT OF STATE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
RASH ON ARMS AND CHEST{FOLLICULITIS}	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Dermatologicals Nos	Topical Cream {Dermatological Nos}	.,	.		.		RASH (?FOLLICULITIS)
RESPIRATORY	Guaifenesin	Robitussin	19,	.	17SEP95	19SEP95		COUGH
			55,	.	23OCT95	23OCT95		COUGH
	Pseudoephedrine Hydrochloride	Actifed	15,	.	13SEP95	14SEP95		RUNNY NOSE,COUGH
	Triprolidine Hydrochloride	Actifed	15,	.	13SEP95	14SEP95		RUNNY NOSE,COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	16, .	30 Mins	0	1	MIL	NO	UNR	No	No
Hemic and Lymphatic System	Eosinophilia	INCREASED EOSINOPHILS	-8, .	Not Stated	0	CON	MIL	NO	UNR	No	No
			58, .	Not Stated	0	CON	MIL	NO	UNR	No	No
Metabolic and Nutritional Disorders	Hyperglycemia	INCREASED GLUCOSE	-8, .	Not Stated	0	CON	MIL	NO	UNR	No	No
			58, .	Not Stated	0	CON	MIL	NO	UNR	No	No
Nervous System	Euphoria	LAUGHING A LOT {EUPHORIA}	21, .	17 Days	0	3	MOD	NO	UNR	No	No
	Nervousness	NERVOUS	21, .	2 Days	0		MIL	NO	UNR	No	No
			23, .	8 Days	0	CON	MIL	NO	UNR	No	No
Respiratory System	Cough Increased	COUGH	14, .	8 Days	0	CON	MOD	NO	UNR	Yes	No
		COUGHING	55, .	Not Stated	0	CON	MIL	NO	UNR	Yes	No
	Rhinitis	RUNNY NOSE	14, .	7 Days	0	CON	MIL	NO	UNR	Yes	No
Urogenital System	Kidney Function Abnormal	DECREASED UREA NITROGEN	-8, .	66 Days	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22AUG95	-8, .	0	124	60	96	120	60	98	152.00	61.5
BL	30AUG95	1, .	0	110	72	72	106	66	80	152.15	
1	07SEP95	9, .	0	104	62	68	108	66	84	155.23	
2	14SEP95	16, .	0	112	66	80	108	66	84	159.20	
3	21SEP95	23, .	0	116	72	84	114	70	88	160.52	
4	28SEP95	30, .	0	116	68	84	110	66	88	159.86	
5	05OCT95	37, .	0	108	72	68	104	68	68	162.51	
6	12OCT95	44, .	0	116	66	68	114	68	72	162.51	
7	19OCT95	51, .	0	122	68	72	116	66	76	164.71 H	
8	26OCT95	58, .	0	120	64	88	116	68	80	166.04 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.7	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	9.1	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	340	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	270	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00120 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	145	H	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	06SEP95	1	13SEP95	8	8
00151	Oral	2	20 MG	14SEP95	9	19SEP95	14	6
00151	Oral	3	20 MG	20SEP95	15	27SEP95	22	8
00151	Oral	4	20 MG	28SEP95	23	02OCT95	27	5
00151	Oral	4	20 MG	03OCT95	28	10OCT95	35	8
00151	Oral	4	20 MG	11OCT95	36	18OCT95	43	8
00151	Oral	4	20 MG	19OCT95	44	25OCT95	50	7
00151	Oral	4	20 MG	26OCT95	51	01NOV95	57	7
00030	Oral	4	20 MG	02NOV95	58	27NOV95	83	26
00030	Oral	4	20 MG	28NOV95	84	03JAN96	120	37
00030	Oral	5	30 MG	04JAN96	121	30JAN96	147	27
00030	Oral	5	30 MG	31JAN96	148	26FEB96	174	27
00192	Oral	5	30 MG	27FEB96	175	26MAR96	203	29
00192	Oral	5	30 MG	27MAR96	204	30APR96	238	35
00350	Oral	4	20 MG	01MAY96	239	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	Yes	239	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACK PAIN	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1989
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	41, -17	16OCT95	02NOV95	750MG	EAR INFECTION STREP THROAT
	Erythromycin	Erythromycin	48, -10	23OCT95	07NOV95		URI
CENTRAL NERVOUS SYSTEM	Paracetamol	Extra Strength Tylenol	1, -57	06SEP95	06SEP95	2TABS A DAY	BACK PAIN
		Tylenol	-25, -82	12AUG95	12AUG95#	650MG	HEADACHE
			40, -18	15OCT95	17OCT95	2GM	SORE THROAT/STREP
			44, -14	19OCT95	19OCT95	1GM	BACK PAIN
		Tylenol Extra Strength	., .		03SEP95#	650MG	BACK PAIN
DERMATOLOGICALS	Erythromycin	Erythromycin	48, -10	23OCT95	07NOV95		URI
SENSORY ORGANS	Erythromycin	Erythromycin	48, -10	23OCT95	07NOV95		URI
	Polyvidone	Refresh	156, 99	08FEB96	08MAR96		FOREIGN OBJECT IN EYE
	Polyvinyl Alcohol	Refresh	156, 99	08FEB96	08MAR96		FOREIGN OBJECT IN EYE
	Sodium Chloride	Refresh	156, 99	08FEB96	08MAR96		FOREIGN OBJECT IN EYE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK PAIN	1, -57	1 Days	20	1	MOD	NO	UNR	Yes	No
			44, -14	02:00 Hrs	20	1	MIL	NO	UNR	Yes	No
	Infection	SORE THROAT AND EAR INFECTION DIAGNOSIS:STREP THROAT	40, -18	12 Days	20	CON	SEV	NO	UNR	Yes	No
	Trauma	FOREIGN OBJECT IN EYE	154, 97	3 Days	30	CON	MOD	NO	UNR	Yes	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN	84, 27	156 Days	20	CON	MOD	NO	PSR	No	No
Respiratory System	Respiratory Disorder	UPPER RESPIRATORY INFECTION	47, -11	17 Days	20	CON	MOD	NO	UNR	Yes	No
Urogenital System	Albuminuria	PROTEIN IN URINE	148, 91	92 Days	30	CON	MOD	NO	PBU	No	No
	Urinary Casts	COURSE GRANULAR CASTS HYALINE CAST IN URINE	148, 91	92 Days	30	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	29AUG95	-8, -65	0	110	60	82	108	64	86	112.46	63.0
BL	06SEP95	1, -57	0	102	64	76	106	66	88	110.91	
1	14SEP95	9, -49	20	110	60	68	90	60	68	109.00	
2	20SEP95	15, -43	20	100	60	64	110	70	64	107.50	
3	28SEP95	23, -35	20	100	60	70	90	62	70	108.00	
4	03OCT95	28, -30	20	100	60	88	104	60	92	105.20	
5	11OCT95	36, -22	20	90	50	84	96	56	96	107.00	
6	19OCT95	44, -14	20	100	64	80	102	66	88	109.59	
7	26OCT95	51, -7	20	108	70	84	100	60	88	108.50	
8	02NOV95	58, 1	20	106	66	84	104	64	88	109.81	
12	28NOV95	84, 27	20	98	50	88	98	48	92	111.00	
16	02JAN96	119, 62	20	120	80	80	120	70	86	114.00	
20	31JAN96	148, 91	30	104	70	84	98	68	88	114.00	
24	27FEB96	175, 118	30	90	50	72	90	60	88	116.70	
28	27MAR96	204, 147	30	100	60	78	94	60	76	118.41	
32	01MAY96	239, 182	20	98	68	68	92	64	78	119.75 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.9	.	.	.	30 - 70	%
				Lymphocytes	36.5	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	11.5	H	.	+	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	131000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	89	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.3	.	.	.	30 - 70	%
				Lymphocytes	44.3	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	148	Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	175	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	239 (1)	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.1	.	.	.	30 - 70	%
				Lymphocytes	46.6	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00151 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	239 (1)	Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	26OCT95	1	30OCT95	5	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	5	20	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1985

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	5, .	24:00 Hrs	20	CON	SEV	STP	REL	No	No
Digestive System	Diarrhea	DIARRHEA	5, .	24:00 Hrs	20	CON	SEV	STP	REL	No	No
	Nausea	NAUSEA	2, .	4 Days	20	CON	SEV	STP	REL	No	No
	Vomiting	NAUSEA AND VOMITING	2, .	4 Days	20	8	SEV	STP	REL	No	No
		VOMITING	5, .	24:00 Hrs	20	CON	SEV	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12OCT95	-14, .	0	100	70	78	94	70	84	128.00	66.0
BL	23OCT95	-3, .	0	104	70	76	100	70	84	128.50	
1	02NOV95	8, .	20	100	60	72	90	60	76	126.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.8	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	308000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	-3	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00152 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-3	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	25JAN96	1	31JAN96	7	7
00153	Oral	2	100 MG	01FEB96	8	07FEB96	14	7
00153	Oral	3	150 MG	08FEB96	15	14FEB96	21	7
00153	Oral	4	200 MG	15FEB96	22	21FEB96	28	7
00153	Oral	5	250 MG	22FEB96	29	28FEB96	35	7
00153	Oral	5	250 MG	29FEB96	36	05MAR96	41	6
00153	Oral	5	250 MG	06MAR96	42	13MAR96	49	8
00153	Oral	5	250 MG	14MAR96	50	20MAR96	56	7
00125	Oral	5	250 MG	21MAR96	57	16APR96	83	27
00125	Oral	6	300 MG	17APR96	84	14MAY96	111	28
00125	Oral	6	300 MG	15MAY96	112	11JUN96	139	28
00125	Oral	6	300 MG	12JUN96	140	09JUL96	167	28
00125	Oral	6	300 MG	10JUL96	168	04AUG96	193	26
00125	Oral	6	300 MG	05AUG96	194	03SEP96	223	30
00153	Oral	5	250 MG	04SEP96	224	05SEP96	225	2
00153	Oral	4	200 MG	06SEP96	226	07SEP96	227	2
00153	Oral	3	150 MG	08SEP96	228	09SEP96	229	2
00153	Oral	2	100 MG	10SEP96	230	13SEP96	233	4
00153	Oral	1	50 MG	14SEP96	234	16SEP96	236	3

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	Yes	Yes	236	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
INCREASED LYMPHOCYTES	LYMPHOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
INCREASED NEUTROPHIL SEGS	LEUCOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
TRACE PROTEIN IN URINE	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Tetracycline	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	7, -50	31JAN96	31JAN96	6 TABS	MENSTRUAL CRAMPS
	Caffeine	Midol	7, -50	31JAN96	31JAN96	6 TABS	MENSTRUAL CRAMPS
	Chlorphenamine Maleate	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
	Cinnamedrine Hydrochloride	Midol	7, -50	31JAN96	31JAN96	6 TABS	MENSTRUAL CRAMPS
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
	Paracetamol	Tylenol	., .		17APR96	2 EXTRA STRENGTH	HEADACHE X3
			28, -29	21FEB96	21FEB96	1000 MG	HEADACHE
			38, -19	02MAR96	02MAR96	1000 MG	HEADACHE
			57, 1	21MAR96	17APR96	1000 MG	HEADACHE X3
			84, 28	17APR96	15MAY96	1000 MG	HEADACHE X2
			112, 56	15MAY96	12JUN96	1000 MG	HEADACHE X6
			140, 84	12JUN96	10JUL96	1000 MG	HEADACHE X2
			168, 112	10JUL96	05AUG96	1000 MG	HEADACHE X1
		Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
		Tylenol Extra Strength	-2, -58	23JAN96	23JAN96#	500 MG	BACK PAIN
			17, -40	10FEB96	10FEB96	1000 MG	HEADACHE
		Tylenol Gelcaps	-9, -65	16JAN96	27JAN96		COLD
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
DERMATOLOGICALS	Tetracycline	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	., .		.	200 MG	HEADACHE
			84, 28	17APR96	15MAY96	400 MG	HEADACHE X1
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
			-9, -65	16JAN96	27JAN96		COLD
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
			-9, -65	16JAN96	27JAN96		COLD

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Paracetamol	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
			-9, -65	16JAN96	27JAN96		COLD
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-9, -65	16JAN96	27JAN96		COLD
			-9, -65	16JAN96	27JAN96		COLD
SENSORY ORGANS	Tetracycline	Tetracycline	-389, -445	01JAN95	.	1000MG	ACNE
			-389, -445	01JAN95	.	1000MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK PAIN	-2, -58	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	Headache	HEADACHE	17, -40	05:00 Hrs	150	CON	MIL	NO	PBU	Yes	No
			28, -29	03:00 Hrs	200	CON	MIL	NO	PBU	Yes	No
			38, -19	03:30 Hrs	250	CON	MIL	NO	UNR	Yes	No
			57, 1	28 Days	250	3	MOD	NO	UNR	Yes	No
			84, 28	57 Days	300	9	MIL	NO	UNR	Yes	No
			140, 84	55 Days	300	3	MIL	NO	UNR	Yes	No
Cardiovascular System	Palpitation	PALPITATIONS	9, -48	9 Days	100		MIL	NO	PSR	No	No
	Tachycardia	INCREASED PULSE ON EXERTION	33, -24	4 Days	250	4	MIL	NO	PSR	No	No
		TACHYCARDIA INCREASED PULSE	10, -47	8 Days	100		MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	DECREASED APPETITE	1, -56	42 Days	50	CON	MOD	NO	PSR	No	No
Nervous System	Dizziness	LIGHTHEADED	1, -56	29 Days	50	7	MIL	NO	PSR	No	No
Skin and Appendages	Sweating	SWEATING	23, -34	13 Days	200	5	MIL	NO	PSR	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	7, -50	12:00 Hrs	50	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
BL	25JAN96	1, -56	0	110	62	72	102	64	80	174.20	
1	01FEB96	8, -49	100	102	64	96	96	60	104	171.99	
2	08FEB96	15, -42	150	98	70	104	90	68	108	172.65	
3	15FEB96	22, -35	200	102	70	108	96	72	112	174.64	
4	22FEB96	29, -28	250	98	74	112	92	74	116	176.40	
5	29FEB96	36, -21	250	110	72	104	100	68	112	179.71	
6	06MAR96	42, -15	250	120	82	96	122	80	116	179.93	
7	14MAR96	50, -7	250	116	70	104	114	70	112	179.93	
8	21MAR96	57, 1	250	108	72	84	100	72	104	180.59	
12	17APR96	84, 28	300	106	66	100	100	68	108	184.12	
16	15MAY96	112, 56	300	116	76	96	108	72	104	188.50 H	
20	12JUN96	140, 84	300	120	80	100	116	74	108	187.20 H	
24	10JUL96	168, 112	300	102	72	108	96	70	112	193.00 H	
28	05AUG96	194, 138	300	106	78	100	96	78	104	191.20 H	
32	04SEP96	224, 168	250	114	72	108	114	70	112		

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	32	L	.	.	40 - 75	%
				Lymphocytes	58	H	.	.	16 - 46	%
				Monocytes	9	.	.	.	0 - 12	%
				Eosinophils	1	.	.	.	0 - 7	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	228000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	53	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-3	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	9.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.4	.	.	.	40 - 75	%
				Lymphocytes	31.2	.	.	.	16 - 46	%
				Monocytes	4.1	.	.	.	0 - 12	%
				Eosinophils	7.6	H	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.8	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	15.8	H	.	.	12 - 15.6	G/DL
				Hematocrit	45.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	60.3	.	.	.	40 - 75	%
				Lymphocytes	27.9	.	.	.	16 - 46	%
				Monocytes	6	.	.	.	0 - 12	%
				Eosinophils	4.8	.	.	.	0 - 7	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	60	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 13/CONTINUATION-WEEK 20	142	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	224	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	40 - 75	%
				Lymphocytes	31.4	.	.	.	16 - 46	%
				Monocytes	4.3	.	.	.	0 - 12	%
				Eosinophils	6.4	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	282000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00153 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 16/CONTINUATION-WEEK 32	224	Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	55	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	08FEB96	1	13FEB96	6	6
00253	Oral	2	0 MG	14FEB96	7	20FEB96	13	7
00253	Oral	3	0 MG	21FEB96	14	27FEB96	20	7
00253	Oral	4	0 MG	28FEB96	21	05MAR96	27	7
00253	Oral	5	0 MG	06MAR96	28	13MAR96	35	8
00253	Oral	6	0 MG	14MAR96	36	19MAR96	41	6
00253	Oral	6	0 MG	20MAR96	42	26MAR96	48	7
00253	Oral	6	0 MG	27MAR96	49	02APR96	55	7
	Oral	5	0 MG	03APR96	56	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	56	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	CUR	1996
POSITIVE URINE DRUG SCREEN FOR CODEINE AND MORPHINE.	DRUG DEPEND	MENTAL DISORD	CUR	1996

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
	Doxycycline	Doxycycline	26, .	04MAR96	12MAR96	200 MG BID	CHLAMYDIA
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-6, .	02FEB96	14FEB96	650 MG	HEADACHE
	Paracetamol	Tylenol	19, .	26FEB96	26FEB96	650 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	20, .	27FEB96	27FEB96		HEADACHE
	Naproxen Sodium	Aleve	45, .	23MAR96	23MAR96	1 TAB	HEADACHE
RESPIRATORY	Codeine	Promethazine With Codeine	-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
	Promethazine Hydrochloride	Promethazine With Codeine	-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
			-10, .	29JAN96	31JAN96#		BRONCHITIS
	Salbutamol	Proventil Inhaler	-10, .	29JAN96	08FEB96	3 PUFFS	BRONCHITIS
			-10, .	29JAN96	08FEB96	3 PUFFS	BRONCHITIS

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	-6, .	04:00 Hrs	0	2	MIL	NO	UNR	Yes	No
			19, .	05:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			20, .	03:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
			45, .	04:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
	Infection	CHLAMYDIA	26, .	9 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	31JAN96	-8, .	0	106	62	72	102	60	80	133.40	63.0
BL	08FEB96	1, .	0	96	68	72	94	66	78	133.62	
1	14FEB96	7, .	0	122	72	76	118	70	88	133.18	
2	21FEB96	14, .	0	118	64	96	108	62	108	133.84	
3	28FEB96	21, .	0	120	76	80	110	76	104	132.30	
4	06MAR96	28, .	0	108	72	72	106	72	80	132.74	
5	14MAR96	36, .	0	118	72	84	116	70	96	134.51	
6	20MAR96	42, .	0	104	66	88	102	62	92	133.84	
7	28MAR96	50, .	0	104	68	80	100	60	100	133.84	
8	03APR96	56, .	0	112	66	76	106	62	88	129.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.4	.	.	.	30 - 70	%
				Lymphocytes	45.9	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	5	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8		Serum BHCG pregnancy test	NEGATIVE	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	(1)	Hemoglobin	14.6	.	.	.	12 - 15.6	G/DL
					Hematocrit	42.9	.	.	.	35 - 46	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	56.1	.	.	.	30 - 70	%
					Lymphocytes	35.2	.	.	.	21 - 51	%
					Monocytes	6.1	.	.	.	0 - 10	%
					Eosinophils	1.9	.	.	.	0 - 5	%
					Basophils	0.7	.	.	.	0 - 2	%
					Platelets	249000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	61	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00253 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56 (1)	Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	4		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEC		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	15FEB96	1	20FEB96	6	6
00254	Oral	2	0 MG	21FEB96	7	27FEB96	13	7
00254	Oral	3	0 MG	28FEB96	14	05MAR96	20	7
00254	Oral	4	0 MG	06MAR96	21	12MAR96	27	7
00254	Oral	4	0 MG	13MAR96	28	19MAR96	34	7
00254	Oral	4	0 MG	20MAR96	35	26MAR96	41	7
00254	Oral	4	0 MG	27MAR96	42	02APR96	48	7
00254	Oral	4	0 MG	03APR96	49	09APR96	55	7
00146	Oral	4	0 MG	10APR96	56	08MAY96	84	29
00146	Oral	4	0 MG	09MAY96	85	11JUN96	118	34
00146	Oral	4	0 MG	12JUN96	119	09JUL96	146	28
00146	Oral	4	0 MG	10JUL96	147	07AUG96	175	29
00146	Oral	4	0 MG	08AUG96	176	11SEP96	210	35
00146	Oral	4	0 MG	12SEP96	211	15OCT96	244	34
00254	Oral	4	0 MG	16OCT96	245	17OCT96	246	2
00254	Oral	3	0 MG	18OCT96	247	19OCT96	248	2
00254	Oral	2	0 MG	20OCT96	249	22OCT96	251	3
00254	Oral	1	0 MG	23OCT96	252	29OCT96	258	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	258	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Bayer Aspirin	104, 49	28MAY96	28MAY96	UNKNOWN	MENSTRUAL CRAMPS
	Paracetamol	Tylenol	-13, -68	02FEB96	06FEB96#	500MG	HEADACHE
			-4, -59	11FEB96	11FEB96#	500MG	HEADACHE
			23, -33	08MAR96	08MAR96	500MG	HEADACHE
			53, -3	07APR96	07APR96	500MG	HEADACHE
			201, 146	02SEP96	02SEP96	500 MG	HEADACHE
			202, 147	03SEP96	03SEP96	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	24, -32	09MAR96	09MAR96		MENSTRUAL CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	14, -42	03:00 Hrs	0	CON	MOD	NO	UNR	No	No
	Asthenia	TIRED	31, -25	Not Stated	0	CON	MIL	NO	PSR	No	No
	Chest Pain	CHEST PAIN	14, -42	03:00 Hrs	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	2, -54	5 Days	0	3	MIL	NO	PSR	No	No
			-4, -59	03:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			10, -46	1 Days	0	2	MIL	NO	PBU	No	No
			23, -33	02:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			53, -3	02:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			201, 146	02:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
			202, 147	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
Musculoskeletal System	Arthralgia	SHOULDER PAIN IN AM	33, -23	3 Days	0	3	MOD	NO	UNR	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	24, -32	12:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			104, 49	06:30 Hrs	0	CON	SEV	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08FEB96	-7, -62	0	94	72	76	90	68	84	130.00	67.0
BL	14FEB96	-1, -56	0	82	60	80	80	60	80	126.00	
1	21FEB96	7, -49	0	104	68	80	90	60	76	130.00	
2	28FEB96	14, -42	0	90	60	80	100	70	84	128.50	
3	06MAR96	21, -35	0	80	60	76	78	58	80	130.00	
4	13MAR96	28, -28	0	88	60	76	80	64	76	127.00	
5	20MAR96	35, -21	0	90	60	76	90	60	80	129.50	
6	27MAR96	42, -14	0	90	60	76	94	60	80	129.50	
7	03APR96	49, -7	0	98	70	80	98	68	80	128.00	
8	10APR96	56, 1	0	90	60	80	88	60	80	128.00	
12	22MAY96	98, 43	0	104	70	80	98	60	84	125.00	
16	12JUN96	119, 64	0	102	70	80	90	70	80	122.20	
20	10JUL96	147, 92	0	112	70	76	110	70	80	122.50	
28	12SEP96	211, 156	0	94	70	74	90	60	80	129.00	
32	16OCT96	245, 190	0	90	60	80	90	64	84	128.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.4	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	1.7	.	.	.	0 - 2	%
				Platelets	243000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	209000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	15.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	45	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.2	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	147	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00254 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEC		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	04MAR96	1	10MAR96	7	7
00255	Oral	2	100 MG	11MAR96	8	17MAR96	14	7
00255	Oral	3	150 MG	18MAR96	15	24MAR96	21	7
00255	Oral	4	200 MG	25MAR96	22	31MAR96	28	7
00255	Oral	5	250 MG	01APR96	29	07APR96	35	7
00255	Oral	6	300 MG	08APR96	36	14APR96	42	7
00255	Oral	5	250 MG	15APR96	43	22APR96	50	8
00255	Oral	5	250 MG	23APR96	51	28APR96	56	6
	Oral	4	200 MG	29APR96	57	13MAY96	71	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	71	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1986
ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
URINARY TRACT INFECTION	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	CUR	1996
STRABISMUS	EYE DISORD, OTHER	NERVOUS SYST/SENSE ORGAN DIS	PRV	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole	Sulfamethoxazole/Trimethoprim Ds	36, .	08APR96	15APR96	1 X 2 DAY	UTI (URINARY TRACT INFECTION)
	Trimethoprim	Sulfamethoxazole/Trimethoprim Ds	36, .	08APR96	15APR96	1 X 2 DAY	UTI (URINARY TRACT INFECTION)
DERMATOLOGICALS	Butoconazole Nitrate	Femstat	38, .	10APR96	15APR96		YEAST INFECTION
	Terconazole	Terazol-7	47, .	19APR96	21APR96		YEAST INFECTION
GU SYSTEM/SEX HORMONES	Butoconazole Nitrate	Femstat	38, .	10APR96	15APR96		YEAST INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-3, .	01MAR96	03MAR96#	2 TABS	HA (HEADACHE)
			8, .	11MAR96	11MAR96	2 TABS	HA (HEADACHE)
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	32, .	04APR96	04APR96	1 X DAY	ENVIRONMENTAL ALLERGIES
			45, .	17APR96	18APR96	1 X DAY	ENVIRONMENTAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	2, .	04:00 Hrs	50	1	MOD	NO	PBU	No	No
	Headache	HEADACHE	1, .	22 Days	50	16	MOD	NO	PSR	Yes	No
		HEADACHES	21, .	9 Days	150	4	MOD	NO	PBU	No	No
		SOMATIC COMPLAINT HEADACHE	57, .	Not Stated	200		MOD	NO	PSR	No	No
Cardiovascular System	Vasodilatation	FLUSHED FACE	8, .	04:00 Hrs	100	1	MOD	NO	PSR	No	No
Digestive System	Nausea	SOMATIC COMPLAINT NAUSEA	57, .	Not Stated	200		MOD	NO	PSR	No	No
Hemic and Lymphatic System	Eosinophilia	EOSINOPHILS ELEVATED	57, .	Not Stated	200	CON	MOD	NO	PBU	No	No
Nervous System	Tremor	"SHAKINESS"	2, .	4 Days	50	CON	MOD	NO	PSR	No	No
		HAND TREMORS	33, .	19 Days	250	CON	MOD	DCR	REL	No	No
Respiratory System	Pharyngitis	SORE THROAT	42, .	4 Days	300	CON	MIL	NO	PBU	No	No
Special Senses	Abnormal Vision	BLURRED VISION	43, .	8 Days	250	15	SEV	DCR	REL	No	No
Urogenital System	Vaginal Moniliasis	YEAST INFECTION (VAGINAL)	47, .	5 Days	250	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26FEB96	-7, .	0	120	80	60	120	78	76	150.20	69.0
BL	04MAR96	1, .	0	100	60	86	90	50	82	149.30	
1	11MAR96	8, .	100	110	78	86	100	70	96	151.00	
2	18MAR96	15, .	150	104	80	76	100	70	76	149.00	
3	25MAR96	22, .	200	102	66	96	100	60	108	149.50	
4	01APR96	29, .	250	112	80	86	100	70	104	148.50	
5	08APR96	36, .	300	112	70	106	118	80	110	153.50	
6	15APR96	43, .	250	110	80	90	110	76	100	145.00	
7	23APR96	51, .	250	110	80	90	120	84	102	150.50	
8	29APR96	57, .	200	90	60	96	90	60	100	147.25	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2	.	.	.	30 - 70	%
				Lymphocytes	30.5	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	17.7	H	.	+	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	299000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	53	.	.	.	30 - 70	%
				Lymphocytes	34	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	299000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00255 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05MAR96	1	11MAR96	7	7
00256	Oral	2	100 MG	12MAR96	8	20MAR96	16	9
00256	Oral	3	150 MG	21MAR96	17	25MAR96	21	5
00256	Oral	4	200 MG	26MAR96	22	01APR96	28	7
00256	Oral	5	250 MG	02APR96	29	10APR96	37	9
00256	Oral	5	250 MG	11APR96	38	15APR96	42	5
00256	Oral	5	250 MG	16APR96	43	22APR96	49	7
00256	Oral	6	300 MG	23APR96	50	29APR96	56	7
00133	Oral	6	300 MG	30APR96	57	27MAY96	84	28
00133	Oral	6	300 MG	28MAY96	85	01JUL96	119	35
00256	Oral	5	250 MG	02JUL96	120	03JUL96	121	2
00256	Oral	4	200 MG	04JUL96	122	05JUL96	123	2
00256	Oral	3	150 MG	06JUL96	124	07JUL96	125	2
00256	Oral	2	100 MG	08JUL96	126	10JUL96	128	3
00256	Oral	1	50 MG	11JUL96	129	17JUL96	135	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	135	50	Other reason	PT CHOSING TO WITHDRAW AS SHE WANTS TO BEGIN KNOWN MED THERAPY

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DECREASED LYMPHOCYTES	LYMPHOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Nizatidine	Axid	129, 73	11JUL96	.		GI UPSET
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	1, -56	05MAR96	07MAR96	650 MG	HA
			13, -44	17MAR96	20MAR96	500 MG	H/A AND BACKACHE
			16, -41	20MAR96	21MAR96		MENSTRUAL CRAMPS
		Tylenol Extra Strength	28, -29	01APR96	01APR96		SORE THROAT
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	1, -56	05MAR96	07MAR96		HA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	13, -44	4 Days	100	CON	MOD	NO	UNR	Yes	No
	Fever	FEVER	1, -56	2 Days	50	1	MOD	NO	PBU	No	No
	Headache	HEADACHE	1, -56	3 Days	50	1	MOD	NO	PBU	Yes	No
			13, -44	4 Days	100	CON	MOD	NO	UNR	Yes	No
Carciovascular System	Vasodilatation	HOT FLASHES	19, -38	3 Days	150	2	MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	26, -31	33 Days	200	CON	MOD	NO	PSR	No	No
	Dyspepsia	GI UPSET	129, 73	Not Stated	50	CON	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	1, -56	3 Days	50	1	MOD	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS UPON STANDING	31, -26	13 Days	250	4	MIL	NO	REL	No	No
Respiratory System	Pharyngitis	SORE THROAT	24, -33	5 Days	200	CON	MOD	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	16, -41	2 Days	100	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20FEB96	-14, -70	0	96	58	86	90	56	94	111.00	64.0
BL	05MAR96	1, -56	0	98	66	88	92	60	98	110.50	
1	12MAR96	8, -49	100	98	70	88	90	60	104	110.50	
2	21MAR96	17, -40	150	90	60	88	90	58	90	111.00	
3	26MAR96	22, -35	200	88	50	82	80	48	104	111.00	
4	02APR96	29, -28	250	100	60	94	94	58	108	111.00	
5	11APR96	38, -19	250	100	60	98	90	58	108	111.50	
6	16APR96	43, -14	250	110	60	96	100	56	108	111.50	
7	23APR96	50, -7	300	110	70	102	100	60	108	111.50	
8	30APR96	57, 1	300	100	60	98	100	60	104	113.00	
12	28MAY96	85, 29	300	80	40 L	96	80	40 L	96	114.50	
16	02JUL96	120, 64	250	90	60	92	80	52	90	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.6	.	.	.	30 - 70	%
				Lymphocytes	20.9	L	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	98	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	32.4	.	.	.	21 - 51	%
				Monocytes	8.7	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	179000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	23.7	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	5.7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	218000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
		VISIT 12/CONTINUATION-WEEK 16	120	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	28	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	206000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00256 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 12/CONTINUATION-WEEK 16	120	Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11MAR96	1	17MAR96	7	7
00257	Oral	2	20 MG	18MAR96	8	24MAR96	14	7
00257	Oral	3	20 MG	25MAR96	15	31MAR96	21	7
00257	Oral	4	20 MG	01APR96	22	07APR96	28	7
00257	Oral	4	20 MG	08APR96	29	14APR96	35	7
00257	Oral	4	20 MG	15APR96	36	21APR96	42	7
00257	Oral	5	30 MG	22APR96	43	28APR96	49	7
00257	Oral	5	30 MG	29APR96	50	05MAY96	56	7
00144	Oral	5	30 MG	06MAY96	57	02JUN96	84	28
00144	Oral	5	30 MG	03JUN96	85	07JUL96	119	35
00144	Oral	5	30 MG	08JUL96	120	06AUG96	149	30
00144	Oral	5	30 MG	07AUG96	150	26AUG96	169	20
00144	Oral	5	30 MG	27AUG96	170	30SEP96	204	35
00144	Oral	5	30 MG	01OCT96	205	21OCT96	225	21
00257	Oral	4	20 MG	22OCT96	226	23OCT96	227	2
00257	Oral	3	20 MG	24OCT96	228	25OCT96	229	2
00257	Oral	2	20 MG	26OCT96	230	28OCT96	232	3
00257	Oral	1	20 MG	29OCT96	233	04NOV96	239	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	Yes	239	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ascorbic Acid	Vitamin C	3, -54	13MAR96	.		"A COLD"
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	145, 89	02AUG96	09AUG96		SWIMMER'S EAR
	Antibiotic Nos	Antibiotics Ear Drops {Nos}	145, 89	02AUG96	09AUG96		SWIMMER'S EAR
	Cefaclor	Ceclor	15, -42	25MAR96	05APR96		SINUS INFECTION
			43, -14	22APR96	06MAY96		SINUS INFECTION
	Miconazole Nitrate	Monistat 7	242, 186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
CARDIOVASCULAR	Theophylline	Slo-Bid	54, -3	03MAY96	10MAY96	150 MG BID	UPPER RESPIRATORY INFECTION AND SINUS IN
DERMATOLOGICALS	Fluticasone Propionate	Flonase	43, -14	22APR96	28APR96	2 SQUIRTS	SINUS INFECTION
	Isotretinoin	Accutane	-121, -177	11NOV95	.		ACNE
			-121, -177	11NOV95	.		ACNE
	Miconazole Nitrate	Monistat 7	242, 186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
GU SYSTEM/SEX HORMONES	Miconazole Nitrate	Monistat 7	242, 186	07NOV96	14NOV96	TOPICAL	YEAST INFECTION
MUSCULO-SKELETAL	Ibuprofen	Advil	157, 101	14AUG96	21AUG96		HEADACHE
RESPIRATORY	Acrivastine	Semprex-D	14, -43	24MAR96	24MAR96		"A COLD"
			14, -43	24MAR96	24MAR96		"A COLD"
			14, -43	24MAR96	24MAR96		"A COLD"
	Chlorphenamine Tannate	Rynatan	15, -42	25MAR96	27MAR96		SINUS INFECTION
	Ephedrine Sulfate	Marax	202, 146	28SEP96	.		EXERCISE INDUCED ASTHMA
	Fluticasone Propionate	Flonase	43, -14	22APR96	28APR96	2 SQUIRTS	SINUS INFECTION
	Hydroxyzine Hydrochloride	Marax	202, 146	28SEP96	.		EXERCISE INDUCED ASTHMA
	Mepyramine Tannate	Rynatan	15, -42	25MAR96	27MAR96		SINUS INFECTION
	Phenylephrine Tannate	Rynatan	15, -42	25MAR96	27MAR96		SINUS INFECTION
	Pseudoephedrine	Semprex-D	14, -43	24MAR96	24MAR96		"A COLD"
			14, -43	24MAR96	24MAR96		"A COLD"

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Pseudoephedrine	Semprex-D	14, -43	24MAR96	24MAR96		"A COLD"
	Salbutamol	Albuterol	43, -14	22APR96	06MAY96	2 PUFF X 4	SINUS INFECTION
			43, -14	22APR96	06MAY96	2 PUFF X 4	SINUS INFECTION
	Theophylline	Marax	202, 146	28SEP96	.		EXERCISE INDUCED ASTHMA
		Slo-Bid	54, -3	03MAY96	10MAY96	150 MG BID	UPPER RESPIRATORY INFECTION AND SINUS IN

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	157, 101	8 Days	30	2	MIL	NO	PBU	Yes	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN	85, 29	Not Stated	30	CON	MOD	NO	PSR	No	No
Nervous System	Nervousness	"JITTERINESS"	225, 169	Not Stated	30	CON	MOD	NO	PSR	No	No
Respiratory System	Asthma	EXERCISE INDUCED ASTHMA	175, 119	Not Stated	30	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	SORE THROAT (COLD SYMPTOM)	8, -49	9 Days	20	CON	MOD	NO	PBU	Yes	No
		STUFFY NOSE (COLD SYMPTOMS)	8, -49	9 Days	20	CON	MOD	NO	PBU	Yes	No
	Sinusitis	SINUS INFECTION	14, -43	7 Days	20		MOD	NO	PBU	Yes	No
			35, -22	37 Days	20	CON	MOD	NO	PBU	Yes	No
Special Senses	Otitis Externa	SWIMMER'S EAR	143, 87	3 Days	30	CON	MOD	NO	PBU	Yes	No
Urogenital System	Haematuria	RBC IN URINE (PT MENSTRUATING WHEN SAMPLE TAKEN)	225, 169	Not Stated	30	CON	MOD	NO	UNR	No	No
	Urinary Tract Infection	YEAST INFECTION (SQUAMOUS EPITHELIAL CELLS IN URINE)	219, 163	Not Stated	30	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05MAR96	-6, -62	0	110	68	102	100	60	96	112.00	63.0
BL	11MAR96	1, -56	0	90	60	76	90	60	70	112.50	
1	18MAR96	8, -49	20	100	50	80	98	48	98	108.00	
2	25MAR96	15, -42	20	90	60	86	88	58	96	109.00	
3	01APR96	22, -35	20	100	70	74	102	68	86	111.00	
4	08APR96	29, -28	20	110	80	70	110	86	80	112.00	
5	15APR96	36, -21	20	100	60	72	90	52	90	110.00	
6	22APR96	43, -14	30	110	64	84	110	68	80	112.00	
7	29APR96	50, -7	30	100	60	80	100	60	80	112.75	
8	06MAY96	57, 1	30	120	68	86	118	78	94	112.00	
12	03JUN96	85, 29	30	100	70	74	106	80	90	117.25	
16	08JUL96	120, 64	30	112	70	86	108	70	86	122.25 H	
20	07AUG96	150, 94	30	122	72	80	120	80	84	124.50 H	
24	27AUG96	170, 114	30	120	80	84	110	70	86	122.00 H	
28	01OCT96	205, 149	30	118	70	78	118	80	84	123.00 H	
32	21OCT96	225, 169	30	116	72	80	110	70	86	123.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.8	.	.	.	30 - 70	%
				Lymphocytes	22.3	.	.	.	21 - 51	%
				Monocytes	9.5	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	136000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	60 - 110	MG/DL
				Globulin	2.7	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Hemoglobin	24.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	72.4	H	.	.	35 - 46	%
				Red Blood Cell Count	8.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	19.1	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.7	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	17000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.4	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Segmented Neutrophils	58.6	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	3.3	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	129	H	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	150	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	150	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	225	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	30.4	.	.	.	21 - 51	%
				Monocytes	3.6	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00257 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 16/CONTINUATION-WEEK 32	225	Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	12MAR96	1	18MAR96	7	7
00258	Oral	2	20 MG	19MAR96	8	25MAR96	14	7
00258	Oral	3	20 MG	26MAR96	15	01APR96	21	7
00258	Oral	4	20 MG	02APR96	22	08APR96	28	7
00258	Oral	5	30 MG	09APR96	29	17APR96	37	9
00258	Oral	6	40 MG	18APR96	38	22APR96	42	5
00258	Oral	6	40 MG	23APR96	43	29APR96	49	7
00258	Oral	6	40 MG	30APR96	50	06MAY96	56	7
	Oral	5	30 MG	07MAY96	57	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	57	30		PT TO HAVE SURGERY UNDER GENERAL ANETHESIA 6/24/96

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCULT BLOOD IN URINE - PATIENT MENSTRUATING	HEMATURIA	GENITOURINARY SYST DIS	CUR	1996
PROTEIN IN URINE - PATIENT MENSTRUATING	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	21, .	01APR96	01APR96	2 TABS	ORTHODONTIC DISCOMFORT
			28, .	08APR96	08APR96	2 TABS	ORTHODONTIC DISCOMFORT
RESPIRATORY	Guaifenesin	Robitussin	2, .	13MAR96	13MAR96		COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	10, .	02:00 Hrs	20	1	MOD	NO	PBU	No	No
			25, .	4 Days	20	4	MOD	NO	PBU	No	No
	Headache	HEADACHE	10, .	4 Days	20	2	MOD	NO	PBU	No	No
			25, .	4 Days	20	3	MOD	NO	PBU	No	No
Digestive System	Tooth Disorder	ORTHODONTIC DISCOMFORT	21, .	03:30 Hrs	20	1	MOD	NO	UNR	Yes	No
			28, .	02:40 Hrs	20	1	MOD	NO	UNR	Yes	No
Respiratory System	Cough Increased	COUGH	-4, .	8 Days	0	1	MOD	NO	UNR	Yes	No
Urogenital System	Urine Abnormality	ABNORMAL URINE ROUTINE & MICROSCOPIC(URINALYSIS	57, .	Not Stated	30	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06FEB96	-35, .	0	102	60	98	100	60	104	169.50	64.0
BL	20FEB96	-21, .	0	118	70	100	110	70	104	171.70	
1	19MAR96	8, .	20	100	60	98	98	68	102	171.00	
2	26MAR96	15, .	20	120	78	80	110	70	98	168.50	
3	02APR96	22, .	20	120	70	80	110	70	98	171.00	
4	09APR96	29, .	30	112	76	82	110	80	100	169.00	
5	18APR96	38, .	40	104	70	80	100	70	84	169.00	
6	23APR96	43, .	40	126	70	84	122	76	102	171.50	
7	30APR96	50, .	40	112	70	88	120	80	106	167.50	
8	07MAY96	57, .	30	120	80	88	120	80	102	168.75	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-21	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	35.8	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	153	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-21		Serum BHCG pregnancy test	NEGATIVE	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/UNSCHEDULED LAB 1	-14		Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	4	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick	2	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
					Hematocrit	35.9	.	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	47.6	.	.	.	30 - 70	%
					Lymphocytes	37.2	.	.	.	21 - 51	%
					Monocytes	7.7	.	.	.	0 - 10	%
					Eosinophils	6.6	H	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	275000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00258 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	12MAR97	1	18MAR97	7	7
00293	Oral	2	0 MG	19MAR97	8	24MAR97	13	6
00293	Oral	3	0 MG	25MAR97	14	01APR97	21	8
00293	Oral	4	0 MG	02APR97	22	08APR97	28	7
00293	Oral	5	0 MG	09APR97	29	15APR97	35	7
00293	Oral	6	0 MG	16APR97	36	22APR97	42	7
00293	Oral	6	0 MG	23APR97	43	29APR97	49	7
00293	Oral	6	0 MG	30APR97	50	07MAY97	57	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	57	0		STUDY MEDICATION FOR PHASE II UNAVAILABLE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
RBC IN URINE POST PARTUM	HEMATURIA	GENITOURINARY SYST DIS	CUR	1997
SQUAMOUS CELLS IN URINE POST PARTUM	URINARY CASTS/WBC'S	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
2 VAGINAL DELIVERY BIRTHS	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTINEOPLASTIC & IMMUNOSUP	Medroxyprogesterone Acetate	Depo-Provera	21, .	01APR97	01APR97		BIRTH CONTROL
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-23, .	17FEB97	18FEB97#	1 GM	POST PARTUM PAIN
			26, .	06APR97	06APR97	500 MG	HEADACHE
			39, .	19APR97	19APR97	2 TABS	HEADACHE
GU SYSTEM/SEX HORMONES	Medroxyprogesterone Acetate	Depo-Provera	21, .	01APR97	01APR97		BIRTH CONTROL
RESPIRATORY	Guaifenesin	Humibid	7, .	18MAR97	18MAR97	2 PUFFS	RESPIRATORY CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	26,	.	03:30 Hrs	0	1	MOD	NO	PBU	Yes	No
			39,	.	01:00 Hrs	0	1	MOD	NO	PBU	Yes	No
			56,	.	45 Mins	0	1	MOD	NO	PBU	No	No
Respiratory System	Respiratory Disorder	RESPIRATORY CONGESTION	7,	.	8 Days	0	CON	MOD	NO	PBU	Yes	No
Skin and Appendages	Acne	ACNE	15,	.	Not Stated	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06MAR97	-6, .	0	108	70	70	106	70	74	175.00	63.0
BL	12MAR97	1, .	0	122	78	80	108	70	96	171.75	
1	19MAR97	8, .	0	110	80	68	110	80	78	174.00	
2	25MAR97	14, .	0	120	74	90	116	68	106	173.25	
3	02APR97	22, .	0	120	80	92	110	70	100	173.25	
4	09APR97	29, .	0	124	80	90	118	80	98	175.00	
5	16APR97	36, .	0	120	84	80	110	80	90	174.00	
6	23APR97	43, .	0	128	74	90	118	78	104	172.00	
7	30APR97	50, .	0	120	82	94	126	76	102	174.50	
8	07MAY97	57, .	0	120	70	90	120	82	100	172.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.7	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32.3	.	.	.	30 - 70	%
				Lymphocytes	45	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	12.3	H	.	+	0 - 5	%
				Basophils	2.5	H	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	39	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	68	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	30	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	33.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00293 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28MAR96	1	03APR96	7	7
00295	Oral	2	100 MG	04APR96	8	10APR96	14	7
00295	Oral	3	150 MG	11APR96	15	17APR96	21	7
00295	Oral	4	200 MG	18APR96	22	23APR96	27	6
00295	Oral	4	200 MG	24APR96	28	05MAY96	39	12
00295	Oral	4	200 MG	06MAY96	40	08MAY96	42	3
00295	Oral	5	250 MG	09MAY96	43	15MAY96	49	7
00295	Oral	5	250 MG	16MAY96	50	19MAY96	53	4
00295	Oral	5	250 MG	20MAY96	54	04JUN96	69	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	69	250	Adverse event, including intercurrent illness	INVESTIGATOR'S DECISION TO DISCONTINUE STUDY BECAUSE PT. THREATENED TO KILL PARENTS.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BODY ACHES	PAIN, GENERAL	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
COLD {COMMON}	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
DIARRHEA	DIARRHEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
FLU	INFLUENZA	RESPIRATORY SYST DIS	CUR	1996
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ascorbic Acid	Vitamin C	-24, .	04MAR96	06MAR96#		COLD SYMPTOMS
	Bismuth Subsalicylate	Pepto-Bismol	-9, .	19MAR96	19MAR96#	2TBSP	DIARRHEA
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-9, .	19MAR96	19MAR96#	500MG	FLU-BODY ACHES
MUSCULO-SKELETAL	Ibuprofen	Advil	-7, .	21MAR96	21MAR96#	250MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN	19, .	2 Days	150	2	MOD	NO	PSR	No	No
	Headache	HEADACHE	22, .	03:30 Hrs	200	CON	MIL	NO	PBU	No	No
			39, .	04:30 Hrs	200	CON	MOD	NO	PSR	No	No
		HEADACHES	-7, .	1 Days	0	1	MOD	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	11, .	55 Days	100	CON	MOD	NO	REL	No	No
	Nausea	NAUSEA	39, .	02:00 Hrs	200	CON	MIL	NO	PSR	No	No
	Vomiting	VOMITING	49, .	30 Mins	250	CON	MOD	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	38, .	2 Days	200	4	MIL	NO	PSR	No	No
	Emotional Lability	SUICIDAL THREAT WITH SCISSORS	23, .	1 Days	200	1	MOD	NO	PBU	No	No
	Hostility	HOMICIDAL TENDENCIES TOWARDS PARENTS	52, .	04:30 Hrs	250	CON	SEV	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21MAR96	-7, .	0	110	70	80	100	70	84	120.50	61.0
BL	28MAR96	1, .	0	110	72	76	104	70	80	120.50	
1	04APR96	8, .	100	120	78	88	110	68	94	119.20	
2	11APR96	15, .	150	100	70	84	90	60	88	119.50	
3	18APR96	22, .	200	100	68	88	94	60	88	119.00	
4	24APR96	28, .	200	118	80	94	110	70	100	120.00	
6	06MAY96	40, .	200	116	70	86	110	68	86	121.75	
6	09MAY96	43, .	250	120	70	96	110	70	100	122.50	
7	16MAY96	50, .	250	110	70	92	100	70	96	125.00	
8	22MAY96	56, .	250	110	70	104	104	70	110	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62	.	.	.	30 - 70	%
				Lymphocytes	34	.	.	.	21 - 51	%
				Monocytes	2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	29	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	.	.	.	30 - 70	%
				Lymphocytes	22.7	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	277000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00295 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19APR96	1	25APR96	7	7
00297	Oral	2	100 MG	26APR96	8	01MAY96	13	6
00297	Oral	3	150 MG	02MAY96	14	13MAY96	25	12
00297	Oral	4	200 MG	14MAY96	26	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	No	No	26	200	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-5, .	14APR96	16APR96#	1 GM.	HEADCOLD & NASAL CONGESTION
			22, .	10MAY96	11MAY96	2 TABS	HA
RESPIRATORY	Guaifenesin	Robitussin	-5, .	14APR96	16APR96#	4 TSP	HEADCOLD & NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	22, .	02:00 Hrs	150	2	MOD	NO	PSR	Yes	No
Digestive System	Dyspepsia	HEARTBURN	6, .	04:00 Hrs	50	CON	MOD	NO	UNR	No	No
Respiratory System	Respiratory Disorder	HEADCOLD AND NASAL CONGESTION	-5, .	3 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	28MAR96	-22, .	0	124	80	80	114	78	80	184.50	69.0
BL	19APR96	1, .	0	118	72	80	120	70	80	180.00	
1	26APR96	8, .	100	114	74	88	112	78	92	180.50	
2	02MAY96	14, .	150	120	80	88	110	80	90	181.50	
4	14MAY96	26, .	200	130	70	90	120	70	98	181.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-22	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	40 - 75	%
				Lymphocytes	31.3	.	.	.	16 - 46	%
				Monocytes	8.6	.	.	.	0 - 12	%
				Eosinophils	3.8	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	146000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.4	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00297 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-22	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	POS	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-16	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	22MAY96	1	29MAY96	8	8
00298	Oral	2	0 MG	30MAY96	9	05JUN96	15	7
00298	Oral	3	0 MG	06JUN96	16	11JUN96	21	6
00298	Oral	4	0 MG	12JUN96	22	18JUN96	28	7
00298	Oral	4	0 MG	19JUN96	29	25JUN96	35	7
00298	Oral	4	0 MG	26JUN96	36	02JUL96	42	7
00298	Oral	4	0 MG	03JUL96	43	09JUL96	49	7
00298	Oral	4	0 MG	10JUL96	50	16JUL96	56	7
00185	Oral	4	0 MG	17JUL96	57	15AUG96	86	30
00185	Oral	4	0 MG	16AUG96	87	18SEP96	120	34
00185	Oral	4	0 MG	19SEP96	121	16OCT96	148	28
00185	Oral	4	0 MG	17OCT96	149	13NOV96	176	28
00185	Oral	4	0 MG	14NOV96	177	11DEC96	204	28
00185	Oral	4	0 MG	12DEC96	205	12JAN97	236	32
00298	Oral	3	0 MG	13JAN97	237	14JAN97	238	2
00298	Oral	2	0 MG	15JAN97	239	17JAN97	241	3
00298	Oral	1	0 MG	18JAN97	242	24JAN97	248	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	248	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES {SEASONAL}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1988
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol (Teen)	231, 175	07JAN97	09JAN97	4 TABS	MENSTRUAL CRAMPS
	Caffeine	Midol (Teen)	231, 175	07JAN97	09JAN97	4 TABS	MENSTRUAL CRAMPS
	Chlorphenamine Maleate	Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
	Cinnamedrine Hydrochloride	Midol (Teen)	231, 175	07JAN97	09JAN97	4 TABS	MENSTRUAL CRAMPS
	Dextromethorphan	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
	Dextromethorphan Hydrobromide	Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
	Mepyramine Maleate	Pamprin	-7, -63	15MAY96	15MAY96#	PRN	MENSTRUAL CRAMPS
			46, -11	06JUL96	07JUL96	1X DAILY TAB	MENSTRUAL CRAMPS
			167, 111	04NOV96	04NOV96	2 TABS	MENSTRUAL CRAMPS
			200, 144	07DEC96	09DEC96	1 TAB	MENSTRUAL CRAMPS
	Pamabrom	Pamprin	-7, -63	15MAY96	15MAY96#	PRN	MENSTRUAL CRAMPS
			46, -11	06JUL96	07JUL96	1X DAILY TAB	MENSTRUAL CRAMPS
			167, 111	04NOV96	04NOV96	2 TABS	MENSTRUAL CRAMPS
			200, 144	07DEC96	09DEC96	1 TAB	MENSTRUAL CRAMPS
	Paracetamol	Pamprin	-7, -63	15MAY96	15MAY96#	PRN	MENSTRUAL CRAMPS
			46, -11	06JUL96	07JUL96	1X DAILY TAB	MENSTRUAL CRAMPS
			167, 111	04NOV96	04NOV96	2 TABS	MENSTRUAL CRAMPS
			200, 144	07DEC96	09DEC96	1 TAB	MENSTRUAL CRAMPS
		Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
		Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
		Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION
	Pseudoephedrine	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
	Pseudoephedrine Hydrochloride	Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Pseudoephedrine Hydrochloride	Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION
MUSCULO-SKELETAL	Ibuprofen	Advil	26, -31	16JUN96	16JUN96	2X DAILY TABS	RIGHT LEG PAIN
			33, -24	23JUN96	23JUN96	2X DAILY TABS	BACK PAIN
			56, -1	16JUL96	16JUL96	1X DAILY TAB	KNEE INJURY
			133, 77	01OCT96	04OCT96	800 MG	CHARLIE HORSE
		Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
		Ibuprofen	149, 93	17OCT96	17OCT96	300 MG	PULLED MUSCLE
	Pseudoephedrine Hydrochloride	Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
RESPIRATORY	Chlorphenamine Maleate	Tylenol Allergy And Sinus	-26, -82	26APR96	26APR96#	2 DAILY PRN	ALLERGIES
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
			39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
	Dextromethorphan	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
			204, 148	11DEC96	12DEC96	4 TABS	COLD SX
	Dextromethorphan Hydrobromide	Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
			39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
	Ibuprofen	Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
	Loratadine	Claritin	40, -17	30JUN96	01JUL96	2X DAILY TABS	SINUS CONGESTION
	Paracetamol	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
			204, 148	11DEC96	12DEC96	4 TABS	COLD SX
		Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Allergy And Sinus	-26, -82	26APR96	26APR96#	2 DAILY PRN	ALLERGIES
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Paracetamol	Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
		Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION
	Pseudoephedrine	Sudafed Cold And Cough	204, 148	11DEC96	12DEC96	4 TABS	COLD SX
			204, 148	11DEC96	12DEC96	4 TABS	COLD SX
	Pseudoephedrine Hydrochloride	Advil Cold And Sinus	-22, -78	30APR96	30APR96#	1 DAILY PRN	ALLERGIES
		Sudafed Sinus	202, 146	09DEC96	10DEC96	2 TABS	COLD SX.
		Tylenol Allergy And Sinus	-26, -82	26APR96	26APR96#	2 DAILY PRN	ALLERGIES
		Tylenol Cold	39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
			39, -18	29JUN96	29JUN96	2X DAILY TABS	STIFF NECK
		Tylenol Sinus	12, -45	02JUN96	05JUN96	2X DAILY TABS	SINUS H/A AND CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK ACHE	114, 58	3 Days	0	CON	MOD	NO	UNR	No	No
		BACK PAIN (OLD SOCCER INJURY)	33, -24	03:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	169, 113	02:30 Hrs	0	CON	MOD	NO	UNR	No	No
	Trauma	CHARLEY HORSE LEFT LEG-THIGH	133, 77	4 Days	0	CON	MOD	NO	UNR	Yes	No
		KNEE INJURY (SOCCER RELATED)	55, -2	3 Days	0	CON	MOD	NO	UNR	Yes	No
		PAIN IN RIGHT LEG (FOLLOWING AUTOMOBILE ACCIDENT)	26, -31	04:30 Hrs	0	CON	MOD	NO	UNR	Yes	No
		PULLED MUSCLE - LEFT SHIN (SOCCER INJURY)	149, 93	06:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Diarrhea	STOMACH ACHE WITH DIARRHEA	-4, -60	4 Days	0	CON	SEV	NO	UNR	No	No
Nervous System	Dizziness	DIZZINESS WHEN STANDING UP	202, 146	3 Days	0	3	MIL	NO	PBU	No	No
	Hypertonia	STIFF NECK	39, -18	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
Respiratory System	Epistaxis	NOSEBLEEDS	230, 174	7 Days	0	8	SEV	NO	PSR	No	No
	Respiratory Disorder	COLD SYMPTOMS:STUFFY NOSE, SORE THROAT, FEVER	201, 145	12 Days	0	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	40, -17	2 Days	0	CON	MOD	NO	UNR	Yes	No
			99, 43	8 Days	0	CON	MOD	NO	UNR	No	No
		SINUS HEADACHE AND CONGESTION	12, -45	4 Days	0	CON	MOD	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	46, -11	2 Days	0	CON	MOD	NO	UNR	Yes	No
			167, 111	24:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			200, 144	3 Days	0	CON	MOD	NO	UNR	Yes	No
			231, 175	3 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	15MAY96	-7, -63	0	110	80	68	112	80	68	149.50	64.0
BL	22MAY96	1, -56	0	118	80	74	112	80	76	147.70	
1	30MAY96	9, -48	0	90	60	60	90	56	64	147.50	
2	06JUN96	16, -41	0	118	80	60	114	80	60	146.20	
3	12JUN96	22, -35	0	110	60	58	104	68	60	148.00	
4	19JUN96	29, -28	0	98	60	60	94	60	60	147.70	
5	26JUN96	36, -21	0	118	70	54	110	60	58	148.20	
6	03JUL96	43, -14	0	116	74	56	112	72	60	148.70	
7	10JUL96	50, -7	0	100	60	64	110	70	72	146.50	
8	17JUL96	57, 1	0	104	64	60	90	60	62	147.70	
16	19SEP96	121, 65	0	104	60	54	112	60	64	147.50	
20	17OCT96	149, 93	0	90	64	60	90	60	60	148.00	
24	14NOV96	177, 121	0	92	60	60	90	50	62	148.70	
28	12DEC96	205, 149	0	104	78	64	110	76	64	150.00	
32	13JAN97	237, 181	0	100	60	60	100	60	64	149.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 2/ELIGIBILITY	1	Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous	4	.	.	.		
				Epithelial Cells						
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	227000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	144	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	149	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	149	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	41	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/CONTINUATION-WEEK 32	237	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.1	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	112	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00298 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	237	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08JUN96	1	17JUN96	10	10
00299	Oral	2	20 MG	18JUN96	11	24JUN96	17	7
00299	Oral	3	20 MG	25JUN96	18	01JUL96	24	7
00299	Oral	4	20 MG	02JUL96	25	09JUL96	32	8
00299	Oral	4	20 MG	10JUL96	33	21JUL96	44	12
	Oral	4	20 MG	22JUL96	45	30JUL96	53	9
00299	Oral	4	20 MG	31JUL96	54	06AUG96	60	7
00169	Oral	4	20 MG	07AUG96	61	02SEP96	87	27
00169	Oral	4	20 MG	03SEP96	88	01OCT96	116	29
00169	Oral	5	30 MG	02OCT96	117	28OCT96	143	27
00169	Oral	5	30 MG	29OCT96	144	04NOV96	150	7
00299	Oral	4	20 MG	05NOV96	151	06NOV96	152	2
00299	Oral	3	20 MG	07NOV96	153	08NOV96	154	2
00299	Oral	2	20 MG	09NOV96	155	11NOV96	157	3
00299	Oral	1	20 MG	12NOV96	158	18NOV96	164	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	164	20	Lack of Efficacy	PT. REMOVED AT PARENTS REQUEST. PT HAD AN INC IN AFFECTIVE SYMPTOMS AFTER INITIAL IMPROVEMENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
KNEE PAIN {RIGHT-MILD AFTER RUNNING}	PAIN, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Calcium Carbonate	Tums	.,	.		.		STOMACH
			.,	.		.		STOMACH
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	138,	78	23OCT96	23OCT96	2 TABS	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	.,	.		.		HEADACHE
RESPIRATORY	Guaifenesin	Robitussin	109,	49	24SEP96	02OCT96	2 TSP	"COLD"
			140,	80	25OCT96	25OCT96	2 TSP	COLD SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	54, -7	3 Days	20	2	MOD	NO	PSR	Yes	No
	Headache	HEADACHE	54, -7	5 Days	20	2	MOD	NO	PSR	Yes	No
			88, 28	03:00 Hrs	20	4	MOD	NO	PBU	No	No
			138, 78	02:00 Hrs	30	1	MOD	NO	PBU	Yes	No
			165, 105	04:00 Hrs	20	1	MOD	NO	PBU	No	No
		HEADACHE UPON RISING	7, -54	27 Days	20		MOD	NO	PSR	No	No
Carciovascular System	Syncope	FAINTED	10, -51	1 Mins	20	1	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	151, 91	8 Days	20	CON	MOD	NO	PSR	No	No
		DIZZINESS UPON RISING	7, -54	27 Days	20		MOD	NO	PSR	No	No
Respiratory System	Epistaxis	NOSEBLEED	158, 98	10 Mins	20	1	MIL	NO	PSR	No	No
	Respiratory Disorder	COLD {SYMPTOMS}	95, 35	Not Stated	20	CON	MOD	NO	UNR	Yes	No
Special Senses	Abnormal Vision	BLURRED VISION	139, 79	6 Days	30	CON	MIL	NO	PBU	No	No
			151, 91	8 Days	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	28MAY96	-11, -71	0	118	82	72	116	78	78	123.20	63.0
BL	04JUN96	-4, -64	0	120	80	64	120	80	76	124.00	
1	18JUN96	11, -50	20	92	64	84	92	60	100	123.00	
2	25JUN96	18, -43	20	92	64	84	92	60	96	125.75	
3	02JUL96	25, -36	20	110	70	82	110	80	84	124.00	
5	10JUL96	33, -28	20	90	68	80	92	56	88	124.00	
6	22JUL96	45, -16	20	100	48 L	84	90	42 L	100	124.00	
8	31JUL96	54, -7	20	110	60	80	90	54	84	127.20	
8	07AUG96	61, 1	20	106	70	80	100	60	84	125.75	
12	03SEP96	88, 28	20	120	70	72	120	76	86	128.75	
16	01OCT96	116, 56	20	92	58	84	88 L	54	92	128.00	
20	29OCT96	144, 84	30	104	60	82	100	60	88	131.25	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	22.7	H	.	.	12 - 15.6	G/DL
				Hematocrit	67.3	H	.	.	35 - 46	%
				Red Blood Cell Count	7.9	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	14	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	25.1	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	10000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	266	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-11	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-4	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70	.	.	.	30 - 70	%
				Lymphocytes	18.5	L	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	232000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 2/ELIGIBILITY	-4	Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.4	.	.	.	30 - 70	%
				Lymphocytes	23.4	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	226	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	144	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.5	H	.	.	30 - 70	%
				Lymphocytes	15.1	L	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	131	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00299 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 13/CONTINUATION-WEEK 20	144	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	19SEP96	1	25SEP96	7	7
00300	Oral	2	20 MG	26SEP96	8	02OCT96	14	7
00300	Oral	3	20 MG	03OCT96	15	09OCT96	21	7
00300	Oral	4	20 MG	10OCT96	22	16OCT96	28	7
00300	Oral	4	20 MG	17OCT96	29	23OCT96	35	7
00300	Oral	4	20 MG	24OCT96	36	30OCT96	42	7
00300	Oral	4	20 MG	31OCT96	43	06NOV96	49	7
00300	Oral	4	20 MG	07NOV96	50	13NOV96	56	7
	Oral	3	20 MG	14NOV96	57	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	57	20		

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	55, .	02:00 Hrs	20	CON	MOD	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	6, .	27 Days	20	CON	MOD	NO	REL	No	No
			33, .	10 Days	20	CON	MIL	NO	REL	No	No
Nervous System	Hostility	OPPOSITIONAL BEHAVIOR (PHYSICALLY AND VERBALLY FIGHTING WITH MOTHER)	30, .	7 Days	20	6	SEV	NO	PBU	No	No
			37, .	Not Stated	20		MOD	NO	PBU	No	No
	Somnolence	SLEEPINESS (IN AM)	13, .	11 Days	20	CON	MOD	NO	REL	No	No
			24, .	Not Stated	20	CON	SEV	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12SEP96	-7, .	0	90	60	60	90	58	62	96.20	62.0
BL	19SEP96	1, .	0	80	50	60	88	50	62	96.50	
1	26SEP96	8, .	20	80	50	74	84	60	78	95.50	
2	03OCT96	15, .	20	88	60	64	84	58	68	94.20	
3	10OCT96	22, .	20	98	60	80	104	50	86	94.75	
4	17OCT96	29, .	20	90	60	60	80	60	64	97.50	
5	24OCT96	36, .	20	70	50	60	90	60	62	95.70	
6	31OCT96	43, .	20	80	60	60	58 L	54	60	95.50	
7	07NOV96	50, .	20	80	60	60	78	50	62	95.70	
8	14NOV96	57, .	20	90	60	60	80	58	64	99.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.8	.	.	.	30 - 70	%
				Lymphocytes	46.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	327000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.3	L	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	306	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	38	L	.	.	41 - 50	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	44.4	.	.	.	30 - 70	%
					Lymphocytes	43.1	.	.	.	21 - 51	%
					Monocytes	8.9	.	.	.	0 - 10	%
					Eosinophils	3.1	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	290000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
					Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	2	L	.	.	2.6 - 7	MG/DL
					Alkaline Phosphatase	259	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00300 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21NOV96	1	26NOV96	6	6
00331	Oral	2	0 MG	27NOV96	7	03DEC96	13	7
00331	Oral	3	0 MG	04DEC96	14	11DEC96	21	8
00331	Oral	4	0 MG	12DEC96	22	18DEC96	28	7
00331	Oral	4	0 MG	19DEC96	29	25DEC96	35	7
00331	Oral	4	0 MG	26DEC96	36	01JAN97	42	7
00331	Oral	4	0 MG	02JAN97	43	09JAN97	50	8
00331	Oral	4	0 MG	10JAN97	51	16JAN97	57	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	57	0		DRUG SUPPLIES NOT AVAILABLE FROM SKB

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
25% HEARING LOSS RIGHT EAR	HEARING LOSS	NERVOUS SYST/SENSE ORGAN DIS	CUR	1982
ALLERGIES {CAT AND DOG HAIR, DUST, TREES}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
RECURRENT EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1982
SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1996
TUBES PLACED IN RIGHT EAR X6	OPERATION, EAR	OPERATIONS	CUR	1982

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	27, .	17DEC96	27DEC96	2 CAPS	SINUS INFECTION
	Azithromycin	Zithromax	-22, .	30OCT96	06NOV96#		EAR INFECTION
	Clavulanic Acid	Augmentin	27, .	17DEC96	27DEC96	2 CAPS	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	1, .	21NOV96	21NOV96	500 MG	HEADACHE
			36, .	26DEC96	26DEC96	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	3, .	23NOV96	23NOV96	4 CAPS	HEADACHE
RESPIRATORY	Decongestant Nos	Unknown Decongestant {Nos}	-14, .	07NOV96	17NOV96#		SINUS INFECTION
			-14, .	07NOV96	17NOV96#		SINUS INFECTION
	Guaifenesin	Robitussin	23, .	13DEC96	17DEC96	2 TSP.	SINUS INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	30, .	6 Days	0	CON	MIL	NO	UNR	No	No
			48, .	2 Days	0	CON	MIL	NO	UNR	No	No
	Headache	HEADACHE	1, .	4 Days	0	4	MOD	NO	REL	Yes	No
			3, .	1 Days	0	2	MIL	NO	PSR	No	No
			4, .	1 Days	0	CON	MIL	NO	PSR	No	No
			10, .	2 Days	0	2	MOD	NO	REL	Yes	No
			36, .	02:30 Hrs	0	CON	MOD	NO	UNR	Yes	No
			50, .	02:30 Hrs	0	CON	MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	3, .	5 Days	0	CON	MIL	NO	REL	No	No
Nervous System	Depersonalization	"SPACED OUT" FEELING	18, .	5 Days	0	CON	MIL	DCR	PSR	No	No
	Dizziness	DIZZINESS	29, .	5 Mins	0	CON	MIL	NO	PBU	No	No
		DIZZINESS IN AM	19, .	4 Days	0	3	MIL	NO	PBU	No	No
	Nervousness	FIDGETINESS	3, .	10:00 Hrs	0	CON	MIL	NO	PSR	No	No
Respiratory System	Sinusitis	SINUS INFECTION	27, .	11 Days	0	CON	SEV	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14NOV96	-7, .	0	100	70	84	90	70	88	163.00	66.0
BL	21NOV96	1, .	0	90	60	84	90	60	88	162.50	
1	27NOV96	7, .	0	120	70	88	112	70	100	164.70	
2	04DEC96	14, .	0	110	70	84	104	70	88	164.00	
3	12DEC96	22, .	0	100	70	88	110	74	84	164.00	
4	19DEC96	29, .	0	104	70	92	112	70	96	163.00	
6	02JAN97	43, .	0	124	80	80	120	70	84	166.70	
7	10JAN97	51, .	0	100	64	80	90	60	84	162.00	
8	16JAN97	57, .	0	100	70	74	90	60	80	162.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	24	H	.	.	12 - 15.6	G/DL
				Hematocrit	69.9	H	.	.	35 - 46	%
				Red Blood Cell Count	7.3	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	19.1	H	.	+	4.5 - 13	THOU/MCL
				Segmented Neutrophils	74	H	.	.	30 - 70	%
				Lymphocytes	17	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	12000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	7	Hemoglobin	14.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	28.6	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 3/ACUTE PHASE-WEEK 1	7	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		
				Urine Benzodiazepines NEG		.	.	.		
				Urine Cannabinoids NEC		.	.	.		
				Urine Cocaine NEG		.	.	.		
				Urine Methadone NEG		.	.	.		
				Urine Methaqualone NEG		.	.	.		
				Urine Opiates NEG		.	.	.		
				Urine Phencyclidine NEG		.	.	.		
				Urine Propoxyphene NEG		.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	25.6	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	266000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	92	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00331 TREATMENT GROUP: PLACEBO

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	12DEC96	1	18DEC96	7	7
00332	Oral	2	100 MG	19DEC96	8	25DEC96	14	7
00332	Oral	3	150 MG	26DEC96	15	01JAN97	21	7
00332	Oral	4	200 MG	02JAN97	22	08JAN97	28	7
00332	Oral	5	250 MG	09JAN97	29	15JAN97	35	7
00332	Oral	6	300 MG	16JAN97	36	22JAN97	42	7
00332	Oral	6	300 MG	23JAN97	43	29JAN97	49	7
00332	Oral	6	300 MG	30JAN97	50	05FEB97	56	7
	Oral	5	250 MG	06FEB97	57	21FEB97	72	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	72	250	Lack of Efficacy	

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE - AFTER GYM CLASS OR EXERCISE	5, .	30 Mins	50	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	23, .	4 Days	200	CON	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS IN GYM CLASS X1	9, .	5 Mins	100	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05DEC96	-7, .	0	104	70	58	100	68	64	119.00	67.0
BL	12DEC96	1, .	0	100	70	60	110	70	60	118.70	
1	19DEC96	8, .	100	120	82	60	112	80	64	120.00	
2	26DEC96	15, .	150	104	70	68	100	64	72	123.00	
3	02JAN97	22, .	200	108	68	78	100	60	80	120.70	
4	09JAN97	29, .	250	100	70	76	100	68	78	121.00	
5	16JAN97	36, .	300	110	80	76	100	70	76	122.70	
6	23JAN97	43, .	300	120	80	68	112	80	72	123.70	
7	30JAN97	50, .	300	112	80	80	110	70	88	123.50	
8	06FEB97	57, .	250	118	84	80	112	80	84	122.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	UNSATISFACTO	U	.	U	22 - 180	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEC		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.5	.	.	.	41 - 50	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	1	Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.6	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	8.7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	46.4	.	.	.	40 - 75	%
				Lymphocytes	37.4	.	.	.	16 - 46	%
				Monocytes	7.3	.	.	.	0 - 12	%
				Eosinophils	8.1	H	.	.	0 - 7	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	183	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00332 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	23JAN97	1	30JAN97	8	8
00333	Oral	2	20 MG	31JAN97	9	05FEB97	14	6
00333	Oral	3	20 MG	06FEB97	15	12FEB97	21	7
00333	Oral	4	20 MG	13FEB97	22	19FEB97	28	7
00333	Oral	4	20 MG	20FEB97	29	24FEB97	33	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	33	20	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ENVIRONMENTAL ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
TONSILLECTOMY AND ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1990

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Loperamide Hydrochloride	Imodium-Ad	30,	.	21FEB97	21FEB97	1 TBSP	DIARRHEA
CENTRAL NERVOUS SYSTEM	Caffeine	Vivarin	14,	.	05FEB97	05FEB97	1 TAB	SLEEPINESS
	Paracetamol	Tylenol	2,	.	24JAN97	24JAN97	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	23,	.	14FEB97	16FEB97	800 MG	HEADACHE
			33,	.	24FEB97	24FEB97	400 MG	HEADACHE
RESPIRATORY	Fexofenadine Hydrochloride	Allegra	-236,	.	01JUN96	.		ENVIRONMENTAL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, .	03:20 Hrs	20	CON	MIL	NO	UNR	Yes	No
			4, .	02:30 Hrs	20	CON	MIL	NO	UNR	No	No
			22, .	8 Days	20	7	MOD	NO	PSR	Yes	No
			33, .	03:00 Hrs	20	CON	MOD	NO	PBU	Yes	No
Digestive System	Diarrhea	DIARRHEA	30, .	08:00 Hrs	20	CON	SEV	NO	UNR	Yes	No
Nervous System	Abnormal Dreams	VIVID DREAMS	19, .	11 Days	20	10	MOD	NO	PSR	No	No
	Emotional Lability	SUICIDAL IDEATION	37, .	103 Days	20	CON	SEV	NO	UNR	No	Yes
	Somnolence	SLEEPINESS	10, .	7 Days	20	CON	SEV	NO	PSR	Yes	No
			30, .	Not Stated	20	CON	SEV	NO	PSR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	20, .	3 Days	20	5	MIL	NO	PBU	No	No
	Rhinitis	"STUFFY" NOSE	1, .	Not Stated	20	CON	MOD	NO	UNR	No	No
Skin and Appendages	Rash	BLOTCHES (RED) ON LEGS	19, .	3 Days	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15JAN97	-8, .	0	122	70	82	124	78	86	123.00	64.0
BL	23JAN97	1, .	0	126	60	80	128	80	88	123.40	
1	31JAN97	9, .	20	118	70	74	120	74	76	123.70	
2	06FEB97	15, .	20	132	74	60	128	70	64	125.20	
3	13FEB97	22, .	20	124	74	88	118	70	100	124.00	
4	20FEB97	29, .	20	124	70	80	120	70	80	124.70	
5	26FEB97	35, .	20	120	80	68	120	80	74	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	384000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00333 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	31JAN97	1	05FEB97	6	6
00334	Oral	2	0 MG	06FEB97	7	12FEB97	13	7
00334	Oral	3	0 MG	13FEB97	14	20FEB97	21	8
00334	Oral	4	0 MG	21FEB97	22	25FEB97	26	5
00334	Oral	4	0 MG	26FEB97	27	06MAR97	35	9
00334	Oral	5	0 MG	07MAR97	36	13MAR97	42	7
00334	Oral	5	0 MG	14MAR97	43	21MAR97	50	8
00334	Oral	5	0 MG	22MAR97	51	27MAR97	56	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	56	0		LACK OF STUDY MEDICATION AVAILABLE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ABNORMAL LAB VALUES URINALYSIS +3 OCCULT BLOOD/RED	HEMATURIA	GENITOURINARY SYST DIS	CUR	1997
ABNORMAL LAB VALUES URINALYSIS MODERATE BACTERIA/CLOUDY	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	CUR	1997
REPAIR OF LEFT FOOT - BONE REALIGNMENT	OPERATION, BONE/JOINT	OPERATIONS	CUR	1997
BROKEN ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	7, .	06FEB97	16FEB97	750 MG	SORE THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-50, .	12DEC96	19DEC96#	1 GM	POST-OP FOOT SURGERY
			32, .	03MAR97	03MAR97	500 MG	HEADACHE
			41, .	12MAR97	12MAR97	500 MG	HEADACHE
			48, .	19MAR97	20MAR97	1000 MG	FEVER
MUSCULO-SKELETAL	Ibuprofen	Advil	48, .	19MAR97	20MAR97	800 MG	BACKACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACK ACHE	48, .	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
		BACKACHE	21, .	04:00 Hrs	0	CON	MOD	NO	UNR	No	No
	Fever	FEVER - 102 DEGREES[FEVER]	48, .	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	32, .	02:30 Hrs	0	CON	MIL	NO	PBU	Yes	No
			41, .	05:00 Hrs	0	CON	SEV	NO	PBU	Yes	No
Digestive System	Gastrointestinal Disorder	FOOD POISONING	47, .	3 Days	0	CON	SEV	NO	UNR	No	No
	Tooth Disorder	{TOOTH DISORDER}	-2, .	01:00 Hrs	0	CON	SEV	NO	UNR	No	No
Respiratory System	Pharyngitis	SORE THROAT	4, .	8 Days	0	CON	MOD	NO	UNR	Yes	No
Urogenital System	Albuminuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS POSITIVE PROTEIN]	56, .	1 Days	0	CON	MOD	NO	UNR	No	No
	Pyuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS MODERATE BACTERIA]	56, .	1 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JAN97	-7, .	0	112	70	72	100	70	76	174.00	63.0
BL	29JAN97	-2, .	0	112	78	84	110	70	88	173.00	
1	06FEB97	7, .	0	120	80	88	118	80	96	172.50	
2	13FEB97	14, .	0	112	70	80	114	80	84	173.00	
3	21FEB97	22, .	0	118	70	78	112	70	80	175.50	
4	26FEB97	27, .	0	112	70	64	100	60	68	170.00	
5	06MAR97	35, .	0	118	80	80	104	80	80	171.00	
6	13MAR97	42, .	0	98	60	80	98	60	80	173.00	
7	21MAR97	50, .	0	114	70	76	90	60	80	167.50	
8	27MAR97	56, .	0	98	70	72	90	60	76	167.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	45.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	26.8	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	201000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	143	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	16.1	H	.	.	12 - 15.6	G/DL
				Hematocrit	48.2	H	.	.	35 - 46	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7	.	.	.	30 - 70	%
				Lymphocytes	30.9	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00334 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28FEB97	1	06MAR97	7	7
00335	Oral	2	100 MG	07MAR97	8	13MAR97	14	7
00335	Oral	3	150 MG	14MAR97	15	20MAR97	21	7
00335	Oral	4	200 MG	21MAR97	22	26MAR97	27	6
00335	Oral	5	250 MG	27MAR97	28	02APR97	34	7
00335	Oral	4	200 MG	03APR97	35	09APR97	41	7
00335	Oral	4	200 MG	10APR97	42	16APR97	48	7
00335	Oral	4	200 MG	17APR97	49	24APR97	56	8
	Oral	3	150 MG	25APR97	57	06MAY97	68	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	68	150	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1997

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-21, .	07FEB97	08FEB97#	500 MG	MENSTRUAL CRAMPS
			-1, .	27FEB97	27FEB97#	500 MG	HEADACHE
			43, .	11APR97	11APR97	500 MG	HEADACHE
			54, .	22APR97	22APR97	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-20, .	08FEB97	09FEB97#	400 MG	MENSTRUAL CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	-1, .	03:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			11, .	03:30 Hrs	100	CON	MIL	NO	UNR	No	No
			18, .	4 Days	150	6	MOD	NO	UNR	No	No
			22, .	6 Days	200	5	MOD	NO	UNR	No	No
			31, .	4 Days	250	3	MOD	NO	UNR	No	No
			43, .	04:00 Hrs	200	CON	SEV	NO	PBU	Yes	No
			54, .	03:30 Hrs	200	CON	MOD	NO	PBU	Yes	No
Carciovascular System	Electrocardiogram Abnormal	EKG CHANGE	35, .	1 Days	200	CON	MOD	DCR	REL	No	No
Digestive System	Diarrhea	UPSET STOMACH WITH DIARRHEA	11, .	2 Days	100	CON	SEV	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	9, .	Not Stated	100	CON	MOD	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	2, .	4 Days	50	CON	MIL	NO	REL	No	No
			6, .	01:00 Hrs	50	CON	SEV	NO	REL	No	No
	Tremor	HAND TREMORS	2, .	4 Days	50	CON	MIL	NO	REL	No	No
			6, .	12:00 Hrs	50	CON	SEV	NO	REL	No	No
			7, .	14 Days	50	CON	MOD	NO	REL	No	No
			33, .	5 Days	250	CON	MOD	NO	REL	No	No
			38, .	4 Days	200	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20FEB97	-8, .	0	100	70	60	100	70	64	111.50	65.0
BL	28FEB97	1, .	0	100	70	64	100	68	68	111.50	
1	07MAR97	8, .	100	104	78	76	104	70	76	110.50	
2	14MAR97	15, .	150	108	70	92	90	60	84	113.50	
3	21MAR97	22, .	200	110	72	72	94	60	74	109.50	
4	27MAR97	28, .	250	98	70	96	80	60	96	110.70	
5	03APR97	35, .	200	110	80	104	100	70	88	113.20	
6	10APR97	42, .	200	112	76	76	90	60	76	112.70	
7	17APR97	49, .	200	110	80	100	100	70	88	113.00	
8	24APR97	56, .	200	114	70	80	90	60	80	113.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.3	.	.	.	30 - 70	%
				Lymphocytes	36.8	.	.	.	21 - 51	%
				Monocytes	3.5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	359000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	32.3	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00335 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	04MAR97	1	11MAR97	8	8
00336	Oral	2	20 MG	12MAR97	9	18MAR97	15	7
00336	Oral	3	20 MG	19MAR97	16	24MAR97	21	6
00336	Oral	4	20 MG	25MAR97	22	01APR97	29	8
00336	Oral	4	20 MG	02APR97	30	08APR97	36	7
00336	Oral	4	20 MG	09APR97	37	15APR97	43	7
00336	Oral	4	20 MG	16APR97	44	22APR97	50	7
00336	Oral	4	20 MG	23APR97	51	30APR97	58	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	58	20		MEETS CRITERIA FOR ENTRANCE INTO CONTINUATION PHASE BUT NO MEDS ARE AVAILABLE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACKACHE	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1997

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin Extra-Strength	32, .	04APR97	09APR97	2 GM	SORE THROAT WITH COUGH
			38, .	10APR97	12APR97	2 GM	STUFFY NOSE, COUGH
			48, .	20APR97	23APR97	2 GM	BACKACHE
	Caffeine	Excedrin Extra-Strength	32, .	04APR97	09APR97	2 GM	SORE THROAT WITH COUGH
			38, .	10APR97	12APR97	2 GM	STUFFY NOSE, COUGH
			48, .	20APR97	23APR97	2 GM	BACKACHE
	Paracetamol	Excedrin Extra-Strength	32, .	04APR97	09APR97	2 GM	SORE THROAT WITH COUGH
			38, .	10APR97	12APR97	2 GM	STUFFY NOSE, COUGH
			48, .	20APR97	23APR97	2 GM	BACKACHE
		Tylenol	-12, .	20FEB97	21FEB97#	500 MG	BACKACHE
RESPIRATORY	Brompheniramine Maleate	Dimetapp	-18, .	14FEB97	16FEB97#	2	COLD SX
	Phenylephrine Hydrochloride	Dimetapp	-18, .	14FEB97	16FEB97#	2	COLD SX
	Phenylpropanolamine Hydrochloride	Dimetapp	-18, .	14FEB97	16FEB97#	2	COLD SX

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	25, .	2 Days	20	CON	MIL	NO	UNR	No	No
			48, .	4 Days	20	CON	MIL	NO	UNR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	6, .	39 Days	20	CON	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	7, .	13 Days	20	2	MIL	NO	REL	No	No
		GIDDINESS	11, .	4 Days	20	4	MIL	NO	PSR	No	No
			24, .	3 Days	20	CON	MIL	NO	PSR	No	No
	Myoclonus	LEG TWITCHES	47, .	4 Days	20	4	MIL	NO	PSR	No	No
		LEG TWITCHES (NIGHTLY)	26, .	5 Days	20	4	SEV	NO	PSR	No	No
			30, .	8 Days	20	7	MIL	NO	PSR	No	No
	Tremor	HAND TREMORS	5, .	4 Days	20	CON	MOD	NO	REL	No	No
			10, .	7 Days	20	CON	MIL	NO	REL	No	No
			32, .	13 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	32, .	6 Days	20	CON	MOD	NO	UNR	Yes	No
			38, .	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	32, .	6 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	STUFFY NOSE	38, .	3 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26FEB97	-6, .	0	114	74	64	100	70	68	119.00	65.0
BL	04MAR97	1, .	0	100	70	64	90	60	68	119.70	
1	12MAR97	9, .	20	100	70	68	98	60	68	118.70	
2	19MAR97	16, .	20	104	70	60	90	60	64	116.50	
3	25MAR97	22, .	20	88	64	68	80	60	72	120.50	
4	02APR97	30, .	20	82	60	78	80	60	78	121.00	
5	09APR97	37, .	20	80	60	84	88	60	88	124.00	
6	16APR97	44, .	20	100	60	68	90	60	72	122.50	
7	23APR97	51, .	20	110	70	78	90	60	80	123.00	
8	30APR97	58, .	20	100	70	72	90	60	76	121.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	7.9	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.5	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.005.00336 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Lymphocytes	46.4	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEC		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28JAN95	1	02FEB95	6	6
00037	Oral	2	0 MG	03FEB95	7	12FEB95	16	10
00037	Oral	3	0 MG	13FEB95	17	21FEB95	25	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	25	0	Protocol violation, including non-compliance	LOST INTEREST,PATIENT HAS REFUSED FOLLOW-UP SAFETY EVALUATION AND ASSISTANCE WITH REFERRAL

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Doxycycline	Doxycycline	10, .	06FEB95	13FEB95	UNKNOWN	BRONCHITIS
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Ovcon 35	-119, .	01OCT94	.	1 TAB	BIRTH CONTROL
	Norethisterone	Ovcon 35	-119, .	01OCT94	.	1 TAB	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	10, .	Not Stated	0	CON	MOD	NO	REL	No	No
Digestive System	Nausea	NAUSEA	19, .	Not Stated	0	CON	MIL	NO	REL	No	No
Nervous System	Insomnia	INSOMNIA	10, .	Not Stated	0	CON	MOD	NO	REL	No	No
Respiratory System	Bronchitis	BRONCHITIS	10, .	8 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20JAN95	-8, .	0	135	68	82	.	.	.	144.43	65.0
BL	27JAN95	-1, .	0	128	70	88	132	70	92	144.43	
1	03FEB95	7, .	0	125	78	85	.	.	.	144.43	
2	13FEB95	17, .	0	120	76	84	120	70	72	142.22	
4	22FEB95	26, .	0	110	80	72	130	70	78	142.22	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7	.	.	.	30 - 70	%
				Lymphocytes	26.1	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	360000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	56	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00037 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	15FEB95	1	21FEB95	7	7
00038	Oral	2	20 MG	22FEB95	8	02MAR95	16	9
00038	Oral	3	20 MG	03MAR95	17	07MAR95	21	5
00038	Oral	4	20 MG	08MAR95	22	15MAR95	29	8
00038	Oral	4	20 MG	16MAR95	30	22MAR95	36	7
00038	Oral	4	20 MG	23MAR95	37	29MAR95	43	7
00038	Oral	4	20 MG	30MAR95	44	04APR95	49	6
00038	Oral	4	20 MG	05APR95	50	12APR95	57	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	57	20	Adverse event, including intercurrent illness	SEVERAL PERSONAL CRISIS LED PATIENT TO OVERDOSE ON SEVERAL MEDICATIONS INCLUDING STUDY MEDICATIONS ON 12APR95-MOVE TO WITHDRAW.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CARDIOVASCULAR	Benzocaine	Benzocaine	-410, .	01JAN94	.	9 TABLETS	DIETING
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Fiorinal	57, .	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
	Butalbital	Fiorinal	57, .	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
	Caffeine	Fiorinal	57, .	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
	Paracetamol	Tylenol	57, .	12APR95	12APR95	1300MG	ATTEMPTED SUICIDE
	Phenacetin	Fiorinal	57, .	12APR95	12APR95	10TABLETS	ATTEMPTED SUICIDE
	Tranquilizer	Tranquilizer {Nos}	17, .	03MAR95	03MAR95	UNKNOWN	DENTAL PROCEDURE
DERMATOLOGICALS	Benzocaine	Benzocaine	-410, .	01JAN94	.	9 TABLETS	DIETING
MUSCULO-SKELETAL	Ibuprofen	Advil	57, .	12APR95	12APR95	4600MG	ATTEMPTED SUICIDE
		Ibuprofen	57, .	12APR95	12APR95	4800MG	ATTEMPTED SUICIDE
			57, .	12APR95	12APR95	13800MG	ATTEMPTED SUICIDE
RESPIRATORY	Benzocaine	Benzocaine	-410, .	01JAN94	.	9 TABLETS	DIETING
	Salbutamol	Albuterol	-1871, .	01JAN90	.	1PUFF	ASTHMA
			-1871, .	01JAN90	.	1PUFF	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN-APPROXIMATELY 3 OCCASIONS-INTENSE JAB THEN REMITS	41,	.	3 Days	20	3	SEV	NO	PSR	No	No
	Headache	HEADACHE	57,	.	3 Days	20	CON	MOD	STP	UNR	No	No
Digestive System	Constipation	CONSTIPATION	57,	.	3 Days	20	CON	MOD	STP	UNR	No	No
Musculoskeletal System	Myalgia	MUSCLE ACHE	57,	.	3 Days	20	CON	MOD	STP	UNR	No	No
	Myasthenia	MUSCLE WEAKNESS	57,	.	3 Days	20	CON	MOD	STP	UNR	No	No
Nervous System	Dizziness	DIZZINESS	57,	.	3 Days	20	CON	MOD	STP	UNR	No	No
	Emotional Lability	ATTEMPTED SUICIDE {INTENTIONAL}	57,	.	1 Days	20	1	SEV	STP	UNR	No	Yes
	Hostility	ANGRY(PATIENT NOTICED)	29,	.	8 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Sinusitis	COLD-SINUS SYMPTOMS	8,	.	10 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01FEB95	-14, .	0	108	60	64	103	61	72	171.00	67.0
BL	08FEB95	-7, .	0	90	60	80	90	60	80	171.00	
1	22FEB95	8, .	20	110	80	68	128	68	72	164.49	
2	03MAR95	17, .	20	100	70	.	110	80	.	166.92	
3	08MAR95	22, .	20	90	60	60	100	60	80		
4	15MAR95	29, .	20	100	60	60	100	70	80	161.00	
5	22MAR95	36, .	20	90	70	60	100	60	100		
6	29MAR95	43, .	20	110	70	80	120	70	.	168.68	
7	05APR95	50, .	20	100	80	60	108	68	80	166.48	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	286000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00038 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08FEB95	1	13FEB95	6	6
00039	Oral	2	20 MG	14FEB95	7	21FEB95	14	8
00039	Oral	3	20 MG	22FEB95	15	01MAR95	22	8
00039	Oral	4	20 MG	02MAR95	23	07MAR95	28	6
00039	Oral	4	20 MG	08MAR95	29	17MAR95	38	10
00039	Oral	4	20 MG	18MAR95	39	23MAR95	44	6
00039	Oral	5	30 MG	24MAR95	45	28MAR95	49	5
00039	Oral	5	30 MG	29MAR95	50	09APR95	61	12
00057	Oral	5	30 MG	10APR95	62	30APR95	82	21
00039	Oral	4	20 MG	01MAY95	83	05MAY95	87	5
00039	Oral	3	20 MG	06MAY95	88	07MAY95	89	2
00039	Oral	2	20 MG	08MAY95	90	08MAY95	90	1
00039	Oral	1	20 MG	09MAY95	91	10MAY95	92	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	92	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES-FREQUENT	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-1134,-1195	01JAN92	.	PRN-600MG	HEADACHES
	Naproxen Sodium	Anaprox	76, 15	24APR95	28APR95	275MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	VERY TIRED	43, -19	7 Days	20	CON	SEV	NO	PSR	No	No
	Headache	HEADACHES-MORE SEVERE THAN USUAL	76, 15	5 Days	30	3	SEV	NO	PBU	Yes	No
	Trauma	SUPERFICIAL SCRATCHES	18, -44	12 Days	20	CON	MIL	NO	PBU	No	No
Nervous System	Depression	MORE DEPRESSED	43, -19	7 Days	20	CON	SEV	NO	PSR	No	No
	Myoclonus	GRIMACING FACE WITH BLINKING EYES {TIC}	43, -19	7 Days	20	CON	MIL	NO	PSR	No	No
	Nervousness	IRRITABLE MOOD	43, -19	7 Days	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	03FEB95	-5, -66	0	100	60	68	107	66	88	142.22	64.6
BL	10FEB95	3, -59	20	116	70	71	108	70	66	142.22	
1	13FEB95	6, -56	20	100	60	60	103	66	60	143.33	
2	22FEB95	15, -47	20	98	68	70	100	72	80	143.33	
3	01MAR95	22, -40	20	90	60	60	90	60	66	138.92	
4	08MAR95	29, -33	20	110	70	68	102	70	80		
5	17MAR95	38, -24	20	100	60	84	110	60	80	135.61	
6	22MAR95	43, -19	20	88	58	70	85	62	90		
7	29MAR95	50, -12	30	98	78	80	98	70	90	136.71	
8	05APR95	57, -5	30	100	60	70	96	60	100	136.71	
12	01MAY95	83, 22	20	108	78	80	90	60	80	143.33	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	234000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7		.	.	12 - 15.6	G/DL
				Hematocrit	36		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2		.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	78.3	H	.	.	30 - 70	%
				Lymphocytes	13.2	L	.	.	21 - 51	%
				Monocytes	5.5		.	.	0 - 10	%
				Eosinophils	2.8		.	.	0 - 5	%
				Basophils	0.3		.	.	0 - 2	%
				Platelets	200000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1		.	.	25 - 35	PG
				Mean Corpuscle Volume	86		.	.	80 - 100	FL
				Blood Urea Nitrogen	11		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	83		.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00039 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	16FEB95	1	22FEB95	7	7
00040	Oral	2	100 MG	23FEB95	8	28FEB95	13	6
00040	Oral	1	50 MG	01MAR95	14	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	No	No	14	50	Adverse event, including intercurrent illness	FATIGUE,EYE DILATION,MEDICATION REACTION

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1985
OVARIAN CYST	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Loestrin	-63, .	15DEC94	.	120	OVARIAN CYST
			-63, .	15DEC94	.	120	OVARIAN CYST
	Norethisterone Acetate	Loestrin	-63, .	15DEC94	.	120	OVARIAN CYST
			-63, .	15DEC94	.	120	OVARIAN CYST
MUSCULO-SKELETAL	Baclofen	Baclofen	-3698, .	01JAN85	.	1TAB PRN	ASTHMA
RESPIRATORY	Beclometasone Dipropionate	Vancenase	-3698, .	01JAN85	.	1TAB PRN	ALLERGIES
			-3698, .	01JAN85	.	1TAB PRN	ALLERGIES
	Salbutamol	Ventolin	-3698, .	01JAN85	.	1TAB PRN	ALLERGIES
			-3698, .	01JAN85	.	1TAB PRN	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	7, .	8 Days	50	CON	SEV	STP	REL	No	No
Carciovascular System	Tachycardia	ELEVATED HEART RATE	14, .	14 Days	50	CON	MOD	STP	REL	No	No
Digestive System	Constipation	CONSTIPATION	7, .	8 Days	50	CON	MOD	STP	REL	No	No
	Dyspepsia	INDIGESTION	7, .	8 Days	50	CON	MOD	STP	PSR	No	No
Nervous System	Dizziness	DIZZINESS	7, .	8 Days	50	CON	MOD	STP	REL	No	No
	Nervousness	IRRITABLE MOOD	7, .	8 Days	50	CON	MOD	STP	REL	No	No
Special Senses	Mydriasis	EYE DILATION	7, .	8 Days	50	CON	MOD	STP	REL	No	No
Urogenital System	Urinary Retention	URINARY RETENTION	7, .	8 Days	50	CON	MOD	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	10FEB95	-6, .	0	113	72	72	110	70	72	102.75	63.4
BL	15FEB95	-1, .	0	118	70	72	110	70	84	102.75	
1	22FEB95	7, .	50	110	80	88	106	76	90	102.97	
2	01MAR95	14, .	50	90	60	132 H	90	60	140 H	103.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.6	.	.	.	40 - 75	%
				Lymphocytes	34	.	.	.	16 - 46	%
				Monocytes	6.7	.	.	.	0 - 12	%
				Eosinophils	1.4	.	.	.	0 - 7	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	310000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	48	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00040 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	EGYPTIAN

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05APR95	1	09APR95	5	5
00041	Oral	2	100 MG	10APR95	6	18APR95	14	9
00041	Oral	3	150 MG	19APR95	15	23APR95	19	5
00041	Oral	4	200 MG	24APR95	20	30APR95	26	7
00041	Oral	4	200 MG	01MAY95	27	07MAY95	33	7
00041	Oral	4	200 MG	08MAY95	34	14MAY95	40	7
00041	Oral	4	200 MG	15MAY95	41	23MAY95	49	9
00041	Oral	5	250 MG	24MAY95	50	02JUN95	59	10
00041	Oral	6	300 MG	03JUN95	60	07JUN95	64	5
00059	Oral	6	300 MG	08JUN95	65	04JUL95	91	27
00059	Oral	6	300 MG	05JUL95	92	30JUL95	117	26
00059	Oral	6	300 MG	31JUL95	118	23AUG95	141	24
00059	Oral	6	300 MG	24AUG95	142	20SEP95	169	28
00059	Oral	6	300 MG	21SEP95	170	23OCT95	202	33
00059	Oral	6	300 MG	24OCT95	203	20NOV95	230	28
00041	Oral	5	250 MG	21NOV95	231	22NOV95	232	2
00041	Oral	4	200 MG	23NOV95	233	24NOV95	234	2
00041	Oral	3	150 MG	25NOV95	235	26NOV95	236	2
00041	Oral	2	100 MG	27NOV95	237	29NOV95	239	3
00041	Oral	1	50 MG	30NOV95	240	05DEC95	245	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	Yes	Yes	245	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
RIGHTWARD AXIS ON ELECTROCARDIOGRAM	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
BLOOD/BLOOD FORM ORGANS	Cyanocobalamin	Vitamin B12	-63, -127	01FEB95	05APR95	500MG	VITAMIN SUPPLEMENT
MUSCULO-SKELETAL	Ibuprofen	Advil	12, -53	16APR95	18APR95	600MG	SORE THROAT
		Nuprin	141, 77	23AUG95	23AUG95	TABLETSX2	HEADACHE
RESPIRATORY	Cough Cold Preparations Nos	Osco Brand Cold And Flu Medication {Nos}	12, -53	16APR95	18APR95	2TABS	SORE THROAT
	Dextromethorphan Hydrobromide	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
	Guaifenesin	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
	Paracetamol	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
	Pseudoephedrine Hydrochloride	Dayquil	140, 76	22AUG95	22AUG95	2CAPSULES	COLD SYMPTOM
VARIOUS	Nutritional Supplement Nos	Met-Rx {Nutritional Supplement}	134, 70	16AUG95	23AUG95	1PACKET	HEALTH MAINTENANCE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	141, 77	1 Days	300	1	SEV	NO	PBU	Yes	No
Cardiovascular System	Syncope	LIGHTHEADED FAINT SYNCOPE	18, -47	1 Mins	150	1	MIL	NO	PSR	No	No
Digestive System	Vomiting	EMESIS	140, 76	1 Days	300	2	MIL	NO	UNR	No	No
Nervous System	Insomnia	INSOMNIA	134, 70	8 Days	300	6	MOD	NO	UNR	No	No
	Nervousness	IRRITABLE MOOD	12, -53	3 Days	100	1	MOD	NO	UNR	No	No
Respiratory System	Pharyngitis	SORE THROAT	12, -53	3 Days	100	1	MOD	NO	PBU	Yes	No
	Respiratory Disorder	COLD SYMPTOMS	140, 76	3 Days	300	CON	MOD	NO	UNR	Yes	No
Urogenital System	Nocturia	NOCTURIA	50, -15	8 Days	250	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22MAR95	-14, -78	0	100	75	65	100	78	68	151.48	71.3
BL	05APR95	1, -64	0	98	68	60	98	68	66	151.50	
1	10APR95	6, -59	100	98	55	60	100	58	80	151.50	
2	19APR95	15, -50	150	110	65	70	100	80	90	156.50	
3	24APR95	20, -45	200	120	70	88	116	70	100	152.00	
4	01MAY95	27, -38	200	110	65	80	100	80	100	154.00	
5	08MAY95	34, -31	200	110	75	78	90	75	90	154.00	
6	15MAY95	41, -24	200	108	70	78	90	75	95	154.50	
7	24MAY95	50, -15	250	110	80	90	100	70	102	154.00	
8	31MAY95	57, -8	250	108	85	85	100	80	109	160.50	
12	05JUL95	92, 28	300	102	78	78	92	78	120	162.00	
16	31JUL95	118, 54	300	110	70	80	108	80	72	166.00 H	
20	24AUG95	142, 78	300	110	70	100	92	78	100	167.00 H	
24	21SEP95	170, 106	300	114	80	72	90	78	114	167.00 H	
28	24OCT95	203, 139	300	118	80	85	100	80	90	170.00 H	
32	21NOV95	231, 167	250	115	90	90	112	90	96	172.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	40 - 75	%
				Lymphocytes	37.5	.	.	.	16 - 46	%
				Monocytes	7.3	.	.	.	0 - 12	%
				Eosinophils	3.3	.	.	.	0 - 7	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	98	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	53	.	.	.	40 - 75	%
				Lymphocytes	35.5	.	.	.	16 - 46	%
				Monocytes	8	.	.	.	0 - 12	%
				Eosinophils	3.1	.	.	.	0 - 7	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	98	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	39	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	92	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	142	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	44.4	.	.	.	40 - 75	%
				Lymphocytes	28.2	.	.	.	16 - 46	%
				Monocytes	12	.	.	.	0 - 12	%
				Eosinophils	14.4	H	.	+	0 - 7	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	201000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	107	.	.	.	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 13/CONTINUATION-WEEK 20	142	Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	54	H	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	48	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
		VISIT 15/CONTINUATION-WEEK 28	203	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	231	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	58.1	.	.	.	40 - 75	%
				Lymphocytes	31.3	.	.	.	16 - 46	%
				Monocytes	7.6	.	.	.	0 - 12	%
				Eosinophils	2.5	.	.	.	0 - 7	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00041 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 16/CONTINUATION-WEEK 32	231	Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	07DEC95	1	12DEC95	6	6
00042	Oral	2	0 MG	13DEC95	7	19DEC95	13	7
00042	Oral	3	0 MG	20DEC95	14	26DEC95	20	7
00042	Oral	4	0 MG	27DEC95	21	02JAN96	27	7
00042	Oral	4	0 MG	03JAN96	28	09JAN96	34	7
00042	Oral	5	0 MG	10JAN96	35	16JAN96	41	7
00042	Oral	5	0 MG	17JAN96	42	22JAN96	47	6
00042	Oral	6	0 MG	23JAN96	48	01FEB96	57	10
00111	Oral	6	0 MG	02FEB96	58	28FEB96	84	27
00111	Oral	6	0 MG	29FEB96	85	25MAR96	110	26
00111	Oral	6	0 MG	26MAR96	111	22APR96	138	28
00111	Oral	6	0 MG	23APR96	139	20MAY96	166	28
00111	Oral	6	0 MG	21MAY96	167	17JUN96	194	28
00111	Oral	6	0 MG	18JUN96	195	16JUL96	223	29
00042	Oral	5	0 MG	17JUL96	224	18JUL96	225	2
00042	Oral	4	0 MG	19JUL96	226	20JUL96	227	2
00042	Oral	3	0 MG	21JUL96	228	22JUL96	229	2
00042	Oral	2	0 MG	23JUL96	230	25JUL96	232	3
00042	Oral	1	0 MG	26JUL96	233	31JUL96	238	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	Yes	Yes	238	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ECG-SINUS ARRHYTHMIA(MILD)	ARRHYTHMIA	CIRCULATORY SYST	CUR	1995
OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	32, -26	07JAN96	07JAN96	2/3C.	STOMACH UPSET
CENTRAL NERVOUS SYSTEM	Paracetamol	Acetaminophen	140, 83	24APR96	24APR96	200 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	108, 51	23MAR96	23MAR96	600 MG	HEADACHE
			209, 152	02JUL96	02JUL96	400 MG	ORTHODONTAL/DENTAL PAIN
			210, 153	03JUL96	03JUL96	800 MG	DENTAL PAIN
			211, 154	04JUL96	04JUL96	200 MG	DENTAL PAIN
			212, 155	05JUL96	05JUL96	600 MG	DENTAL PAIN
			213, 156	06JUL96	06JUL96	400 MG	DENTAL PAIN
			216, 159	09JUL96	09JUL96	200 MG	HEADACHE
			218, 161	11JUL96	11JUL96	200 MG	HEADACHE
			220, 163	13JUL96	13JUL96	200 MG	HEADACHE
	Naproxen Sodium	Aleve	211, 154	04JUL96	04JUL96	220 MG	DENTAL PAIN

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	108, 51	30 Mins	0	1	MOD	NO	PBU	Yes	No
			140, 83	01:30 Hrs	0	1	MOD	NO	PBU	Yes	No
			216, 159	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			218, 161	06:00 Hrs	0	1	SEV	NO	UNR	Yes	No
			220, 163	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
		HEADACHES	22, -36	6 Days	0	7	MIL	NO	UNR	No	No
Carciovascular System	Palpitation	HEART PALPITATION {ONE TIME ONLY}	164, 107	1 Mins	0	1	MIL	NO	PBU	No	No
Digestive System	Dyspepsia	INDIGESTION(MEXICAN SPICY FOOD)	25, -33	3 Days	0	3	MOD	NO	UNR	No	No
		UPSET STOMACH	32, -26	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	32, -26	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	Tooth Disorder	ORTHODONTIC PAIN	209, 152	5 Days	0	CON	SEV	NO	UNR	Yes	No
	Vomiting	EMESIS	32, -26	1 Mins	0	1	MOD	NO	UNR	No	No
Musculoskeletal System	Myalgia	MUSCLE ACHE	32, -26	34:00 Hrs	0	1	MIL	NO	UNR	No	No
Respiratory System	Sinusitis	SINUS HEADACHE	32, -26	5 Days	0	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01DEC95	-6, -63	0	120	90	84	120	90	96	226.01	65.4
BL	06DEC95	-1, -58	0	123	90	90	125	95	90		
1	13DEC95	7, -51	0	120	80	96	120	85	120	233.00	
2	20DEC95	14, -44	0	125	90	90	125	85	120	234.00	
3	27DEC95	21, -37	0	125	85	80	120	80	110	235.00	
4	03JAN96	28, -30	0	120	90	70	120	95	90	233.30	
5	10JAN96	35, -23	0	120	90	78	120	90	78	237.40	
6	17JAN96	42, -16	0	120	90	68	118	80	76	235.50	
7	23JAN96	48, -10	0	120	90	65	120	94	80	235.00	
8	02FEB96	58, 1	0	120	94	80	120	94	78	236.00	
12	29FEB96	85, 28	0	120	90	78	118	90	90	236.50	
16	26MAR96	111, 54	0	125	95	74	125	95	82	240.00	
20	23APR96	139, 82	0	120	90	80	120	90	80	238.00	
24	21MAY96	167, 110	0	120	85	62	120	85	60	242.00 H	
28	18JUN96	195, 138	0	120	90	70	120	90	80	250.00 H	
32	16JUL96	223, 166	0	125	85	74	120	80	90	248.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	16.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.8	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	40 - 75	%
				Lymphocytes	26.8	.	.	.	16 - 46	%
				Monocytes	8.7	.	.	.	0 - 12	%
				Eosinophils	2	.	.	.	0 - 7	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	46	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 2/ELIGIBILITY	-1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	50.8	.	.	.	40 - 75	%
				Lymphocytes	33.3	.	.	.	16 - 46	%
				Monocytes	13.2	H	.	.	0 - 12	%
				Eosinophils	1.7	.	.	.	0 - 7	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	113	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	38	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	139	Hemoglobin	16.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.7	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	10.9	H	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	63.1	.	.	.	40 - 75	%
				Lymphocytes	26.2	.	.	.	16 - 46	%
				Monocytes	7.6	.	.	.	0 - 12	%
				Eosinophils	2.3	.	.	.	0 - 7	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	116	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	35	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 13/CONTINUATION-WEEK 20	139	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	223	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.8	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	45.7	.	.	.	40 - 75	%
				Lymphocytes	35.3	.	.	.	16 - 46	%
				Monocytes	10.7	.	.	.	0 - 12	%
				Eosinophils	7.8	H	.	.	0 - 7	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103	L	.	.	110 - 15	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00042 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 16/CONTINUATION-WEEK 32	223	Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	46	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	24MAY96	1	27MAY96	4	4
00259	Oral	2	0 MG	28MAY96	5	05JUN96	13	9
00259	Oral	3	0 MG	06JUN96	14	12JUN96	20	7
00259	Oral	4	0 MG	13JUN96	21	19JUN96	27	7
00259	Oral	5	0 MG	20JUN96	28	27JUN96	35	8
00259	Oral	6	0 MG	28JUN96	36	05JUL96	43	8
00259	Oral	6	0 MG	06JUL96	44	10JUL96	48	5
00259	Oral	6	0 MG	11JUL96	49	17JUL96	55	7
	Oral	6	0 MG	18JUL96	56	02AUG96	71	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	71	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FACIAL ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1994
FATIGUE	MALAISE AND FATIGUE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
NORMAL SINUS RHYTHM WITH SHORT PR ON EKG	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
LOW THYROID FUNCTION	HYPOTHYROIDISM	ENDOCR/METAB/IMMUNITY DISORD	PRV	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Minocycline	Minocin	-540, .	01DEC94	.	50MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22APR96	-32, .	0	125	75	66	120	75	66	136.00	67.0
BL	22MAY96	-2, .	0	120	70	78	110	70	110	132.00	
1	30MAY96	7, .	0	110	70	66	118	84	78	131.00	
2	06JUN96	14, .	0	125	70	78	120	75	68	132.00	
3	13JUN96	21, .	0	120	70	60	113	70	94	130.00	
4	20JUN96	28, .	0	110	70	72	110	75	80	128.50	
5	27JUN96	35, .	0	115	75	60	115	70	76	128.50	
6	03JUL96	41, .	0	120	80	66	115	80	70	128.00	
7	10JUL96	48, .	0	120	70	68	115	70	90	128.50	
8	17JUL96	55, .	0	115	70	60	118	70	60	130.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-32	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.9	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	11.2	H	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	280000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	120	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-32	Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-28	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	14.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.8	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	249000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	99	.	.	.	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00259 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	55	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18JUL96	1	26JUL96	9	9
00260	Oral	2	20 MG	27JUL96	10	31JUL96	14	5
00260	Oral	3	20 MG	01AUG96	15	06AUG96	20	6
00260	Oral	4	20 MG	07AUG96	21	13AUG96	27	7
00260	Oral	5	30 MG	14AUG96	28	20AUG96	34	7
00260	Oral	5	30 MG	21AUG96	35	27AUG96	41	7
00260	Oral	5	30 MG	28AUG96	42	03SEP96	48	7
00260	Oral	5	30 MG	04SEP96	49	13SEP96	58	10
00172	Oral	5	30 MG	14SEP96	59	08OCT96	83	25
00172	Oral	5	30 MG	09OCT96	84	08NOV96	114	31
00172	Oral	5	30 MG	09NOV96	115	04DEC96	140	26
00260	Oral	4	20 MG	05DEC96	141	08DEC96	144	4
00260	Oral	3	20 MG	09DEC96	145	11DEC96	147	3
00260	Oral	2	20 MG	12DEC96	148	13DEC96	149	2
00260	Oral	1	20 MG	14DEC96	150	18DEC96	154	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	154	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Tetracycline	Tetracycline	-6, -64	12JUL96	.	1000MG	ACNE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	56, -3	11SEP96	11SEP96	2 TABS	HEADACHE
		Excedrin	-2390,-2448	01JAN90	.	2 TABS	OCCASIONAL HEADACHES
			6, -53	23JUL96	16SEP96	2 TABS: PRN	HEADACHE
			8, -51	25JUL96	25JUL96	4 TABS	TOOTHACHE PAIN
			20, -39	06AUG96	06AUG96	2 TABS	TOOTHACHE
			83, 25	08OCT96	08OCT96	2 TAB	HEADACHE
	Caffeine	Excedrin	-2390,-2448	01JAN90	.	2 TABS	OCCASIONAL HEADACHES
			6, -53	23JUL96	16SEP96	2 TABS: PRN	HEADACHE
			8, -51	25JUL96	25JUL96	4 TABS	TOOTHACHE PAIN
			20, -39	06AUG96	06AUG96	2 TABS	TOOTHACHE
			83, 25	08OCT96	08OCT96	2 TAB	HEADACHE
	Paracetamol	Excedrin	-2390,-2448	01JAN90	.	2 TABS	OCCASIONAL HEADACHES
			6, -53	23JUL96	16SEP96	2 TABS: PRN	HEADACHE
			8, -51	25JUL96	25JUL96	4 TABS	TOOTHACHE PAIN
			20, -39	06AUG96	06AUG96	2 TABS	TOOTHACHE
			83, 25	08OCT96	08OCT96	2 TAB	HEADACHE
DERMATOLOGICALS	Tetracycline	Tetracycline	-6, -64	12JUL96	.	1000MG	ACNE
MUSCULO-SKELETAL	Ibuprofen	Advil	53, -6	08SEP96	08SEP96	2 TABS	HEADACHE
RESPIRATORY	Chlorphenamine Maleate	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
	Dextromethorphan Hydrobromide	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
	Paracetamol	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
	Phenylpropanolamine Hydrochloride	Contac Cold	83, 25	08OCT96	08OCT96	1 PACKET	COLD
SENSORY ORGANS	Tetracycline	Tetracycline	-6, -64	12JUL96	.	1000MG	ACNE
			-6, -64	12JUL96	.	1000MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	6, -53	45 Mins	20	1	MIL	NO	UNR	Yes	No
			7, -52	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No
			10, -49	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			11, -48	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			12, -47	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			13, -46	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			25, -34	45 Mins	20	1	MIL	NO	PBU	Yes	No
			34, -25	30 Mins	30	1	MIL	NO	PBU	Yes	No
			40, -19	40 Mins	30	1	MOD	NO	PBU	Yes	No
			47, -12	30 Mins	30	1	MIL	NO	PBU	Yes	No
			51, -8	45 Mins	30	1	MOD	NO	PBU	Yes	No
			53, -6	45 Mins	30	1	SEV	NO	PBU	Yes	No
			56, -3	30 Mins	30	1	MOD	NO	PBU	Yes	No
			61, 3	02:00 Hrs	30	1	SEV	NO	PBU	Yes	No
			83, 25	01:00 Hrs	30	1	MIL	NO	PBU	Yes	No
			111, 53	01:00 Hrs	30	1	MIL	NO	PBU	No	No
Digestive System	Esophagitis	BURNING ACHE IN UPPER ESOPHAGUS REGION	19, -40	5 Mins	20	3	MOD	NO	PSR	No	No
		BURNING ACHE IN UPPER ESOPHAGUS REGION-BRIEF	21, -38	45 Mins	20	1	MOD	NO	PSR	No	No
	Tooth Disorder	TOOTHACHE	20, -39	30 Mins	20	1	SEV	NO	UNR	Yes	No
		TOOTHACHE PAIN	8, -51	09:00 Hrs	20	1	MOD	NO	UNR	Yes	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	83, 25	08:00 Hrs	30	1	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12JUL96	-6, -64	0	115	70	62	113	75	78	140.00	67.0
BL	18JUL96	1, -58	0	115	80	68	110	70	74	140.00	
1	26JUL96	9, -50	20	113	80	80	113	78	90	138.00	
2	01AUG96	15, -44	20	113	75	84	115	80	90	136.50	
3	07AUG96	21, -38	20	113	78	78	113	80	84	137.00	
4	14AUG96	28, -31	30	100	70	78	100	80	102	133.00	
5	21AUG96	35, -24	30	100	80	72	100	75	94	133.50	
6	28AUG96	42, -17	30	100	70	70	100	80	80	133.50	
7	04SEP96	49, -10	30	110	70	78	105	70	72	135.00	
8	18SEP96	63, 5	30	100	70	72	115	70	80	137.00	
12	09OCT96	84, 26	30	100	80	78	98	70	102	133.00	
16	06NOV96	112, 54	30	100	75	66	100	75	78	134.00	
20	05DEC96	141, 83	20	115	80	66	100	70	80	140.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.2	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	70	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 6/ACUTE PHASE-WEEK 4	28	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	81.8	H	.	.	30 - 70	%
				Lymphocytes	9.8	L	.	.	21 - 51	%
				Monocytes	0.4	.	.	.	0 - 10	%
				Eosinophils	8	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	103000	L	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	99	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 11/UNSCHEDULED LAB 1	98	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	40 - 75	%
				Lymphocytes	38.3	.	.	.	16 - 46	%
				Monocytes	3.3	.	.	.	0 - 12	%
				Eosinophils	3.3	.	.	.	0 - 7	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/UNSCHEDULED LAB 1	98	Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4		.	.	.	
		VISIT 12/CONTINUATION-WEEK 16	112	Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Amphetamines	NEC		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	40 - 75	%
				Lymphocytes	28.4	.	.	.	16 - 46	%
				Monocytes	3.6	.	.	.	0 - 12	%
				Eosinophils	6.5	.	.	.	0 - 7	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00260 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	141	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	LATINO - MEXICO

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	26NOV96	1	02DEC96	7	7
00261	Oral	2	20 MG	03DEC96	8	09DEC96	14	7
00261	Oral	3	20 MG	10DEC96	15	16DEC96	21	7
00261	Oral	4	20 MG	17DEC96	22	23DEC96	28	7
00261	Oral	5	30 MG	24DEC96	29	01JAN97	37	9
00261	Oral	5	30 MG	02JAN97	38	08JAN97	44	7
00261	Oral	5	30 MG	09JAN97	45	14JAN97	50	6
00261	Oral	5	30 MG	15JAN97	51	22JAN97	58	8
00187	Oral	5	30 MG	23JAN97	59	19FEB97	86	28
00187	Oral	5	30 MG	20FEB97	87	02APR97	128	42
00261	Oral	5	30 MG	02APR97	128	03APR97	129	2
00261	Oral	4	20 MG	04APR97	130	05APR97	131	2
00261	Oral	3	20 MG	06APR97	132	07APR97	133	2
00261	Oral	2	20 MG	08APR97	134	10APR97	136	3
00261	Oral	1	20 MG	11APR97	137	29APR97	155	19

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	155	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA {VERY MILD}	ASTHMA	RESPIRATORY SYST DIS	CUR	1984
DYSHYDROSIS {MILD ON HAND AND PENIS}	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
TINEA PEDIS {BOTH FEET}	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1996

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	58, -1	22JAN97	22JAN97	2 TABS	HEADACHE
RESPIRATORY	Salbutamol	Proventil	-4713,-4771	01JAN84	01JAN96#	PRN	ASTHMA
			-4713,-4771	01JAN84	01JAN96#	PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	58, -1	01:00 Hrs	30	1	MOD	NO	PBU	Yes	No
	Infection	SCABIES ON BOTH ARMS	85, 27	44 Days	30	CON	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07NOV96	-19, -77	0	100	60	72	98	60	72	172.50	66.0
BL	22NOV96	-4, -62	0	113	70	70	113	80	74	171.00	
1	03DEC96	8, -51	20	113	70	60	113	75	80	172.00	
2	10DEC96	15, -44	20	115	70	72	116	80	66	173.50	
3	17DEC96	22, -37	20	117	75	72	117	80	72	172.50	
4	24DEC96	29, -30	30	160	80	70	160	80	72	173.00	
5	02JAN97	38, -21	30	118	80	66	118	80	78	174.00	
6	09JAN97	45, -14	30	120	80	72	120	80	78	178.00	
7	15JAN97	51, -8	30	120	85	66	120	85	72	178.00	
8	23JAN97	59, 1	30	115	75	66	112	80	72	178.50	
12	20FEB97	87, 29	30	116	75	66	116	80	70	178.00	
20	02APR97	128, 70	30	113	80	72	113	80	80	180.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-4	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.1	.	.	.	30 - 70	%
				Lymphocytes	24.8	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	6.8	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	278000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-4	Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.3	.	.	.	30 - 70	%
				Lymphocytes	26	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	6.5	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	89	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	31	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.006.00261 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Alanine Aminotransferase	74	H	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	08MAY95	1	17MAY95	10	10
00139	Oral	2	100 MG	18MAY95	11	25MAY95	18	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	No	No	18	100	Adverse event, including intercurrent illness	CHEST PAIN-RESOLVED ON FOLLOW-UP ASSOCIATED WITH SHORTNESS OF BREATH

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FRACTURED RIGHT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Bc Powder	-9, .	29APR95	01MAY95#	1PACK PRN	FRACTURED RIGHT ARM
	Caffeine	Bc Powder	-9, .	29APR95	01MAY95#	1PACK PRN	FRACTURED RIGHT ARM
	Paracetamol	Tylenol	-9, .	29APR95	01MAY95#	325MG PRN	FRACTURED RIGHT ARM
	Salicylamide	Bc Powder	-9, .	29APR95	01MAY95#	1PACK PRN	FRACTURED RIGHT ARM
MUSCULO-SKELETAL	Ibuprofen	Advil	-9, .	29APR95	01MAY95#	200MG PRN	FRACTURED RIGHT ARM

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN	10, .	8 Days	50	4	MOD	STP	PSR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	10, .	8 Days	50	CON	MIL	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04MAY95	-4, .	0	96	60	72	94	64	76	78.00	56.5
BL	05MAY95	-3, .	0	96	60	77	94	64	76	78.00	
1	18MAY95	11, .	100	102	68	72	98	70	76	75.00	
2	25MAY95	18, .	100	102	68	80	98	70	84	76.00	
6	19JUN95	43, .#	0	102	62	64	100	64	76	78.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-3	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.1	.	.	.	30 - 70	%
				Lymphocytes	45.9	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	270	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	63	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-3		Urine Squamous Epithelial Cells	3	.	.	.		
					Serum BHCG pregnancy test	NEGATIVE		.	.		
					Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	NEG		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	43	(25)	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.8	.	.	.	35 - 46	%
					Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	49.7	.	.	.	30 - 70	%
					Lymphocytes	39.7	.	.	.	21 - 51	%
					Monocytes	7.1	.	.	.	0 - 10	%
					Eosinophils	2.7	.	.	.	0 - 5	%
					Basophils	0.8	.	.	.	0 - 2	%
					Platelets	296000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
					Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	227	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00139 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 5/ACUTE PHASE-WEEK 3	43	(25)	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
					Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
					Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	86	.	.	.	60 - 110	MG/DL
					Globulin	3.1	.	.	.	2.1 - 3.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
11	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	15SEP95	1	20SEP95	6	6
00140	Oral	2	20 MG	21SEP95	7	27SEP95	13	7
00140	Oral	3	20 MG	28SEP95	14	04OCT95	20	7
00140	Oral	4	20 MG	05OCT95	21	11OCT95	27	7
00140	Oral	4	20 MG	12OCT95	28	17OCT95	33	6
00140	Oral	4	20 MG	18OCT95	34	25OCT95	41	8
00140	Oral	4	20 MG	26OCT95	42	01NOV95	48	7
00140	Oral	4	20 MG	02NOV95	49	08NOV95	55	7
00005	Oral	4	20 MG	09NOV95	56	21NOV95	68	13
00140	Oral	4	20 MG	22NOV95	69	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	11	Yes	No	69	20	Other reason	PATIENT WENT TO LIVE WITH HIS FATHER.HIS FATHER IS OPPOSED TO MEDICATION TREATMENT FOR DEPRESSION,FATHER WITHDREW CONSENT.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
VESICULAR DYSHIDROSIS	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Triamcinolone	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-622, -677	01JAN94	.	325MG PRN	HEADACHE
DERMATOLOGICALS	Clotrimazole	Clotrimazole	39, -17	23OCT95	24OCT95	ONCE DAILY	RINGWORM
	Griseofulvin	Gris-Peg	41, -15	25OCT95	03NOV95	250MG	RINGWORM
	Triamcinolone	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
GU SYSTEM/SEX HORMONES	Clotrimazole	Clotrimazole	39, -17	23OCT95	24OCT95	ONCE DAILY	RINGWORM
SENSORY ORGANS	Triamcinolone	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM
SYSTEMIC HORMONAL	Triamcinolone	Triamcinolone	34, -22	18OCT95	22OCT95	ONCE DAILY	RINGWORM

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Skin and Appendages	Fungal Dermatitis	RINGWORM	29, -27	21 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07SEP95	-8, -63	0	104	60	64	102	64	68	74.00	54.0
BL	14SEP95	-1, -56	0	110	60	72	104	62	76	74.00	
1	21SEP95	7, -49	20	100	62	60	98	64	68	72.00	
2	28SEP95	14, -42	20	96	60	60	92	62	68	71.00	
3	05OCT95	21, -35	20	110	60	64	106	62	68	72.00	
4	12OCT95	28, -28	20	104	70	68	102	72	72	72.00	
5	18OCT95	34, -22	20	110	70	64	108	72	68	73.00	
6	26OCT95	42, -14	20	100	60	64	98	62	68	70.00	
7	02NOV95	49, -7	20	102	58	64	100	62	68	72.00	
8	09NOV95	56, 1	20	104	72	64	100	74	73	73.00	
12	22NOV95	69, 14	20	104	68	78	98	66	72	74.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4 - 5.2	10^12/L
				White Blood Cell Count	8.6	.	.	.	4.5 - 13.5	10^9/L
				Segmented Neutrophils	48.9	.	.	.	30 - 60	%
				Lymphocytes	36.1	.	.	.	25 - 55	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	222000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 33	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	226	.	.	.	44 - 330	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	60 - 110	MG/DL
				Globulin	2.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.7	L	.	-	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.3	.	.	.	30 - 70	%
				Lymphocytes	33.2	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	6.7	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.7	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	175	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.2	.	.	.	5.7 - 8.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 10/ACUTE PHASE-WEEK 8	56		Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	122	H	.	.	60 - 110	MG/DL
					Globulin	2.1	.	.	.	2.1 - 3.8	G/DL
		VISIT 11/CONTINUATION-WEEK 12	69	(1)	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	38.3	L	.	.	41 - 50	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	11.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	63.9	.	.	.	30 - 70	%
					Lymphocytes	24	.	.	.	21 - 51	%
					Monocytes	7.1	.	.	.	0 - 10	%
					Eosinophils	3.9	.	.	.	0 - 5	%
					Basophils	1.2	.	.	.	0 - 2	%
					Platelets	249000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Urine Glucose - Dipstick	NEG	.	.	.		
					Urine Blood - Dipstick	NEG	.	.	.		
					Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00140 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
11	M	VISIT 11/CONTINUATION-WEEK 12	69 (1)	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
				Urine Squamous Epithelial Cells		3	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21SEP95	1	27SEP95	7	7
00141	Oral	2	0 MG	28SEP95	8	04OCT95	14	7
00141	Oral	3	0 MG	05OCT95	15	12OCT95	22	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	No	No	22	0	Adverse event, including intercurrent illness	PHYSICIAN DISCRETION DUE TO COMPARATOR ARM,VIS-A-VIS AE OF CHEST PAIN.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANGINA	ANGINA PECTORIS	CIRCULATORY SYST	CUR	1995
INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
EUSTACHIAN TUBE PLACEMENT	OPERATION, EAR	OPERATIONS	PRV	1982
HYPERTENSION	HYPERTENSION	CIRCULATORY SYST	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-23, .	29AUG95	30AUG95#	25MG	SLEEP ONSET INSOMNIA
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-23, .	29AUG95	30AUG95#	25MG	SLEEP ONSET INSOMNIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Angina Pectoris	ANGINA ON EXERTION	-8, .	30 Days	0	2	MOD	STP	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14SEP95	-7, .	0	128	78	76	124	80	80	181.00	66.0
BL	21SEP95	1, .	0	128	78	81	126	80	87	183.00	
1	28SEP95	8, .	0	128	70	80	122	76	84	184.00	
2	05OCT95	15, .	0	128	78	72	126	80	68	184.00	
3	12OCT95	22, .	0	126	82	80	122	84	76	185.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	403000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	333	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	3		.	.	.	
				Urine White Blood Cells/HPF	3		.	.	.	
				Urine Bacteria	3		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00141 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18OCT95	1	25OCT95	8	8
00142	Oral	2	20 MG	26OCT95	9	01NOV95	15	7
00142	Oral	3	20 MG	02NOV95	16	08NOV95	22	7
00142	Oral	4	20 MG	09NOV95	23	15NOV95	29	7
00142	Oral	5	30 MG	16NOV95	30	21NOV95	35	6
00142	Oral	5	30 MG	22NOV95	36	29NOV95	43	8
00142	Oral	6	40 MG	30NOV95	44	04DEC95	48	5

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	48	40	Lack of Efficacy	MOTHER WANTS PATIENT TO BE WITHDRAWN BECAUSE HIS DEPRESSION HAS NOT IMPROVED AT MAXIMUM DOSAGE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MILD LYMPHADENOPATHY,LEFT ANTERIOR CERVICAL,PERSISTENT	LYMPHADENOPATHY	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1985
CAT SCRATCH FEVER	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993
INGUINAL HERNIA	HERNIA, ABDOMINAL	DIGESTIVE SYST	PRV	1983
SORE THROAT	PHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	-14, .	04OCT95	13OCT95#	500MG	SORE THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-3942, .	01JAN85	.	500MG PRN	HEADACHE
RESPIRATORY	Chlorphenamine Maleate	Dristan	44, .	30NOV95	30NOV95	2TABS	NASAL CONGESTION
	Paracetamol	Dristan	44, .	30NOV95	30NOV95	2TABS	NASAL CONGESTION
	Phenylephrine Hydrochloride	Dristan	44, .	30NOV95	30NOV95	2TABS	NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU	45, .	8 Days	40	1	MOD	NO	UNR	Yes	No
Respiratory System	Rhinitis	NASAL CONGESTION	44, .	1 Days	40	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12OCT95	-6, .	0	124	80	68	120	82	76	212.00	68.0
BL	18OCT95	1, .	0	124	82	72	120	84	68	213.00	
1	26OCT95	9, .	20	130	78	68	128	80	72	214.00	
2	02NOV95	16, .	20	122	84	72	120	88	68	212.00	
3	09NOV95	23, .	20	124	74	68	118	82	72	211.00	
4	16NOV95	30, .	30	130	70	80	128	74	72	212.00	
5	22NOV95	36, .	30	123	78	88	114	79	110	210.00	
6	30NOV95	44, .	40	140	74	80	132	76	64	214.00	
8	21DEC95	65, .#	0	128	82	88	132	88	88	214.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.9	.	.	.	30 - 70	%
				Lymphocytes	41.6	.	.	.	21 - 51	%
				Monocytes	9.3	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	179	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	123	H	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6		Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	65	(17)	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	43.6	.	.	.	41 - 50	%
					Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	46	.	.	.	30 - 70	%
					Lymphocytes	45	.	.	.	21 - 51	%
					Monocytes	4	.	.	.	0 - 10	%
					Eosinophils	3	.	.	.	0 - 5	%
					Basophils	2	.	.	.	0 - 2	%
					Platelets	239000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.7	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	159	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	35	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00142 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 9/ACUTE PHASE-WEEK 7	65	(17)	Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	97	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.	.	
					Urine Blood - Dipstick	NEG		.	.	.	
					Urine Red Blood Cells/HPF	NEG		.	.	.	
					Urine White Blood Cells/HPF	NEG		.	.	.	
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	09NOV95	1	15NOV95	7	7
00143	Oral	2	100 MG	16NOV95	8	21NOV95	13	6
	Oral	2	100 MG	22NOV95	14	01DEC95	23	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	23	100	Adverse event, including intercurrent illness	ACNE

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1995
MILD OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1994
STATUS POST HOSPITALIZATION FOR DEPRESSION	DEPRESSION	MENTAL DISORD	PRV	1994
URINARY TRACT INFECTION	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-1, .	08NOV95	09NOV95	1000MG	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Skin and Appendages	Acne	ACNE	7, .	Not Stated	50	CON	MOD	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26OCT95	-14, .	0	120	72	72	118	76	74	212.00	63.0
BL	09NOV95	1, .	0	120	72	72	116	74	68	215.00	
1	16NOV95	8, .	100	120	70	76	118	74	80	212.00	
2	22NOV95	14, .	100	125	78	84	112	72	120	211.00	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.2	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	14	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.3	.	.	.	35 - 46	%
				White Blood Cell Count	10	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00143 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 4/ACUTE PHASE-WEEK 2	14	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	07DEC95	1	13DEC95	7	7
00144	Oral	2	0 MG	14DEC95	8	20DEC95	14	7
00144	Oral	3	0 MG	21DEC95	15	27DEC95	21	7
00144	Oral	4	0 MG	28DEC95	22	04JAN96	29	8
00144	Oral	4	0 MG	05JAN96	30	10JAN96	35	6
00144	Oral	5	0 MG	11JAN96	36	17JAN96	42	7
00144	Oral	5	0 MG	18JAN96	43	24JAN96	49	7
00144	Oral	5	0 MG	25JAN96	50	31JAN96	56	7
00115	Oral	5	0 MG	01FEB96	57	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	57	0	Lost to follow-up	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	39, -18	14JAN96	15JAN96	1,500MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	39, -18	2 Days	0	1	MIL	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	30NOV95	-7, -63	0	132	52	76	122	70	56	155.00	60.0
BL	07DEC95	1, -56	0	120	70	72	110	70	80	158.00	
1	14DEC95	8, -49	0	110	70	68	92	72	88	160.00	
2	21DEC95	15, -42	0	136	64	76	112	56	88	162.00	
3	28DEC95	22, -35	0	124	72	76	104	74	88	159.00	
4	04JAN96	29, -28	0	128	70	80	124	76	76	160.00	
5	11JAN96	36, -21	0	120	74	80	118	78	78	165.00	
6	18JAN96	43, -14	0	126	70	68	120	74	72	168.00	
7	25JAN96	50, -7	0	128	82	72	126	84	80	165.00	
8	01FEB96	57, 1	0	118	80	76	120	82	72	166.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.3	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	179	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	37.7	.	.	.	35 - 46	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	56.1	.	.	.	30 - 70	%
					Lymphocytes	32.2	.	.	.	21 - 51	%
					Monocytes	7.5	.	.	.	0 - 10	%
					Eosinophils	2.2	.	.	.	0 - 5	%
					Basophils	2	.	.	.	0 - 2	%
					Platelets	301000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
					Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
					Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	169	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00144 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11JAN96	1	17JAN96	7	7
00145	Oral	2	20 MG	18JAN96	8	24JAN96	14	7
00145	Oral	3	20 MG	25JAN96	15	31JAN96	21	7
	Oral	4	20 MG	01FEB96	22	07FEB96	28	7
00348	Oral	5	30 MG	08FEB96	29	11FEB96	32	4
00348	Oral	5	30 MG	12FEB96	33	20FEB96	41	9
00348	Oral	5	30 MG	21FEB96	42	25FEB96	46	5
00348	Oral	6	40 MG	26FEB96	47	06MAR96	56	10
00190	Oral	6	40 MG	07MAR96	57	03APR96	84	28
00190	Oral	6	40 MG	04APR96	85	01MAY96	112	28
00190	Oral	5	30 MG	02MAY96	113	13MAY96	124	12
00190	Oral	4	20 MG	14MAY96	125	29MAY96	140	16
00190	Oral	4	20 MG	30MAY96	141	26JUN96	168	28
00190	Oral	4	20 MG	27JUN96	169	24JUL96	196	28
00190	Oral	4	20 MG	25JUL96	197	22AUG96	225	29
00348	Oral	3	20 MG	23AUG96	226	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	Yes	226	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ELEVATED MONOCYTES	MONOCYTOSIS	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
LOW WHITE BLOOD CELL COUNT	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
BROKEN LEFT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1991

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Extra Strength Excedrin	111, 55	30APR96	13MAY96	1 TAB	HEADACHE
	Caffeine	Extra Strength Excedrin	111, 55	30APR96	13MAY96	1 TAB	HEADACHE
	Paracetamol	Extra Strength Excedrin	111, 55	30APR96	13MAY96	1 TAB	HEADACHE
		Extra Strength Tylenol	125, 69	14MAY96	15MAY96	1,000 MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	22, -35	01FEB96	01FEB96	1TSP.	NASAL CONGESTION
RESPIRATORY	Cough Cold Preparations Nos	Ggg-Cold {Cold Preparation Nos}	224, 168	21AUG96	23AUG96	6 TSP	COLD SYMPTOMS
	Diphenhydramine Hydrochloride	Benadryl	22, -35	01FEB96	01FEB96	1TSP.	NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	111, 55	16 Days	40	CON	SEV	DCR	PSR	Yes	No
Cardiovascular System	Hypertension	HYPERTENSION	125, 69	17 Days	20	CON	MOD	DCR	PSR	No	No
Hemic and Lymphatic System	Thrombocytopenia	THROMBOCYTOPENIA	141, 85	29 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Hyperkinesia	AKATHISIA	113, 57	29 Days	30	CON	MOD	DCR	REL	No	No
Respiratory System	Respiratory Disorder	FEVER, COLD SYMPTOMS, SORE THROAT	224, 168	3 Days	20	CON	MIL	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	22, -35	2 Days	20	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04JAN96	-7, -63	0	110	60	68	108	64	72	107.00	62.0
BL	11JAN96	1, -56	0	110	68	76	108	70	80	106.00	
1	18JAN96	8, -49	20	118	70	76	116	74	80	106.00	
2	25JAN96	15, -42	20	118	64	72	116	68	64	106.00	
3	01FEB96	22, -35	20	118	76	80	112	78	84	108.00	
4	08FEB96	29, -28	30	112	68	76	110	72	88	107.00	
5	12FEB96	33, -24	30	118	68	72	114	70	80	108.00	
6	21FEB96	42, -15	30	114	68	80	112	70	72	107.00	
7	26FEB96	47, -10	40	112	64	72	110	66	64	106.00	
8	07MAR96	57, 1	40	120	60	80	118	66	72	107.00	
12	04APR96	85, 29	40	114	74	64	110	76	72	106.00	
16	02MAY96	113, 57	30	118	84	68	114	86	74	110.00	
20	30MAY96	141, 85	20	118	70	68	116	74	76	112.00	
24	27JUN96	169, 113	20	98	58	88	100	74	88	110.00	
28	25JUL96	197, 141	20	110	62	58	104	66	58	113.00	
32	23AUG96	226, 170	20	118	68	72	108	60	68	111.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.5	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	22.5	.	.	.	21 - 51	%
				Monocytes	16.5	H	.	+	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	115	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.4	L	.	-	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	280000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	1	Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	15	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.1	.	.	.	30 - 70	%
				Lymphocytes	42.1	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%
				Lymphocytes	47	.	.	.	21 - 51	%
				Monocytes	1	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	107000 L	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 180	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	141	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	169	Platelets	235000	.	.	.	130000 - 400000	PER CUMM
		VISIT 16/CONTINUATION-WEEK 32	226 (1)	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.5	.	.	.	30 - 70	%
				Lymphocytes	37.3	.	.	.	21 - 51	%
				Monocytes	9.3	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00145 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 16/CONTINUATION-WEEK 32	226 (1)	Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	106	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	38	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	59	H	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	25JAN96	1	31JAN96	7	7
00347	Oral	2	100 MG	01FEB96	8	04FEB96	11	4
00347	Oral	3	150 MG	05FEB96	12	11FEB96	18	7
00347	Oral	4	200 MG	12FEB96	19	18FEB96	25	7
00347	Oral	5	250 MG	19FEB96	26	25FEB96	32	7
00347	Oral	5	250 MG	26FEB96	33	03MAR96	39	7
00347	Oral	5	250 MG	04MAR96	40	10MAR96	46	7
00347	Oral	4	200 MG	11MAR96	47	17MAR96	53	7
00188	Oral	4	200 MG	18MAR96	54	14APR96	81	28
00188	Oral	5	250 MG	15APR96	82	24APR96	91	10
00188	Oral	4	200 MG	25APR96	92	12MAY96	109	18
00188	Oral	4	200 MG	13MAY96	110	05JUN96	133	24
00188	Oral	4	200 MG	06JUN96	134	07JUL96	165	32
00188	Oral	4	200 MG	08JUL96	166	04AUG96	193	28
00188	Oral	4	200 MG	05AUG96	194	08SEP96	228	35
00347	Oral	4	200 MG	09SEP96	229	09SEP96	229	1
00347	Oral	3	150 MG	10SEP96	230	11SEP96	231	2
00347	Oral	2	100 MG	12SEP96	232	14SEP96	234	3
00347	Oral	1	50 MG	15SEP96	235	21SEP96	241	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	Yes	241	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	CUR	1996
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
JOINT PAIN{RIGHT WRIST}	PAIN, JOINT	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1983
SWELLING{LEFT CALF}	SWELLING, LIMB	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	58,	5	22MAR96	22MAR96	2 TABS	UPSET STOMACH
			162,	109	04JUL96	04JUL96	2 TABS	DIARRHEA
CENTRAL NERVOUS SYSTEM	Cyclobenzaprine	Cyclobenzaprine	7,	-47	31JAN96	31JAN96	10MG	MUSCLE SORENESS
			238,	185	18SEP96	18SEP96	1 TAB	LEFT KNEE MUSCLE SPASMS
	Paracetamol	Tylenol	-15,	-68	10JAN96	10JAN96#	1,000MG	MENSTRUAL CRAMP
			-8,	-61	17JAN96	17JAN96#	500MG	WRIST PAIN(RIGHT)
		Tylenol Gelcaps	-754,	-807	01JAN94	.	750MG PRN	OCCASIONAL HEADACHE
			172,	119	14JUL96	14JUL96	1,000 MG	ANXIETY
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-24,	-77	01JAN96	.	50MG PRN	SEASONAL ALLERGIES
MUSCULO-SKELETAL	Cyclobenzaprine	Cyclobenzaprine	7,	-47	31JAN96	31JAN96	10MG	MUSCLE SORENESS
			238,	185	18SEP96	18SEP96	1 TAB	LEFT KNEE MUSCLE SPASMS
RESPIRATORY	Brompheniramine Maleate	Dimetapp	220,	167	31AUG96	01SEP96	1 TAB	NASAL ALLERGIES
	Cough Cold Preparations Nos	Flu Relief {Nos}	12,	-42	05FEB96	06FEB96	15TABS	PROPHYLACTIC - FEVER
	Dexbrompheniramine Maleate	Drixoral	-16,	-69	09JAN96	09JAN96#	2TABS	COLD
	Diphenhydramine Hydrochloride	Benadryl	-24,	-77	01JAN96	.	50MG PRN	SEASONAL ALLERGIES
	Phenylephrine Hydrochloride	Dimetapp	220,	167	31AUG96	01SEP96	1 TAB	NASAL ALLERGIES
	Phenylpropanolamine Hydrochloride	Dimetapp	220,	167	31AUG96	01SEP96	1 TAB	NASAL ALLERGIES
	Pseudoephedrine Hydrochloride	Efidac	222,	169	02SEP96	06SEP96	1 TAB	NASAL ALLERGIES
		Efidac/24	178,	125	20JUL96	22JUL96	1 TAB	COLD
	Pseudoephedrine Sulfate	Drixoral	-16,	-69	09JAN96	09JAN96#	2TABS	COLD
VARIOUS	Allergenic Extract, Nos	Homeopathic Allergy Medicine	222,	169	02SEP96	07SEP96	3 TABS	NASAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Diarrhea	DIARRHEA	162, 109	02:00 Hrs	200	CON	MOD	NO	UNR	Yes	No
	Dyspepsia	UPSET STOMACH	58, 5	04:00 Hrs	200	CON	MOD	NO	PBU	Yes	No
Musculoskeletal System	Myalgia	LEFT KNEE MUSCLE SPASMS	238, 185	06:00 Hrs	50	CON	MIL	NO	UNR	Yes	No
Nervous System	Anxiety	ANXIETY	172, 119	04:00 Hrs	200	CON	MIL	NO	UNR	Yes	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS	178, 125	3 Days	200	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JAN96	-7, -60	0	130	80	88	128	86	96	228.00	63.0
BL	25JAN96	1, -53	0	130	80	88	128	84	80	226.00	
1	01FEB96	8, -46	100	138	84	88	136	88	96	227.00	
2	05FEB96	12, -42	150	138	86	72	132	88	88	234.00	
3	12FEB96	19, -35	200	130	84	76	128	88	68	231.00	
4	19FEB96	26, -28	250	126	84	72	126	88	80	231.00	
5	26FEB96	33, -21	250	128	82	76	130	86	84	232.00	
6	04MAR96	40, -14	250	124	82	88	122	86	96	232.00	
7	11MAR96	47, -7	200	128	86	84	126	90	96	234.00	
8	18MAR96	54, 1	200	128	86	88	126	88	96	231.00	
12	15APR96	82, 29	250	120	82	72	124	86	88	235.00	
16	13MAY96	110, 57	200	128	88	88	124	92	96	234.00	
20	06JUN96	134, 81	200	130	86	98	132	90	100	232.00	
24	08JUL96	166, 113	200	116	84	104	124	92	96	234.00	
28	05AUG96	194, 141	200	140	92	100	138	88	92	237.00	
32	09SEP96	229, 176	200	126	98	106	128	99	126 H	235.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	25.7	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	2.4	H	.	.	0 - 2	%
				Platelets	233000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	89	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	24.7	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	209000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	54	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	134	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	5	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	134	Alkaline Phosphatase	82	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	34	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	229	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.6	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00146 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 16/CONTINUATION-WEEK 32	229	Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
		VISIT 16/UNSCHEDULED LAB 1	232	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	01FEB96	1	14FEB96	14	14
00265	Oral	2	20 MG	15FEB96	15	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	15	20	Lost to follow-up	NONCOMPLIANCE WITH MAKING STUDY APPOINTMENTS

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-3, .	29JAN96	31JAN96#	1,000MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25JAN96	-7, .	0	110	62	66	118	70	70	140.00	64.0
BL	01FEB96	1, .	0	112	68	68	110	72	72	140.00	
2	15FEB96	15, .	20	116	64	64	112	66	72	136.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	10.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	32.7	L	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	65.8	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	221000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	21.7	L	.	.	25 - 35	PG
				Mean Corpuscle Volume	67	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	51	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	10	L	.	.	12 - 15.6	G/DL
				Hematocrit	30.9	L	.	-	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	68.5	.	.	.	30 - 70	%
				Lymphocytes	21.9	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	21.4	L	.	.	25 - 35	PG
				Mean Corpuscle Volume	66	L	.	.	80 - 100	FL
		VISIT 3/ACUTE PHASE-WEEK 1	15 (1)	Serum BHCG pregnancy test	NEGATIVE	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00265 TREATMENT GROUP: PAROXETINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	07MAR96	1	13MAR96	7	7
00266	Oral	2	0 MG	14MAR96	8	24MAR96	18	11
00266	Oral	3	0 MG	25MAR96	19	27MAR96	21	3
00266	Oral	4	0 MG	28MAR96	22	03APR96	28	7
00266	Oral	5	0 MG	04APR96	29	10APR96	35	7
00266	Oral	5	0 MG	11APR96	36	17APR96	42	7
00266	Oral	5	0 MG	18APR96	43	28APR96	53	11
00266	Oral	5	0 MG	29APR96	54	02MAY96	57	4
00266	Oral	4	0 MG	03MAY96	58	16MAY96	71	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	71	0		PATIENT MOVING OUT OF STATE FOR SUMMER.

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Cefalexin Monohydrate	Keflex	52, .	27APR96	10MAY96	1,000MG	SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	2, .	04:00 Hrs	0	1	SEV	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	2, .	04:00 Hrs	0	1	MIL	NO	PSR	No	No
Nervous System	Hyperkinesia	AKATHISIA	5, .	46 Days	0	CON	MIL	NO	REL	No	No
Respiratory System	Pharyngitis	SORE THROAT	52, .	13 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	29FEB96	-7, .	0	118	76	72	116	78	68	98.00	61.0
BL	07MAR96	1, .	0	108	58	60	106	62	68	99.00	
1	14MAR96	8, .	0	108	70	72	104	74	76	98.00	
3	25MAR96	19, .	0	112	64	72	110	66	80	100.00	
3	28MAR96	22, .	0	114	64	72	110	68	76	103.00	
4	04APR96	29, .	0	110	74	76	108	76	80	103.00	
5	11APR96	36, .	0	118	76	72	114	78	74	105.00	
6	18APR96	43, .	0	112	64	68	110	70	72	103.00	
8	29APR96	54, .	0	110	62	56	106	70	64	102.00	
8	02MAY96	57, .	0	108	72	60	104	74	68	102.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.8	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	35.9	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	253	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	63	.	.	.	60 - 110	MG/DL
				Globulin	2.5	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	44	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	251000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	190	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00266 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	07MAR96	1	13MAR96	7	7
00267	Oral	2	0 MG	14MAR96	8	20MAR96	14	7
00267	Oral	3	0 MG	21MAR96	15	27MAR96	21	7
00267	Oral	4	0 MG	28MAR96	22	03APR96	28	7
00267	Oral	4	0 MG	04APR96	29	10APR96	35	7
00267	Oral	4	0 MG	11APR96	36	17APR96	42	7
00267	Oral	5	0 MG	18APR96	43	24APR96	49	7
00267	Oral	5	0 MG	25APR96	50	01MAY96	56	7
	Oral	.		02MAY96	57	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	56	0	Protocol violation, including non-compliance	POSITIVE MULTIPLE DRUG SCREENS,MULTIPLES GIVEN PER JIM MCCAFERTY.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
OBESE{MILDLY}	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
POSITIVE DRUG SCREEN{CANNABINOIDS}	DRUG ABUSE	MENTAL DISORD	CUR	1996
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1981

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol Gelcaps	10, .	16MAR96	16MAR96	1000MG	HEADACHE
			31, .	06APR96	06APR96	1000MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	26, .	01APR96	01APR96	400MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE,NO VOMITING	71, .	04:00 Hrs	0	CON	MOD	NO	PBU	No	No
	Headache	HEADACHE	-1, .	01:00 Hrs	0	1	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	29FEB96	-7, .	0	120	80	64	118	82	64	258.00	73.0
BL	07MAR96	1, .	0	120	76	72	118	78	76	258.00	
1	14MAR96	8, .	0	128	70	84	126	78	88	263.00	
2	21MAR96	15, .	0	130	76	72	128	82	76	262.00	
3	28MAR96	22, .	0	120	82	76	118	86	80	260.00	
4	04APR96	29, .	0	132	86	80	130	88	88	257.00	
5	11APR96	36, .	0	130	74	68	124	80	78	257.00	
6	18APR96	43, .	0	120	78	68	118	82	72	257.00	
7	25APR96	50, .	0	120	74	80	118	80	76	257.00	
8	02MAY96	57, .	0	120	72	64	118	76	72	257.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.8	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	50		Urine Amphetamines	NEG		.	.		
					Urine Barbiturates	NEG		.	.		
					Urine Benzodiazepines	NEG		.	.		
					Urine Cannabinoids	POS		.	.		
					Urine Cocaine	NEG		.	.		
					Urine Methadone	NEG		.	.		
					Urine Methaqualone	NEG		.	.		
					Urine Opiates	NEG		.	.		
					Urine Phencyclidine	NEG		.	.		
					Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	(1)	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	43.2	.	.	.	41 - 50	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	51.8	.	.	.	30 - 70	%
					Lymphocytes	41.6	.	.	.	21 - 51	%
					Monocytes	4.5	.	.	.	0 - 10	%
					Eosinophils	1.6	.	.	.	0 - 5	%
					Basophils	0.5	.	.	.	0 - 2	%
					Platelets	245000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	8	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	73	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00267 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57 (1)	Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	128	H	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEC		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	01APR96	1	10APR96	10	10
00268	Oral	2	20 MG	11APR96	11	17APR96	17	7
00268	Oral	3	20 MG	18APR96	18	24APR96	24	7
00268	Oral	4	20 MG	25APR96	25	01MAY96	31	7
00268	Oral	4	20 MG	02MAY96	32	08MAY96	38	7
00268	Oral	4	20 MG	09MAY96	39	15MAY96	45	7
00268	Oral	5	30 MG	16MAY96	46	23MAY96	53	8
00268	Oral	5	30 MG	24MAY96	54	29MAY96	59	6
00157	Oral	5	30 MG	30MAY96	60	26JUN96	87	28
00157	Oral	5	30 MG	27JUN96	88	31JUL96	122	35
00157	Oral	6	40 MG	01AUG96	123	29AUG96	151	29
00157	Oral	6	40 MG	30AUG96	152	29SEP96	182	31
00157	Oral	5	30 MG	30SEP96	183	06NOV96	220	38
00157	Oral	5	30 MG	07NOV96	221	04DEC96	248	28
00268	Oral	4	20 MG	05DEC96	249	18DEC96	262	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	262	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
LYMPH NODE INFECTION{BILATERAL GROIN NODES}	LYMPHADENITIS, ACUTE	SKIN/SUBCUTANEOUS TISSUE DIS	PRV	1991

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bisacodyl	Dulcolax	233, 174	19NOV96	19NOV96	2 TABS	CONSTIPATION
			233, 174	19NOV96	19NOV96	2 TABS	CONSTIPATION
	Neomycin	Neomycin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
			88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
	Polymyxin B	Polymyxin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
ANTIINFECTIVES,SYSTEMIC	Cefalexin	Cephalexin	82, 23	21JUN96	23JUN96	1000 MG	LEFT EAR INFECTION
			87, 28	26JUN96	29JUN96	1000 MG	LEFT EAR INFECTION
			92, 33	01JUL96	10JUL96	250 MG	LEFT INNER EAR INFECTION
	Cefalexin Monohydrate	Keflex	10, -50	10APR96	14APR96	750MG	EAR INFECTION
	Neomycin	Neomycin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
	Polymyxin B	Polymyxin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	29, -31	29APR96	29APR96	4TABS	NAUSEA{FROM RIDE}
	Prochlorperazine	Compazine	218, 159	04NOV96	04NOV96	5 MG	NAUSEA
DERMATOLOGICALS	Neomycin	Neomycin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	10, -50	10APR96	10APR96	800MG	HEADACHE
			57, -3	27MAY96	30MAY96	1600MG	PAIN{DUE TO ACCIDENT}
		Motrin	-821, -880	01JAN94	.	800MG PRN	HEADACHES
			57, -3	27MAY96	07JUN96	1600 MG	NECK PAIN DUE TO ACCIDENT
			98, 39	07JUL96	10JUL96	1 - 2 TABS	MUSCLE ACHES DUE TO CAR ACCIDENT
			102, 43	11JUL96	07NOV96	800 MG PRN	MUSCLE ACHES DUE TO CAR ACCIDENT
			184, 125	01OCT96	07NOV96	400 MG PRN	HEADACHES
SENSORY ORGANS	Neomycin	Neomycin	88, 29	27JUN96	29JUN96	2 DROPS	LEFT EAR INFECTION
VARIOUS	Nutritional Supplement Nos	T-Lite {Dietary Supplement}	154, 95	01SEP96	02OCT96	4 TABS	WEIGHT GAIN

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	NECK PAIN	56, -4	5 Days	30	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	56, -4	5 Days	30	CON	MOD	NO	UNR	Yes	No
		HEADACHES (DAILY)	184, 125	38 Days	30	35	MIL	NO	PSR	Yes	No
	Trauma	HEADACHE DUE TO ACCIDENT	56, -4	5 Days	30	CON	MOD	NO	UNR	Yes	No
		NECK PAIN DUE TO ACCIDENT	56, -4	13 Days	30	CON	MOD	NO	UNR	Yes	No
		PATIENT ACCIDENTALLY THROWN FROM 3 WHEELER STRIKING HEAD AND A NUMBER OF ABRASIONS	56, -4	5 Mins	30	1	SEV	NO	UNR	Yes	No
Carciovascular System	Syncope	BLACKNESS IN FRONT OF EYES, LIGHTHEADED, SWEATING {PRE-SYNCOPAL EPISODE/HEAT EXPOSURE}	123, 64	20 Mins	40	CON	MIL	NO	UNR	No	No
Digestive System	Constipation	CONSTIPATION	233, 174	02:00 Hrs	30	1	MOD	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	3, -57	8 Days	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	210, 151	10 Days	30	CON	MOD	NO	PBU	Yes	No
		NAUSEA DUE TO RIDES AT AMUSEMENT PARK	29, -31	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN	183, 124	95 Days	30	CON	MOD	NO	PSR	Yes	No
Musculoskeletal System	Myalgia	MUSCLE PAIN	98, 39	124 Days	30	CON	MIL	NO	UNR	Yes	No
Nervous System	Agitation	FIDGETY/PSYCHOMOTOR AGITATION	169, 110	17 Days	40	CON	MIL	DCR	PSR	No	No
	Insomnia	TERMINAL INSOMNIA	162, 103	24 Days	40	12	MOD	DCR	PSR	No	No
	Vestibular Disorder	LEFT INNER EAR INFECTION	92, 33	10 Days	30	CON	MOD	NO	UNR	Yes	No
Special Senses	Otitis Media	EAR INFECTION	10, -50	5 Days	20	CON	MOD	NO	UNR	Yes	No
		LEFT EAR INFECTION	82, 23	9 Days	30	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21MAR96	-11, -70	0	120	70	64	122	76	72	224.00	64.0
BL	01APR96	1, -59	0	118	68	68	116	72	72	225.00	
1	11APR96	11, -49	20	118	68	64	114	74	68	224.00	
2	18APR96	18, -42	20	122	74	72	118	76	76	221.00	
3	25APR96	25, -35	20	122	70	64	120	70	62	221.00	
4	02MAY96	32, -28	20	120	74	72	118	82	76	223.00	
5	09MAY96	39, -21	20	122	80	72	120	84	80	224.00	
6	16MAY96	46, -14	30	124	78	60	122	80	64	220.00	
8	30MAY96	60, 1	30	128	74	72	126	80	80	222.00	
12	27JUN96	88, 29	30	104	72	70	92	58	70	221.00	
16	01AUG96	123, 64	40	130	76	90	140	84	100	227.00	
20	30AUG96	152, 93	40	124	92	90	130	80	92	231.00	
24	30SEP96	183, 124	30	110	78	80	104	74	84	234.00	
32	07NOV96	221, 162	30	122	76	78	124	76	80	244.00 H	
32	05DEC96	249, 190	20	106	78	76	112	92	84	243.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	351000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	186	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-11	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	60	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.6	L	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.2	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	285000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	165	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	60	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	111	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	38	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	150	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	152		Glucose - Random	116	H	.	.	70 - 115	MG/DL
					Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	183		Hemoglobin	12	.	.	.	12 - 15.6	G/DL
					Hematocrit	35.5	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	13	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	53.3	.	.	.	30 - 70	%
					Lymphocytes	38.4	.	.	.	21 - 51	%
					Monocytes	4.8	.	.	.	0 - 10	%
					Eosinophils	3.3	.	.	.	0 - 5	%
					Basophils	0.2	.	.	.	0 - 2	%
					Platelets	382000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
		VISIT 17/DOWN TITRATION	277	(15)	Hemoglobin	11.6	L	.	.	12 - 15.6	G/DL
					Hematocrit	34.9	L	.	.	35 - 46	%
					Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	12	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	51.2	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 17/DOWN TITRATION	277 (15)	Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	324000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	123	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00268 TREATMENT GROUP: PAROXETINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11APR96	1	17APR96	7	7
00269	Oral	2	100 MG	18APR96	8	25APR96	15	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	15	100	Adverse event, including intercurrent illness	TACHYCARDIA,NEGATIVE/LOW T-WAVES

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
RECURRENT SINUSITIS{SEASONAL ALLERGIES}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996
UPSET STOMACH	DYSPEPSIA	DIGESTIVE SYST	CUR	1996
ACHILLES TENDON CASTED TIMES 6 WEEKS	THERAPY, REHAB	PROCEDURES	PRV	1994
BILATERAL HERNIA REPAIR	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980
SEVER'S DISEASE	OSTEOCHONDROPATHIES	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid Ac	-101,	.	01JAN96	.	2 TABS	UPSET STOMACH
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	.,	.		.	500-1,000	HEADACHES
			11,	.	21APR96	21APR96	1TAB	FOOT PAIN
RESPIRATORY	Pseudoephedrine	Pseudoephed	-101,	.	01JAN96	.	30MG	ALLERGIES
			-101,	.	01JAN96	.	30MG	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Trauma	FOOT PAIN{INJURY}	11, .	2 Days	100	CON	MIL	NO	UNR	Yes	No
Cardiovascular System	Electrocardiogram Abnormal	LOW OR NEGATIVE T WAVES	8, .	15 Days	100	CON	MIL	STP	REL	No	No
	Tachycardia	TACHYCARDIA	8, .	15 Days	100	CON	MIL	STP	REL	No	No
Digestive System	Nausea	NAUSEA	6, .	1 Days	50	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04APR96	-7, .	0	138	80	64	132	86	72	239.00	68.0
BL	11APR96	1, .	0	120	74	80	126	80	88	241.00	
1	18APR96	8, .	100	132	82	96	130	84	92	237.00	
2	25APR96	15, .	100	138	76	96	130	80	92	239.00	
3	02MAY96	22, .	100	130	76	76	.	.	.	238.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	37.2	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	259	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	22	(7)	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	41	.	.	.	41 - 50	%
					Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	42.9	.	.	.	30 - 70	%
					Lymphocytes	45.4	.	.	.	21 - 51	%
					Monocytes	9	.	.	.	0 - 10	%
					Eosinophils	1.8	.	.	.	0 - 5	%
					Basophils	1	.	.	.	0 - 2	%
					Platelets	272000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.5	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	239	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00269 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	22 (7)	Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEC		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	09MAY96	1	15MAY96	7	7
00270	Oral	2	100 MG	16MAY96	8	22MAY96	14	7
00270	Oral	3	150 MG	23MAY96	15	29MAY96	21	7
00270	Oral	4	200 MG	30MAY96	22	05JUN96	28	7
00270	Oral	4	200 MG	06JUN96	29	13JUN96	36	8
00270	Oral	4	200 MG	14JUN96	37	20JUN96	43	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	43	200	Adverse event, including intercurrent illness	CHEST PAIN, CHEST TIGHTNESS, SHORTNESS OF BREATH (PAGE 227, SECOND COL.)

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FOOD ALLERGIES{MILK PRODUCTS}	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1985
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
RINGWORM	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1996
STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	CUR	1996
BROKEN LEFT FEMUR{FELL OUT OF TREE}	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-8, .	01MAY96	13MAY96	1500MG	STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-494, .	01JAN95	.	750MG PRN	HEADACHE
DERMATOLOGICALS	Bentonite	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Calamine	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Clotrimazole	Lotrimin Cream	-10, .	29APR96	19MAY96	2X	RINGWORM
	Diphenhydramine Hydrochloride	Benadryl	9, .	17MAY96	19MAY96	3 TABS	POISON IVY
	Glycerol	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Phenol, Liquefied	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Sodium Citrate	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
	Topical Antifungal Nos	Antifungal Cream {Nos}	26, .	03JUN96	15JUN96	3X	RINGWORM
	Zinc Oxide	Calamine Lotion	9, .	17MAY96	19MAY96	2X	POISON IVY
GU SYSTEM/SEX HORMONES	Clotrimazole	Lotrimin Cream	-10, .	29APR96	19MAY96	2X	RINGWORM
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	9, .	17MAY96	19MAY96	3 TABS	POISON IVY

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN, CHEST TIGHTNESS	42, .	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes
			43, .	05:00 Hrs	200	CON	MIL	STP	PSR	No	No
	Headache	HEADACHE	47, .	2 Days	200	CON	MOD	NO	UNR	No	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	24, .	4 Days	200	5	MIL	NO	PSR	No	No
Digestive System	Diarrhea	DIARRHEA	42, .	30 Mins	200	CON	MIL	NO	UNR	No	No
			47, .	2 Days	200	CON	MIL	NO	UNR	No	No
	Dry Mouth	DRY MOUTH	15, .	15 Days	150	CON	MIL	NO	PSR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	42, .	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes
Skin and Appendages	Contact Dermatitis	POISON IVY	9, .	3 Days	100	CON	MOD	NO	UNR	Yes	No
	Fungal Dermatitis	RINGWORM	22, .	17 Days	200	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02MAY96	-7, .	0	116	70	64	112	72	72	135.00	68.0
BL	09MAY96	1, .	0	108	74	64	106	76	68	137.00	
1	16MAY96	8, .	100	108	64	68	106	72	72	135.00	
2	23MAY96	15, .	150	114	68	68	110	70	76	135.00	
3	30MAY96	22, .	200	114	70	72	112	72	68	133.00	
4	06JUN96	29, .	200	110	70	72	108	74	76	135.00	
5	13JUN96	36, .	200	118	72	64	114	76	68	132.00	
6	20JUN96	43, .	200	110	72	68	108	80	72	129.00	
7	27JUN96	50, .	200	108	68	88	102	62	88	130.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.5	.	.	.	30 - 70	%
				Lymphocytes	41.6	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	4.7	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	294000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	318	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7		Urine Squamous Epithelial Cells	3	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	50	(7)	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
					Hematocrit	39.5	L	.	.	41 - 50	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	52.7	.	.	.	30 - 70	%
					Lymphocytes	38.3	.	.	.	21 - 51	%
					Monocytes	4.1	.	.	.	0 - 10	%
					Eosinophils	3.9	.	.	.	0 - 5	%
					Basophils	1.1	.	.	.	0 - 2	%
					Platelets	283000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
					Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.9	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	343	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00270 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	50 (7)	Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEG		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEC		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28FEB97	1	09MAR97	10	10
00294	Oral	2	20 MG	10MAR97	11	16MAR97	17	7
00294	Oral	3	20 MG	17MAR97	18	27MAR97	28	11
00294	Oral	4	20 MG	28MAR97	29	02APR97	34	6
00294	Oral	5	30 MG	03APR97	35	09APR97	41	7
00294	Oral	4	20 MG	10APR97	42	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	42	20	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BACKACHES	BACK PAIN	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
RASH, PLANTAR SURFACE RIGHT FOOT	RASH/OTHER SKIN ERUPTION	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
10 BONE FUSIONS IN BACK	OPERATION, BONE/JOINT	OPERATIONS	PRV	1995
ROD PLACEMENT {BACK}	OPERATION, BONE/JOINT	OPERATIONS	PRV	1995
SCOLIOSIS	DEFORMITY, ACQUIRED	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Appetite Suppressant	Appetite Suppressant {Nos}	-58,	.	01JAN97	10FEB97#	3 TABS	WEIGHT GAIN
CENTRAL NERVOUS SYSTEM	Analgesics	Unknown Headache Medicine {Analgesic Nos}	-4,	.	24FEB97	24FEB97#	3 TABS	HEADACHE
	Paracetamol	Extra Strength Tylenol	-2,	.	26FEB97	26FEB97#	3 TABS	HEADACHE
		Tylenol	14,	.	13MAR97	13MAR97	1,000 MG	HEADACHE
			18,	.	17MAR97	17MAR97	1,000 MG	HEADACHE
			22,	.	21MAR97	23MAR97	4 TABS	BACKACHE
			40,	.	08APR97	08APR97	2 TABS	HEADACHE
		Tylenol Es Gel Caps	5,	.	04MAR97	07MAR97	1,000 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-1154,	.	01JAN94	.	2 TABS PRN	HEADACHE
	Naproxen Sodium	Aleve	34,	.	02APR97	02APR97	2 TABS	HEADACHE
			39,	.	07APR97	07APR97	2 TABS	HEADACHE & CRAMPS
RESPIRATORY	Cough Syrup/Med	Unknown Cough Drop	34,	.	02APR97	02APR97	1 TAB	URI

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	CRAMPS (ABDOMINAL)	39, .	02:00 Hrs	30	CON	MOD	NO	UNR	Yes	No
	Back Pain	BACKACHE	22, .	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHES (DAILY, 1-2X /DAY)	5, .	Not Stated	20		MOD	NO	PSR	Yes	No
Nervous System	Somnolence	DROWSINESS DURING DAY	1, .	19 Days	20	CON	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	UPPER RESPIRATORY INFECTION	34, .	6 Days	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20FEB97	-8, .	0	101	64	62	90	64	102	154.00	67.0
BL	27FEB97	-1, .	0	119	64	85	102	69	108	161.00	
1	10MAR97	11, .	20	106	63	71	114	68	98	161.00	
2	17MAR97	18, .	20	109	69	78	106	69	92	159.00	
4	28MAR97	29, .	20	99	63	88	102	63	76	164.00	
5	03APR97	35, .	30	105	71	74	94	72	84	166.00	
6	10APR97	42, .	20	106	72	78	114	74	84	165.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	90	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00294 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	16MAY96	1	22MAY96	7	7
00307	Oral	2	100 MG	23MAY96	8	29MAY96	14	7
00307	Oral	3	150 MG	30MAY96	15	05JUN96	21	7
00307	Oral	4	200 MG	06JUN96	22	12JUN96	28	7
00307	Oral	4	200 MG	13JUN96	29	20JUN96	36	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	36	200	Adverse event, including intercurrent illness	MORBILLIFORM

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1992
INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1993
SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	18,	.	02JUN96	07JUN96	500 MG	SINUSITIS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-1,	.	15MAY96	15MAY96#	1TAB	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-45,	.	01APR96	01APR96#	1TAB	INSOMNIA
			32,	.	16JUN96	21JUN96	150 MG	RASH
MUSCULO-SKELETAL	Ibuprofen	Advil	2,	.	17MAY96	17MAY96	1 TAB PRN	HEADACHE
			14,	.	29MAY96	29MAY96	200 MG	HEADACHE
			19,	.	03JUN96	04JUN96	200 MG	HEADACHE
		Ibuprofen	-1597,	.	01JAN92	.	2 TABS	HEADACHE
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-45,	.	01APR96	01APR96#	1TAB	INSOMNIA
			32,	.	16JUN96	21JUN96	150 MG	RASH
	Pseudoephedrine Hydrochloride	Actifed	31,	.	15JUN96	16JUN96	2 TABS	ALLERGIES
	Triprolidine Hydrochloride	Actifed	31,	.	15JUN96	16JUN96	2 TABS	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	50, .	Not Stated	0	20	MOD	NO	UNR	No	No
Digestive System	Dry Mouth	DRY MOUTH	3, .	39 Days	50	CON	MIL	NO	REL	No	No
Nervous System	Tremor	TREMORS	15, .	25 Days	150	CON	MIL	NO	REL	No	No
Respiratory System	Sinusitis	SINUSITIS	18, .	6 Days	150	CON	MIL	NO	UNR	Yes	No
			69, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No
Skin and Appendages	Maculopapular Rash	MORBILLIFORM "MEASLES LIKE" ERUPTION, GENERALIZED SIMILAR TO TRICYCLIC RASH, ON TRUNK, BACK, EXTREMITIES, CHEST, BUTTOCKS, TORSO/FRONT AND BACK, AND LOWER NECK	32, .	10 Days	200	CON	MOD	STP	REL	Yes	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	09MAY96	-7, .	0	120	72	76	118	76	84	146.00	61.0
BL	16MAY96	1, .	0	122	72	84	118	74	88	148.00	
1	23MAY96	8, .	100	120	80	80	118	84	78	145.00	
2	30MAY96	15, .	150	132	84	82	128	88	88	149.00	
3	06JUN96	22, .	200	120	76	92	118	80	98	148.00	
4	13JUN96	29, .	200	124	82	88	120	84	94	154.00	
5	20JUN96	36, .	200	140	88	92	136	90	98	154.00	
8	25JUL96	71, .#	0	124	74	98	130	88	108	151.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.4	.	.	.	30 - 70	%
				Lymphocytes	32.9	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	328000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	108	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00307 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	20.6	L	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	02JUL96	1	11JUL96	10	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	10	50	Protocol violation, including non-compliance	PATIENT RAN AWAY FROM HOME.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
URINE {1+ PROTEIN}	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SPINAL MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1982

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Loperamide Hydrochloride	Imodium A-D	-2, .	30JUN96	30JUN96#	4 TABS	NAUSEA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	-2, .	01:00 Hrs	0	CON	MIL	NO	PSR	Yes	No
	Vomiting	VOMITING	-2, .	01:00 Hrs	0	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	27JUN96	-5, .	0	102	68	74	102	70	74	142.00	71.0
BL	02JUL96	1, .	0	100	64	72	102	60	72	142.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	25.8	.	.	.	21 - 51	%
				Monocytes	8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	256000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	221	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00308 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	15JUL96	1	17JUL96	3	3
00309	Oral	2	20 MG	18JUL96	4	24JUL96	10	7
00309	Oral	3	20 MG	25JUL96	11	31JUL96	17	7
00309	Oral	4	20 MG	01AUG96	18	07AUG96	24	7
00309	Oral	4	20 MG	08AUG96	25	14AUG96	31	7
00309	Oral	4	20 MG	15AUG96	32	22AUG96	39	8
00309	Oral	4	20 MG	23AUG96	40	29AUG96	46	7
00309	Oral	4	20 MG	30AUG96	47	04SEP96	52	6
00170	Oral	4	20 MG	05SEP96	53	02OCT96	80	28
00170	Oral	4	20 MG	03OCT96	81	30OCT96	108	28
00170	Oral	4	20 MG	31OCT96	109	12DEC96	151	43
00170	Oral	4	20 MG	13DEC96	152	08JAN97	178	27
00170	Oral	4	20 MG	09JAN97	179	09FEB97	210	32
00170	Oral	5	30 MG	10FEB97	211	12MAR97	241	31
00309	Oral	4	20 MG	13MAR97	242	26MAR97	255	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	18	Yes	Yes	255	20		DATE OF DOWN TITRATION VISIT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
"ULCER-LIKE" SYMPTOMS (BURNING, INDIGESTION), NO ULCER	DYSPEPSIA	DIGESTIVE SYST	CUR	1996
HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
NAUSEA {CHRONIC}	NAUSEA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ranitidine Hydrochloride	Zantac	-44, -96	01JUN96	20JUN96#	300 MG	ULCER-LIKE SYMPTOMS
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	61, 9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71, 19	23SEP96	01OCT96	2000 MG	TOOTHACHE
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	34, -19	17AUG96	19AUG96	2 TABS	MENSTRUAL CRAMP
	Caffeine	Midol	34, -19	17AUG96	19AUG96	2 TABS	MENSTRUAL CRAMP
	Cinnamedrine Hydrochloride	Midol	34, -19	17AUG96	19AUG96	2 TABS	MENSTRUAL CRAMP
	Codeine Phosphate	Tylenol Iii	71, 19	23SEP96	27SEP96	3 TABS	TOOTHPAIN
	Epinephrine	Xylocaine-Epinephrine	74, 22	26SEP96	26SEP96	4 CC	ABSCESSED TOOTH
	Fentanyl	Fentanyl	74, 22	26SEP96	26SEP96	1 CC	ABSCESSED TOOTH
	Lidocaine Hydrochloride	Xylocaine-Epinephrine	74, 22	26SEP96	26SEP96	4 CC	ABSCESSED TOOTH
	Methohexital Sodium	Brevital	74, 22	26SEP96	26SEP96	70 MG	ABSCESSED TOOTH
			74, 22	26SEP96	26SEP96	70 MG	ABSCESSED TOOTH
	Midazolam Hydrochloride	Versed	74, 22	26SEP96	26SEP96	5 MG	ABSCESSED TOOTH
	Nitrous Oxide	Nitrous Oxide	74, 22	26SEP96	26SEP96	3.0 L/M	ABSCESSED TOOTH
	Paracetamol	Tylenol	-15, -67	30JUN96	30JUN96#	1 TAB	HEADACHE
			43, -10	26AUG96	26AUG96	500 MG	TOOTHACHE
			46, -7	29AUG96	29AUG96	500 MG	TOOTHACHE
			107, 55	29OCT96	29OCT96	1 TAB	HEADACHE
			237, 185	08MAR97	08MAR97	500 MG	HEADACHE
		Tylenol Iii	71, 19	23SEP96	27SEP96	3 TABS	TOOTHPAIN
DERMATOLOGICALS	Erythromycin	Erythromycin	61, 9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71, 19	23SEP96	01OCT96	2000 MG	TOOTHACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	29, -24	12AUG96	13AUG96	400 MG	HEADACHE
			33, -20	16AUG96	16AUG96	5 TABS	MENSTRUAL CRAMP
			72, 20	24SEP96	03OCT96	1 TAB	HEADACHES
			176, 124	06JAN97	13JAN97	2 TABS	EARACHE
			184, 132	14JAN97	12FEB97	400 MG PRN	HEADACHES
		Ibuprofen	-44, -96	01JUN96	.	1 TAB	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	-44,	-96	01JUN96	.	1-2 TABS	HEADACHE
RESPIRATORY	Chlorphenamine Maleate	Contac	143,	91	04DEC96	04DEC96	1 TAB	FEVER & CONGESTION
			145,	93	06DEC96	06DEC96	1 TAB	FEVER & CONGESTION
			147,	95	08DEC96	08DEC96	1 TAB	CONGESTION
		Histussin Hc	47,	-6	30AUG96	02SEP96	2 TSP	URI
	Dexbrompheniramine Maleate	Drixoral	52,	-1	04SEP96	04SEP96	2 CAPS	URI
			110,	58	01NOV96	01NOV96	1 TAB	ALLERGIES
	Hydrocodone	Hydrocodone	74,	22	26SEP96	26SEP96	1 TAB	ABSCESSED TOOTH
	Hydrocodone Bitartrate	Histussin Hc	47,	-6	30AUG96	02SEP96	2 TSP	URI
	Phenylephrine Hydrochloride	Histussin Hc	47,	-6	30AUG96	02SEP96	2 TSP	URI
	Phenylpropanolamine Hydrochloride	Contac	143,	91	04DEC96	04DEC96	1 TAB	FEVER & CONGESTION
			145,	93	06DEC96	06DEC96	1 TAB	FEVER & CONGESTION
			147,	95	08DEC96	08DEC96	1 TAB	CONGESTION
	Pseudoephedrine Sulfate	Drixoral	52,	-1	04SEP96	04SEP96	2 CAPS	URI
			110,	58	01NOV96	01NOV96	1 TAB	ALLERGIES
SENSORY ORGANS	Erythromycin	Erythromycin	61,	9	13SEP96	19SEP96	750 MG	BRONCHITIS
			71,	19	23SEP96	01OCT96	2000 MG	TOOTHACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	105, 53	3 Days	20	CON	MIL	NO	UNR	No	No
	Fever	FEVER	143, 91	3 Days	20	CON	MIL	NO	UNR	Yes	No
	Headache	HEADACHE (CHANGE IN SEVERITY)	144, 92	04:00 Hrs	20	CON	SEV	NO	PBU	No	No
		HEADACHES (DAILY)	184, 132	30 Days	20	24	MOD	NO	PBU	Yes	No
		HEADACHES (INCREASED FREQUENCY)	72, 20	19 Days	20	20	MOD	NO	PBU	Yes	No
	Infection	FLU (COUGH, HEAD CONGESTION, LOW-GRADE FEVER)	151, 99	11 Days	20	CON	MOD	NO	UNR	No	No
Digestive System	Gingivitis	ABSCESSED TOOTH	74, 22	1 Days	20	CON	SEV	NO	UNR	Yes	No
	Nausea	NAUSEA	105, 53	3 Days	20	CON	MIL	NO	UNR	No	No
			239, 187	Not Stated	30	CON	MIL	NO	UNR	No	No
	Tooth Disorder	TOOTHACHE (CUTTING WISDOM TEETH)	43, -10	17 Days	20	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS	3, -50	2 Days	20	2	MIL	NO	PSR	No	No
	Tremor	TREMOR (HANDS, HEAD, TEETH)	1, -52	47 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Bronchitis	BRONCHITIS	61, 9	7 Days	20	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	UPPER RESPIRATORY ILLNESS	47, -6	9 Days	20	CON	MOD	NO	UNR	Yes	No
		URI (UPPER RESPIRATORY INFECTION)	12, -41	21 Days	20	CON	MIL	NO	UNR	No	No
	Rhinitis	CONGESTION {NOSE}	143, 91	5 Days	20	CON	MOD	NO	UNR	Yes	No
Special Senses	Ear Pain	EARACHE	176, 124	8 Days	20	CON	MIL	NO	UNR	Yes	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	33, -20	4 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02JUL96	-13, -65	0	106	66	80	94	66	96	130.00	67.0
BL	15JUL96	1, -52	0	106	60	78	100	78	110	130.00	
1	18JUL96	4, -49	20	108	58	84	92	60	88	131.00	
1	25JUL96	11, -42	20	120	58	60	104	68	64	128.00	
2	01AUG96	18, -35	20	114	64	77	110	68	80	131.00	
3	08AUG96	25, -28	20	128	76	104	140	78	100	124.00	
4	15AUG96	32, -21	20	118	60	102	120	62	100	130.00	
6	23AUG96	40, -13	20	120	66	82	118	70	82	127.00	
7	30AUG96	47, -6	20	110	70	60	112	70	68	126.00	
7	05SEP96	53, 1	20	109	68	85	114	75	106	128.00	
12	03OCT96	81, 29	20	112	64	86	118	68	80	130.00	
16	31OCT96	109, 57	20	106	72	80	108	76	72	131.00	
20	13DEC96	152, 100	20	104	53	80	103	59	87	128.00	
24	09JAN97	179, 127	20	111	62	94	100	59	88	129.00	
28	10FEB97	211, 159	30	115	61	79	115	74	98	130.00	
32	13MAR97	242, 190	20	100	60	74	100	60	94	129.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-4	Segmented Neutrophils	57	.	.	.	40 - 75	%
				Lymphocytes	33	.	.	.	16 - 46	%
				Monocytes	9	.	.	.	0 - 12	%
				Eosinophils	1	.	.	.	0 - 7	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	28	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
				Urine Amphetamines NEG		.	.	.		
				Urine Barbiturates NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 1/SCREENING (WEEK -1)	-4	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	65.4	.	.	.	40 - 75	%
				Lymphocytes	23.9	.	.	.	16 - 46	%
				Monocytes	5.5	.	.	.	0 - 12	%
				Eosinophils	4.5	.	.	.	0 - 7	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	289000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	53	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	40 - 75	%
				Lymphocytes	25.8	.	.	.	16 - 46	%
				Monocytes	9	.	.	.	0 - 12	%
				Eosinophils	4.4	.	.	.	0 - 7	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	256000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	27 - 33	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 10/ACUTE PHASE-WEEK 8	53	Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	2.6	L	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	4.7	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	55.1	.	.	.	40 - 75	%
				Lymphocytes	28.8	.	.	.	16 - 46	%
				Monocytes	7.6	.	.	.	0 - 12	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 13/CONTINUATION-WEEK 20	152	Eosinophils	7.4	H	.	.	0 - 7	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	64	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	242	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 16/CONTINUATION-WEEK 32	242	Red Blood Cell Count	4.6	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	40 - 75	%
				Lymphocytes	32.8	.	.	.	16 - 46	%
				Monocytes	6.1	.	.	.	0 - 12	%
				Eosinophils	9.8	H	.	.	0 - 7	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	216000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	L	.	.	110 - 15	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00309 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	F	VISIT 16/CONTINUATION-WEEK 32	242	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	26SEP96	1	02OCT96	7	7
00310	Oral	2	20 MG	03OCT96	8	09OCT96	14	7
00310	Oral	3	20 MG	10OCT96	15	16OCT96	21	7
00310	Oral	4	20 MG	17OCT96	22	27OCT96	32	11
00310	Oral	4	20 MG	28OCT96	33	30OCT96	35	3
00310	Oral	4	20 MG	31OCT96	36	07NOV96	43	8
00310	Oral	4	20 MG	08NOV96	44	17NOV96	53	10
00310	Oral	4	20 MG	18NOV96	54	24NOV96	60	7
00180	Oral	4	20 MG	25NOV96	61	01JAN97	98	38
00180	Oral	4	20 MG	02JAN97	99	13FEB97	141	43
00180	Oral	4	20 MG	14FEB97	142	12MAR97	168	27
00180	Oral	4	20 MG	13MAR97	169	16APR97	203	35
00180	Oral	4	20 MG	17APR97	204	14MAY97	231	28
00180	Oral	4	20 MG	15MAY97	232	11JUN97	259	28
00310	Oral	3	20 MG	12JUN97	260	23JUN97	271	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	271	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	52, -9	16NOV96	17NOV96	2 TABS	FOOD POISONING
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	85, 25	19DEC96	29DEC96	1,000 MG	SORE THROAT
	Cefaclor	Ceclor	19, -42	14OCT96	27OCT96	750 MG	SORE THROAT, EARACHE
		Ceclor Cd	173, 113	17MAR97	28MAR97	1,000 MG	POSSIBLE STREP THROAT
	Clavulanic Acid	Augmentin	85, 25	19DEC96	29DEC96	1,000 MG	SORE THROAT
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	218, 158	01MAY97	08MAY97	1 TAB	SUNBURN
		Midol	-8, -68	18SEP96	18SEP96#	2 TABS	MENSTRUAL CRAMPS
	Butalbital	Phrenilin	175, 115	19MAR97	23MAR97	1 TAB	STIFF NECK
			236, 176	19MAY97	23MAY97	1 TAB	HEADACHE
	Caffeine	Midol	-8, -68	18SEP96	18SEP96#	2 TABS	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-8, -68	18SEP96	18SEP96#	2 TABS	MENSTRUAL CRAMPS
	Paracetamol	Phrenilin	175, 115	19MAR97	23MAR97	1 TAB	STIFF NECK
			236, 176	19MAY97	23MAY97	1 TAB	HEADACHE
		Tylenol	15, -46	10OCT96	15OCT96	4000 MG	FEVER, HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	14, -47	09OCT96	09OCT96	500 MG	PAIN IN NECK MUSCLES
			50, -11	14NOV96	17NOV96	1,200 MG	LEFT KNEE PAIN
	Ketoprofen	Orudis Kt	53, -8	17NOV96	30NOV96	1-2 TABS	LEFT KNEE PAIN
	Metaxalone	Skelaxin	14, -47	09OCT96	15OCT96	400 MG PRN	PAIN IN NECK MUSCLES
	Naproxen Sodium	Aleve	-56, -116	01AUG96	.	2 TABS	HEADACHE
			14, -47	09OCT96	09OCT96	1 TAB	PAIN IN NECK MUSCLES
RESPIRATORY	Guaifenesin	Panmist La	19, -42	14OCT96	29OCT96	2 TABS PRN	CONGESTION
	Loratadine	Claritin-D	85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION
			85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION
	Pseudoephedrine	Panmist La	19, -42	14OCT96	29OCT96	2 TABS PRN	CONGESTION
	Pseudoephedrine Sulfate	Claritin-D	85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION
			85, 25	19DEC96	30DEC96	2 TABS	NASAL CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	83, 23	3 Days	20	CON	SEV	NO	PBU	No	No
			170, 110	10 Days	20	CON	MOD	NO	PBU	Yes	No
		MILD HEADACHE	22, -39	03:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Infection	"FLU" HEADACHE, SORE THROAT AND WEAKNESS, FEVER, EARACHE	10, -51	12 Days	20	CON	MOD	NO	PBU	No	No
		POSSIBLE STREP THROAT	173, 113	12 Days	20	CON	MOD	NO	UNR	Yes	No
Digestive System	Gastrointestinal Disorder	FOOD POISONING	52, -9	2 Days	20	CON	MOD	NO	UNR	Yes	No
Musculoskeletal System	Arthralgia	LEFT KNEE PAIN	50, -11	Not Stated	20	CON	MOD	NO	UNR	Yes	No
	Myalgia	PAIN IN NECK MUSCLES	12, -49	9 Days	20	CON	MOD	NO	PBU	Yes	No
Nervous System	Hypertonia	STIFF NECK	170, 110	10 Days	20	CON	MOD	NO	UNR	Yes	No
Respiratory System	Pharyngitis	SORE THROAT	85, 25	11 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	85, 25	12 Days	20	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	10, -51	25 Days	20	CON	MOD	NO	PBU	Yes	No
Skin and Appendages	Photosensitivity	SUNBURN	218, 158	8 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19SEP96	-7, -67	0	100	72	80	100	78	76	116.00	60.0
BL	26SEP96	1, -60	0	104	63	99	109	71	119	116.00	
1	03OCT96	8, -53	20	110	78	76	108	76	80	114.00	
2	10OCT96	15, -46	20	112	70	72	110	72	74	115.00	
3	17OCT96	22, -39	20	102	64	60	100	68	60	115.00	
5	28OCT96	33, -28	20	104	68	70	100	66	72	116.00	
5	31OCT96	36, -25	20	100	72	72	98	68	68	114.00	
6	08NOV96	44, -17	20	96	68	74	100	72	76	114.00	
8	18NOV96	54, -7	20	101	51	70	96	52	80	116.00	
8	25NOV96	61, 1	20	96	50	64	94	52	76	115.00	
12	02JAN97	99, 39	20	98	73	81	100	78	101	109.00	
20	14FEB97	142, 82	20	102	59	66	98	60	74	111.00	
24	13MAR97	169, 109	20	103	63	78	98	66	93	113.00	
28	17APR97	204, 144	20	101	51	78	98	69	89	119.00	
32	15MAY97	232, 172	20	98	63	71	109	69	69	118.00	
32	12JUN97	260, 200	20	102	54	86	100	65	97	119.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.5	H	.	.	30 - 70	%
				Lymphocytes	20.3	L	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	254000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	32.2	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	286000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	169	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.9	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	5.6	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	298000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	169	Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	260	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	33	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.007.00310 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	260	Basophils	0.9	.	.	.	0 - 2	%
				Platelets	268000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	95	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03OCT96	1	09OCT96	7	7
00311	Oral	2	0 MG	10OCT96	8	16OCT96	14	7
00311	Oral	3	0 MG	17OCT96	15	27OCT96	25	11
00311	Oral	4	0 MG	28OCT96	26	30OCT96	28	3
00311	Oral	4	0 MG	31OCT96	29	06NOV96	35	7
00311	Oral	4	0 MG	07NOV96	36	13NOV96	42	7
00311	Oral	4	0 MG	14NOV96	43	21NOV96	50	8
00311	Oral	5	0 MG	22NOV96	51	01DEC96	60	10
00160	Oral	5	0 MG	02DEC96	61	01JAN97	91	31
00160	Oral	5	0 MG	02JAN97	92	29JAN97	119	28
00160	Oral	5	0 MG	30JAN97	120	12MAR97	161	42
00160	Oral	5	0 MG	13MAR97	162	10APR97	190	29
00311	Oral	4	0 MG	11APR97	191	24APR97	204	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	204	0	Lack of Efficacy	*DATE OF FOLLOW-UP VISIT AFTER TAPER FINISHED.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
PROTEIN IN URINE	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	PRV	1996
CONCUSSION	INJURY, INTRACRANIAL	INJURY/POISONING	PRV	1994
EUSTACHIAN TUBES LEFT EAR {FOR SEVERE, CHRONIC EAR INFECTION}	OPERATION, EAR	OPERATIONS	PRV	1984
EUSTACHIAN TUBES RIGHT EAR {FOR SEVERE, CHRONIC EAR INFECTION}	OPERATION, EAR	OPERATIONS	PRV	1987

CUR = Current, PRV = Past

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PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bisacodyl	Dulcolax	7, -54	09OCT96	09OCT96	1 TAB	ABDOMINAL PAIN
			7, -54	09OCT96	09OCT96	1 TAB	ABDOMINAL PAIN
	Bismuth Subsalicylate	Pepto Bismol	113, 53	23JAN97	24JAN97	2TSP	VOMITING AND DIARRHEA DUE TO FLU SYMPTOM
ANTIINFECTIVES,SYSTEMIC	Sulfamethoxazole	Bactrim	-27, -87	06SEP96	20SEP96#	2 TAB	BRONCHITIS
			21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
		Sulfatrim	166, 106	17MAR97	31MAR97	1,000 MG	BRONCHITIS
	Trimethoprim	Bactrim	-27, -87	06SEP96	20SEP96#	2 TAB	BRONCHITIS
			21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
		Sulfatrim	166, 106	17MAR97	31MAR97	1,000 MG	BRONCHITIS
CENTRAL NERVOUS SYSTEM	Venlafaxine Hydrochloride	Effexor	-155, -215	01MAY96	27SEP96#	1 TAB PRN	PRIOR PRESCRIPTION FOR DEPRESSION
DERMATOLOGICALS	Fluticasone Propionate	Flonase	21, -40	23OCT96	23NOV96	2 SPRAYS	SINUSITIS
MUSCULO-SKELETAL	Naproxen	Naprosyn	47, -14	18NOV96	22NOV96	1000 MG	KNEE PAIN
RESPIRATORY	Cough Syrup/Med	Unknown Cough Syrup	166, 106	17MAR97	24MAR97	1 TSP	BRONCHITIS
	Fluticasone Propionate	Flonase	21, -40	23OCT96	23NOV96	2 SPRAYS	SINUSITIS
	Guaifenesin	Entex La	21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
	Phenylpropanolamine Hydrochloride	Entex La	21, -40	23OCT96	24OCT96	2 TABS	BRONCHITIS SYMPTOMS
			28, -33	30OCT96	02NOV96	2 TABS	BRONCHITIS
	Pseudoephedrine Hydrochloride	Sudafed	85, 25	26DEC96	26DEC96	1TAB	SINUS CONGESTION
	Salbutamol	Albuterol	166, 106	17MAR97	24MAR97	1 TSP.	BRONCHITIS
			166, 106	17MAR97	24MAR97	1 TSP.	BRONCHITIS
		Proventil	-27, -87	06SEP96	13SEP96#	2 TSP	BRONCHITIS
			-27, -87	06SEP96	13SEP96#	2 TSP	BRONCHITIS

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	ABDOMINAL PAIN	7, -54	01:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
	Infection	FLU SYMPTOMS	113, 53	2 Days	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Diarrhea	DIARRHEA	16, -45	02:00 Hrs	0	1	MIL	NO	UNR	No	No
			113, 53	2 Days	0	12	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	16, -45	02:00 Hrs	0	1	MIL	NO	UNR	No	No
	Vomiting	VOMITING	113, 53	2 Days	0	12	MOD	NO	UNR	Yes	No
Musculoskeletal System	Arthralgia	KNEE PAIN (RIGHT KNEE)	47, -14	5 Days	0	CON	MOD	NO	UNR	Yes	No
Respiratory System	Bronchitis	BRONCHITIS	166, 106	15 Days	0	CON	MOD	NO	UNR	Yes	No
		BRONCHITIS SYMPTOMS: CONGESTION, COUGH	20, -41	12 Days	0	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	85, 25	2 Days	0	CON	MIL	NO	UNR	Yes	No
		SINUSITIS	21, -40	31 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26SEP96	-7, -67	0	102	75	69	123	72	68	118.00	65.0
BL	03OCT96	1, -60	0	120	78	72	118	76	74	122.00	
1	10OCT96	8, -53	0	120	78	74	118	74	78	120.00	
2	17OCT96	15, -46	0	114	66	83	104	66	100	119.00	
4	28OCT96	26, -35	0	120	74	72	122	76	68	121.00	
4	31OCT96	29, -32	0	118	66	84	120	70	88	119.00	
5	07NOV96	36, -25	0	116	72	72	118	78	76	123.00	
6	14NOV96	43, -18	0	118	74	72	120	68	76	123.00	
7	22NOV96	51, -10	0	110	74	60	118	76	64	123.00	
8	02DEC96	61, 1	0	110	65	85	118	81	68	122.00	
12	02JAN97	92, 32	0	123	57	73	114	62	81	127.00	
16	30JAN97	120, 60	0	118	59	66	122	66	73	127.00	
24	13MAR97	162, 102	0	110	80	83	110	76	86	130.00	
28	11APR97	191, 131	0	108	70	68	106	68	72	126.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.3	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	9.7	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	256	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	+		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	24	.	.	.	21 - 51	%
				Monocytes	13	H	.	.	0 - 10	%
				Eosinophils	11	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	232	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9	.	.	.	30 - 70	%
				Lymphocytes	20.9	L	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	11.2	H	.	+	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	183000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	220	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	162		Urine Red Blood Cells/HPF	NEG	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	6	.	.	.		
					Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 17/DOWN TITRATION	219	(15)	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	44.5	.	.	.	41 - 50	%
					Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54.7	.	.	.	30 - 70	%
					Lymphocytes	32.5	.	.	.	21 - 51	%
					Monocytes	3.8	.	.	.	0 - 10	%
					Eosinophils	8.6	H	.	.	0 - 5	%
					Basophils	0.3	.	.	.	0 - 2	%
					Platelets	206000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.2	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	229	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	103	.	.	.	70 - 115	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00311 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 17/DOWN TITRATION	219	(15)	Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Protein - Dipstick	6	.	.	.		
					Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	02DEC96	1	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	No	No	1	20	Lost to follow-up	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	PRV	1984
EUSTACHIAN TUBE {BILATERAL}	OPERATION, EAR	OPERATIONS	PRV	1985

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Methylphenidate Hydrochloride	Ritalin	-854, .	01AUG94	11AUG96#	10 MG	ADHD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22NOV96	-10, .	0	116	68	85	112	70	76	120.00	65.0
BL	02DEC96	1, .	0	111	61	84	101	72	86	123.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)		Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	31.7	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	254000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	231	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.007.00318 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)		Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	30AUG95	1	04SEP95	6	6
00157	Oral	2	20 MG	05SEP95	7	12SEP95	14	8
00157	Oral	3	20 MG	13SEP95	15	19SEP95	21	7
00157	Oral	4	20 MG	20SEP95	22	26SEP95	28	7
00157	Oral	4	20 MG	27SEP95	29	03OCT95	35	7
00157	Oral	4	20 MG	04OCT95	36	09OCT95	41	6
00157	Oral	4	20 MG	10OCT95	42	15OCT95	47	6
00157	Oral	4	20 MG	16OCT95	48	23OCT95	55	8
	Oral	4	20 MG	24OCT95	56	22NOV95	85	30
00100	Oral	4	20 MG	23NOV95	86	14DEC95	107	22
00100	Oral	4	20 MG	15DEC95	108	22JAN96	146	39
00100	Oral	4	20 MG	23JAN96	147	19FEB96	174	28

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	174	20	Other reason	PATIENT DROPPED OUT. PT. FELT NO FURTHER NEED FOR MEDICATION BECAUSE HE IS DOING WELL.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
SURGERY TO REPAIR A HERNIA	OPERATION, HERNIA REPAIR	OPERATIONS	PRV	1980

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Antihistamine, Nos	Antihistamine {Nos}	-3893,-3948	01JAN85	.		HAY FEVER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	16AUG95	-14, -69	0	138	68	72	136	68	72	278.00	72.0
BL	29AUG95	-1, -56	0	138	78	78	140	78	74	277.00	
1	05SEP95	7, -49	20	138	78	66	138	76	66	277.00	
2	12SEP95	14, -42	20	136	78	68	134	74	72		
3	20SEP95	22, -34	20	136	80	78	138	84	78	277.00	
4	26SEP95	28, -28	20	136	82	66	134	82	62	278.00	
5	04OCT95	36, -20	20	136	80	64	133	78	60	278.00	
6	10OCT95	42, -14	20	122	74	64	120	74	64		
7	16OCT95	48, -8	20	114	78	66	110	80	70	280.00	
8	24OCT95	56, 1	20	120	78	72	118	72	72	279.00	
12	23NOV95	86, 31	20	112	80	58	106	76	60	278.00	
16	15DEC95	108, 53	20	102	72	72	95	70	78	281.00	
20	23JAN96	147, 92	20	118	78	78	116	78	90	280.00	
24	20FEB96	175, 120	20	118	74	90	122	70	96	280.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7	.	.	.	30 - 70	%
				Lymphocytes	41	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	7.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	348000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	173	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-14	Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-1	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	4.8	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Platelets	338000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	162	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	108	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.6	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 12/CONTINUATION-WEEK 16	108	Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	388000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	128	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	147	Hematocrit	43.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.3	.	.	.	30 - 70	%
				Lymphocytes	31.7	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	130	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.008.00157 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	147	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	13SEP95	1	18SEP95	6	6
00158	Oral	2	0 MG	19SEP95	7	26SEP95	14	8
00158	Oral	3	0 MG	27SEP95	15	02OCT95	20	6
00158	Oral	4	0 MG	03OCT95	21	09OCT95	27	7
00158	Oral	4	0 MG	10OCT95	28	15OCT95	33	6
00158	Oral	5	0 MG	16OCT95	34	23OCT95	41	8
00158	Oral	6	0 MG	24OCT95	42	30OCT95	48	7
00158	Oral	6	0 MG	31OCT95	49	13NOV95	62	14
00009	Oral	6	0 MG	14NOV95	63	26DEC95	105	43
00009	Oral	6	0 MG	27DEC95	106	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	106	0	Protocol violation, including non-compliance	PATIENT DROPPED OUT. PT WAS DROPPED BECAUSE OF NON COMPLIANCE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
GASTRIC REFLUX	ESOPHAGITIS	DIGESTIVE SYST	CUR	
APPENDICITIS	APPENDICITIS	DIGESTIVE SYST	PRV	1989

CUR = Current, PRV = Past

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PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urogenital System	Breast Pain	BREAST SORENESS {FEMALE}	-1, -63	16 Days	0		MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06SEP95	-7, -69	0	110	92	76	110	92	96	156.00	62.0
BL	13SEP95	1, -62	0	112	75	100	110	82	108		
1	19SEP95	7, -56	0	118	82	96	105	90	100	158.30	
2	27SEP95	15, -48	0	108	85	92	110	90	100	156.00	
3	03OCT95	21, -42	0	112	75	76	110	82	92	158.00	
4	10OCT95	28, -35	0	110	70	68	110	85	76	155.00	
5	16OCT95	34, -29	0	112	80	84	120	85	104	156.00	
6	24OCT95	42, -21	0	110	78	72	100	80	88	154.00	
7	31OCT95	49, -14	0	110	84	72	104	90	96	154.00	
8	14NOV95	63, 1	0	105	70	80	100	70	100	153.00	
16	26DEC95	105, 43	0	110	80	72	110	85	100	156.00	
20	23JAN96	133, 71#	0	108	78	68	110	80	80	155.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.9	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.9	.	.	.	30 - 70	%
				Lymphocytes	35.7	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	2.1	H	.	.	0 - 2	%
				Platelets	355000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	111	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.1	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	5.7	.	.	.	0 - 10	%
				Eosinophils	7.3	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	335000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00158 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	13SEP95	1	18SEP95	6	6
00159	Oral	2	100 MG	19SEP95	7	26SEP95	14	8
00159	Oral	3	150 MG	27SEP95	15	02OCT95	20	6
00159	Oral	4	200 MG	03OCT95	21	09OCT95	27	7
00159	Oral	5	250 MG	10OCT95	28	15OCT95	33	6
00159	Oral	5	250 MG	16OCT95	34	23OCT95	41	8
00159	Oral	5	250 MG	24OCT95	42	30OCT95	48	7
00159	Oral	4	200 MG	31OCT95	49	13NOV95	62	14
00022	Oral	4	200 MG	14NOV95	63	25DEC95	104	42
00022	Oral	4	200 MG	26DEC95	105	23JAN96	133	29
00191	Oral	4	200 MG	24JAN96	134	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	134	200	Protocol violation, including non-compliance	PATIENT DROPPED OUT, DUE TO NON COMPLIANCE.

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	., .		.	2TABS PRN	HEADACHES
	Sleeping Pill	Sleep Aid {Nos}	21, -42	03OCT95	10OCT95	1TAB PRN	INSOMNIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	22, -41	29 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	42, -21	9 Days	250		MIL	NO	REL	No	No
	Insomnia	TROUBLE GETTING TO SLEEP AND EARLY AWAKENING	47, -16	8 Days	250	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06SEP95	-7, -69	0	100	70	92	100	73	96	104.00	62.0
BL	13SEP95	1, -62	0	103	70	68	100	65	80		
1	19SEP95	7, -56	100	96	62	.	96	62	.	101.00	
2	27SEP95	15, -48	150	96	62	.	94	64	.	101.00	
3	03OCT95	21, -42	200	94	60	72	92	60	72	101.00	
4	10OCT95	28, -35	250	100	78	84	92	62	88	101.00	
5	16OCT95	34, -29	250	110	72	108	96	70	104	101.00	
6	24OCT95	42, -21	250	102	78	118	100	76	118	101.00	
7	31OCT95	49, -14	200	116	78	100	100	76	122 H	101.00	
8	14NOV95	63, 1	200	110	65	88	110	56	120	102.00	
16	26DEC95	105, 43	200	102	74	80	96	70	90	100.00	
20	23JAN96	133, 71	200	104	76	72	98	68	84	104.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.2	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.8	.	.	.	30 - 70	%
				Lymphocytes	19.2	L	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	333000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	63	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	29.2	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	344000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	68	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00159 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	63	Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	43	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	01NOV95	1	09NOV95	9	9
00160	Oral	2	20 MG	10NOV95	10	19NOV95	19	10
00160	Oral	3	20 MG	20NOV95	20	26NOV95	26	7
00160	Oral	4	20 MG	27NOV95	27	04DEC95	34	8
00160	Oral	4	20 MG	05DEC95	35	12DEC95	42	8
00160	Oral	5	30 MG	13DEC95	43	19DEC95	49	7
00160	Oral	5	30 MG	20DEC95	50	26DEC95	56	7
00160	Oral	5	30 MG	27DEC95	57	05JAN96	66	10
00104	Oral	5	30 MG	06JAN96	67	30JAN96	91	25
00104	Oral	5	30 MG	31JAN96	92	04MAR96	125	34
00104	Oral	5	30 MG	05MAR96	126	08APR96	160	35
00104	Oral	5	30 MG	09APR96	161	15MAY96	197	37
00104	Oral	5	30 MG	16MAY96	198	17JUN96	230	33
00104	Oral	5	30 MG	18JUN96	231	22JUL96	265	35
00160	Oral	5	30 MG	23JUL96	266	24JUL96	267	2
00160	Oral	4	20 MG	25JUL96	268	26JUL96	269	2
00160	Oral	3	20 MG	27JUL96	270	28JUL96	271	2
00160	Oral	2	20 MG	29JUL96	272	31JUL96	274	3
00160	Oral	1	20 MG	01AUG96	275	07AUG96	281	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	Yes	281	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EPIGLOTTITIS	EPIGLOTTITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1990

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Doxycycline	Doxycycline	20, -47	20NOV95	.	50 MG	ACNE
RESPIRATORY	Salbutamol	Ventolin Inhaler	20, -47	20NOV95	.		EXERCISE INDUCED SHORTNESS OF BREATH
			20, -47	20NOV95	.		EXERCISE INDUCED SHORTNESS OF BREATH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Nervousness	JITTERINESS	20, -47	8 Days	20	1	MIL	NO	UNR	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH	20, -47	8 Days	20	CON	MIL	NO	UNR	Yes	No
Urogenital System	Breast Enlargement	INCREASE IN BREAST SIZE {FEMALE}	27, -40	Not Stated	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25OCT95	-7, -73	0	102	65	68	110	85	80	161.00	76.0
BL	01NOV95	1, -66	0	110	70	84	102	75	92	159.00	
1	10NOV95	10, -57	20	90	58	76	85	80	80	159.00	
3	20NOV95	20, -47	20	110	58	84	105	65	88	160.00	
4	27NOV95	27, -40	20	110	80	80	110	80	92	160.00	
5	05DEC95	35, -32	20	110	75	80	107	78	92	158.00	
6	13DEC95	43, -24	30	100	70	80	105	78	96	159.00	
7	20DEC95	50, -17	30	110	65	76	100	78	84	156.00	
8	27DEC95	57, -10	30	112	72	72	100	80	88	163.00	
8	05JAN96	66, -1	30	110	50	84	110	78	100	160.00	
12	31JAN96	92, 26	30	112	65	92	110	75	96	160.00	
16	05MAR96	126, 60	30	115	60	84	120	80	84	164.00	
24	09APR96	161, 95	30	110	80	100	90	60	96	168.00	
28	16MAY96	198, 132	30	122	78	92	110	80	96	175.00 H	
32	18JUN96	231, 165	30	120	75	108	110	85	100	175.00 H	
32	23JUL96	266, 200	30	120	60	96	90	70	80	175.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.2	.	.	.	30 - 70	%
				Lymphocytes	34.5	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	9.4	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	110	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	28.7	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	9.5	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	205000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	107	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	161	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	30.8	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	12.4	H	.	+	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	217000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	161	Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	99	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	266	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.8	H	.	.	30 - 70	%
				Lymphocytes	16.8	L	.	.	21 - 51	%
				Monocytes	1.2	.	.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	241000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00160 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	266	Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	93	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	16NOV95	1	21NOV95	6	6
00161	Oral	2	100 MG	22NOV95	7	28NOV95	13	7
00161	Oral	3	150 MG	29NOV95	14	06DEC95	21	8
00161	Oral	4	200 MG	07DEC95	22	14DEC95	29	8
00161	Oral	4	200 MG	15DEC95	30	26DEC95	41	12
00161	Oral	4	200 MG	27DEC95	42	02JAN96	48	7
00161	Oral	4	200 MG	03JAN96	49	09JAN96	55	7
00099	Oral	4	200 MG	10JAN96	56	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	56	200	Lost to follow-up	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
NECROTIZING ENTEROCOLITIS AT BIRTH-NO COMPLICATIONS	CONDITIONS, PERINATAL	PERINATAL COND	PRV	1978

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	1, -55	4 Days	50	CON	MIL	NO	REL	No	No
Nervous System	Hostility	INTENSE ANGER	39, -17	30 Mins	200	2	MOD	NO	PSR	No	No
	Insomnia	POOR SLEEP	1, -55	4 Days	50	CON	MIL	NO	REL	No	No
	Nervousness	RESTLESSNESS	1, -55	4 Days	50	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	31OCT95	-16, -71	0	110	72	60	.	.	.	261.00	73.0
BL	16NOV95	1, -55	0	118	78	78	118	72	80	263.00	
1	22NOV95	7, -49	100	104	78	74	100	76	78	263.00	
2	29NOV95	14, -42	150	106	78	72	96	72	78	266.00	
3	07DEC95	22, -34	200	118	74	72	110	78	86	259.00	
4	15DEC95	30, -26	200	114	78	78	100	72	72	265.00	
6	27DEC95	42, -14	200	120	80	72	118	78	90	268.00	
7	03JAN96	49, -7	200	122	78	66	118	74	84		
8	10JAN96	56, 1	200	118	74	72	110	70	82	272.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65	.	.	.	30 - 70	%
				Lymphocytes	26.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	327000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	77	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-16		Urine Squamous Epithelial Cells	4	.	.	.		
					Urine Amphetamines	NEG	.	.	.		
					Urine Barbiturates	NEG	.	.	.		
					Urine Benzodiazepines	NEG	.	.	.		
					Urine Cannabinoids	NEG	.	.	.		
					Urine Cocaine	NEG	.	.	.		
					Urine Methadone	NEG	.	.	.		
					Urine Methaqualone	NEG	.	.	.		
					Urine Opiates	NEG	.	.	.		
					Urine Phencyclidine	NEG	.	.	.		
					Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	(1)	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	41.7	.	.	.	41 - 50	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	67.4	.	.	.	30 - 70	%
					Lymphocytes	23.2	.	.	.	21 - 51	%
					Monocytes	7	.	.	.	0 - 10	%
					Eosinophils	1.5	.	.	.	0 - 5	%
					Basophils	1	.	.	.	0 - 2	%
					Platelets	312000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.2	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	73	.	.	.	22 - 180	U/L
					Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00161 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	56 (1)	Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	01NOV95	1	09NOV95	9	9
00162	Oral	2	0 MG	10NOV95	10	19NOV95	19	10
00162	Oral	3	0 MG	20NOV95	20	28NOV95	28	9
00162	Oral	4	0 MG	29NOV95	29	06DEC95	36	8
00162	Oral	5	0 MG	07DEC95	37	13DEC95	43	7
00162	Oral	5	0 MG	14DEC95	44	19DEC95	49	6
00162	Oral	6	0 MG	20DEC95	50	26DEC95	56	7
00162	Oral	6	0 MG	27DEC95	57	04JAN96	65	9
00101	Oral	6	0 MG	05JAN96	66	08FEB96	100	35
00101	Oral	6	0 MG	09FEB96	101	07MAR96	128	28
00101	Oral	6	0 MG	08MAR96	129	10APR96	162	34
	Oral	6	0 MG	11APR96	163	30APR96	182	20
00101	Oral	6	0 MG	01MAY96	183	04JUN96	217	35
00101	Oral	6	0 MG	05JUN96	218	01JUL96	244	27
00162	Oral	5	0 MG	02JUL96	245	03JUL96	246	2
00162	Oral	4	0 MG	04JUL96	247	05JUL96	248	2
00162	Oral	3	0 MG	06JUL96	249	07JUL96	250	2
00162	Oral	2	0 MG	08JUL96	251	10JUL96	253	3
00162	Oral	1	0 MG	11JUL96	254	17JUL96	260	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	Yes	260	0		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Antibiotic Nos	Antibiotic {Nos}	29, -37	29NOV95	09DEC95		BRONCHITIS
			37, -29	07DEC95	17DEC95		EYE INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	DROP IN ENERGY	50, -16	8 Days	0	1	MIL	INC	PSR	No	No
Nervous System	Insomnia	DROP IN SLEEP	50, -16	8 Days	0	1	MIL	INC	PSR	No	No
Respiratory System	Bronchitis	BRONCHITIS	29, -37	11 Days	0	1	MIL	NO	UNR	No	No
Special Senses	Eye Disorder	EYE INFECTION	37, -29	11 Days	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26OCT95	-6, -71	0	102	70	66	.	.	.	132.00	74.0
1	10NOV95	10, -56	0	100	68	88	96	70	100		
3	20NOV95	20, -46	0	100	70	76	110	75	84	134.00	
4	29NOV95	29, -37	0	100	60	80	100	68	88	133.00	
5	07DEC95	37, -29	0	100	58	76	100	60	88	132.00	
6	14DEC95	44, -22	0	103	75	96	100	70	100	130.00	
7	20DEC95	50, -16	0	90	58	56	95	70	76	133.00	
8	27DEC95	57, -9	0	105	65	72	105	70	88	131.00	
8	05JAN96	66, 1	0	100	55	68	90	60	88	137.00	
16	09FEB96	101, 36	0	100	70	80	80	50	100	133.00	
20	08MAR96	129, 64	0	90	62	68	90	65	84	136.00	
24	01MAY96	183, 118	0	90	60	84	88	60	80	132.00	
32	05JUN96	218, 153	0	110	55	76	90	60	88	132.00	
32	02JUL96	245, 180	0	128	70	68	138	79	78	133.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	2.9	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	415000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	50	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	37	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 6/ACUTE PHASE-WEEK 4	37	Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	35.2	.	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	387000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	162	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	162	Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	2.5	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	414000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	44	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.8	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	3.2	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	362000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	41	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	62	L	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00162 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 16/CONTINUATION-WEEK 32	245	Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	29NOV95	1	06DEC95	8	8
00187	Oral	2	100 MG	07DEC95	9	14DEC95	16	8
00187	Oral	3	150 MG	15DEC95	17	20DEC95	22	6
00187	Oral	4	200 MG	21DEC95	23	26DEC95	28	6
00187	Oral	4	200 MG	27DEC95	29	03JAN96	36	8
00187	Oral	4	200 MG	04JAN96	37	10JAN96	43	7
00187	Oral	5	250 MG	11JAN96	44	17JAN96	50	7
00187	Oral	4	200 MG	18JAN96	51	25JAN96	58	8
	Oral	4	200 MG	26JAN96	59	09FEB96	73	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	73	200	Lack of Efficacy	PATIENT DEMONSTRATED NO SIGNIFICANT IMPROVEMENT.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLITIS	ENTERITIS/COLITIS	DIGESTIVE SYST	CUR	1981
OCCASIONAL MILD HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
VAGINAL WARTS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Hyoscyamine Sulfate	Levsinex	-5445, .	01JAN81	.	1-3XYR	COLITIS
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	-332, .	01JAN95	.	1-2TABS PRN	HEADACHES
			36, .	03JAN96	04JAN96	2TABLETS	OCCAS.HEADACHE
		Excedrin Extra Strength	44, .	11JAN96	12JAN96	2TABLETS	OCCAS.HEADACHE
			58, .	25JAN96	26JAN96	2TABLETS	OCCAS.HEADACHE
	Caffeine	Excedrin	-332, .	01JAN95	.	1-2TABS PRN	HEADACHES
			36, .	03JAN96	04JAN96	2TABLETS	OCCAS.HEADACHE
		Excedrin Extra Strength	44, .	11JAN96	12JAN96	2TABLETS	OCCAS.HEADACHE
			58, .	25JAN96	26JAN96	2TABLETS	OCCAS.HEADACHE
	Codeine Phosphate	Tylenol #2	19, .	17DEC95	.	2TABS PRN	OCCAS.HEADACHE
	Paracetamol	Excedrin	-332, .	01JAN95	.	1-2TABS PRN	HEADACHES
			36, .	03JAN96	04JAN96	2TABLETS	OCCAS.HEADACHE
		Excedrin Extra Strength	44, .	11JAN96	12JAN96	2TABLETS	OCCAS.HEADACHE
			58, .	25JAN96	26JAN96	2TABLETS	OCCAS.HEADACHE
		Tylenol #2	19, .	17DEC95	.	2TABS PRN	OCCAS.HEADACHE
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Levlen 28	9, .	07DEC95	.	1TAB DAILY	CONTRACEPTION
			9, .	07DEC95	.	1TAB DAILY	CONTRACEPTION
		Ovcon	-332, .	01JAN95	.	1XDAY	BIRTH CONTROL
	Levonorgestrel	Levlen 28	9, .	07DEC95	.	1TAB DAILY	CONTRACEPTION
			9, .	07DEC95	.	1TAB DAILY	CONTRACEPTION
	Norethisterone	Ovcon	-332, .	01JAN95	.	1XDAY	BIRTH CONTROL
MUSCULO-SKELETAL	Ibuprofen	Motrin	4, .	02DEC95	05DEC95	2TABS PRN	NECK SPASMS

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
	Nausea	INFREQUENTLY NAUSEA	12, .	Not Stated	100	CON	MIL	NO	PSR	No	No
Nervous System	Somnolence	SEDATION	24, .	Not Stated	200	CON	MOD	NO	REL	No	No
Respiratory System	Dyspnea	SHORTNESS OF BREATH (WITH EXERCISE)	40, .	Not Stated	200	CON	MIL	NO	PSR	No	No
Skin and Appendages	Acne	INCREASED ACNE (FACE,CHEST,BACK)	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
	Sweating	EPISODIC CALOR AND PERSPIRATION	12, .	Not Stated	100	CON	MIL	NO	PSR	No	No
Special Senses	Photophobia	LIGHT SENSITIVITY	20, .	Not Stated	150	CON	MIL	NO	REL	No	No
	Taste Perversion	BITTER TASTE IN MOUTH	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15NOV95	-14, .	0	100	70	84	100	70	93	108.00	63.0
BL	29NOV95	1, .	0	100	70	84	100	70	93		
1	07DEC95	9, .	100	120	78	88	115	82	92	111.00	
2	14DEC95	16, .	100	116	84	100	90	70	104	111.00	
3	21DEC95	23, .	200	118	78	104	104	78	116	113.00	
4	28DEC95	30, .	200	110	70	108	100	70	120	109.00	
5	04JAN96	37, .	200	124	98	100	118	90	100	115.00	
6	11JAN96	44, .	250	110	82	108	104	80	116	112.00	
7	18JAN96	51, .	200	110	78	100	110	82	100	112.00	
8	26JAN96	59, .	200	100	70	104	100	76	108	113.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.6	.	.	.	30 - 70	%
				Lymphocytes	45.5	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	267000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	16	Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.3	.	.	.	30 - 70	%
				Lymphocytes	38.3	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00187 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEC		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	NATIVE AMERICAN

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	04JAN96	1	09JAN96	6	6
00188	Oral	2	20 MG	10JAN96	7	16JAN96	13	7
00188	Oral	3	20 MG	17JAN96	14	23JAN96	20	7
00188	Oral	4	20 MG	24JAN96	21	30JAN96	27	7
00188	Oral	5	30 MG	31JAN96	28	06FEB96	34	7
00188	Oral	6	40 MG	07FEB96	35	13FEB96	41	7
00188	Oral	6	40 MG	14FEB96	42	20FEB96	48	7
00188	Oral	6	40 MG	21FEB96	49	27FEB96	55	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	55	40	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Migraine	MIGRAINES	48, .	04:00 Hrs	40	2	MOD	NO	UNR	No	No
Nervous System	Anxiety	ANXIETY ATTACKS	52, .	30 Mins	40	1	MIL	NO	PBU	No	No
	Nervousness	JITTERINESS	4, .	Not Stated	20	12	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14DEC95	-21, .	0	110	70	80	100	70	100	156.00	63.0
BL	04JAN96	1, .	0	112	85	88	100	85	132	160.00	
1	10JAN96	7, .	20	110	85	80	105	75	100	162.00	
2	17JAN96	14, .	20	112	60	80	100	75	88	162.00	
3	24JAN96	21, .	20	100	70	88	105	80	112	159.00	
4	31JAN96	28, .	30	120	80	72	112	82	88	162.00	
5	07FEB96	35, .	40	110	75	84	110	70	100	164.00	
6	14FEB96	42, .	40	110	75	88	105	75	120	162.00	
7	21FEB96	49, .	40	110	65	96	110	80	128	163.00	
8	27FEB96	55, .	40	110	80	80	108	75	96	165.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-21	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.5	.	.	.	30 - 70	%
				Lymphocytes	39	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	302000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	66	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-21	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.1	.	.	.	30 - 70	%
				Lymphocytes	28.8	.	.	.	21 - 51	%
				Monocytes	3.4	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00188 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	01FEB96	1	11FEB96	11	11
00191	Oral	2	0 MG	12FEB96	12	19FEB96	19	8
00191	Oral	3	0 MG	20FEB96	20	26FEB96	26	7
00191	Oral	4	0 MG	27FEB96	27	04MAR96	33	7
00191	Oral	4	0 MG	05MAR96	34	11MAR96	40	7
00191	Oral	4	0 MG	12MAR96	41	17MAR96	46	6
00191	Oral	4	0 MG	18MAR96	47	25MAR96	54	8
00191	Oral	4	0 MG	26MAR96	55	01APR96	61	7
00141	Oral	4	0 MG	02APR96	62	01MAY96	91	30
00141	Oral	4	0 MG	02MAY96	92	04JUN96	125	34
00141	Oral	4	0 MG	05JUN96	126	12JUN96	133	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	134	0	Other reason	MOVED OUT OF STATE

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Tetracycline	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE
DERMATOLOGICALS	Tetracycline	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE
SENSORY ORGANS	Tetracycline	Tetracycline	-51, -112	12DEC95	.	500MG	ACNE
			-51, -112	12DEC95	.	500MG	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Decreased Appetite	APPETITE DOWN	3, -59	Not Stated	0	CON	MIL	NO	PSR	No	No
Nervous System	Nervousness	RESTLESS AND JUMPY	28, -34	Not Stated	0	CON	MIL	NO	PSR	No	No
	Somnolence	SLEEPINESS	3, -59	Not Stated	0	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12JAN96	-20, -81	0	104	74	67	.	.	.	119.00	60.0
BL	01FEB96	1, -61	0	108	68	72	96	64	78	117.00	
2	12FEB96	12, -50	0	108	72	78	96	66	86	119.00	
3	20FEB96	20, -42	0	102	68	84	92	58	104	121.00	
4	27FEB96	27, -35	0	98	64	82	88	58	90	119.00	
5	05MAR96	34, -28	0	102	68	72	98	58	78	119.00	
6	12MAR96	41, -21	0	102	64	72	99	56	90	119.00	
7	18MAR96	47, -15	0	102	70	90	94	64	94	119.00	
8	26MAR96	55, -7	0	102	70	78	98	68	90	120.00	
8	02APR96	62, 1	0	102	62	78	94	64	90	119.00	
12	01MAY96	91, 30	0	94	60	84	90	60	90	121.00	
16	05JUN96	126, 65	0	96	64	72	89	60	84	120.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7	.	.	.	30 - 70	%
				Lymphocytes	46.5	.	.	.	21 - 51	%
				Monocytes	6.8	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	229000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	41	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	234000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00191 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05MAR96	1	11MAR96	7	7
00192	Oral	2	100 MG	12MAR96	8	18MAR96	14	7
00192	Oral	3	150 MG	19MAR96	15	24MAR96	20	6
00192	Oral	4	200 MG	25MAR96	21	03APR96	30	10
00192	Oral	4	200 MG	04APR96	31	11APR96	38	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	No	No	38	200	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid Ac	-2, .	03MAR96	.	1TIMES DAY	HEARTBURN
CENTRAL NERVOUS SYSTEM	Methylphenidate Hydrochloride	Ritalin	-643, .	01JUN94	01FEB96#	5MG/DAY	ATTENTION DEFICIT HYPERACTIVITY DISORDER

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	22, .	Not Stated	200	CON	MIL	DCR	PBU	No	No
	Dyspepsia	HEARTBURN	26, .	Not Stated	200	CON	MIL	DCR	PSR	No	No
Nervous System	Dizziness	LIGHTHEADEDNESS	22, .	Not Stated	200	CON	MIL	DCR	PBU	No	No
	Somnolence	DROWSINESS	22, .	Not Stated	200	CON	MIL	DCR	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14FEB96	-20, .	0	114	66	84	104	60	96	126.00	65.0
BL	05MAR96	1, .	0	110	72	72	98	64	90	126.00	
1	11MAR96	7, .	50	100	70	78	94	62	90	133.00	
2	18MAR96	14, .	100	102	70	78	94	70	90	133.00	
3	25MAR96	21, .	200	102	60	90	92	60	120	131.00	
4	03APR96	30, .	200	102	70	90	94	68	98	133.00	
5	12APR96	39, .	200	100	68	72	96	68	90	130.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-20	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.5	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35	.	.	.	30 - 70	%
				Lymphocytes	54	H	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	357	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00192 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-20	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	11MAR96	1	17MAR96	7	7
00271	Oral	2	20 MG	18MAR96	8	24MAR96	14	7
00271	Oral	3	20 MG	25MAR96	15	31MAR96	21	7
00271	Oral	4	20 MG	01APR96	22	07APR96	28	7
00271	Oral	4	20 MG	08APR96	29	14APR96	35	7
00271	Oral	5	30 MG	15APR96	36	21APR96	42	7
00271	Oral	6	40 MG	22APR96	43	01MAY96	52	10
00271	Oral	6	40 MG	02MAY96	53	13MAY96	64	12
00137	Oral	6	40 MG	14MAY96	65	09JUN96	91	27
00137	Oral	6	40 MG	10JUN96	92	11JUL96	123	32
00137	Oral	6	40 MG	12JUL96	124	08AUG96	151	28
00137	Oral	6	40 MG	09AUG96	152	09SEP96	183	32
00137	Oral	6	40 MG	10SEP96	184	06OCT96	210	27
00137	Oral	6	40 MG	07OCT96	211	04NOV96	239	29
00271	Oral	5	30 MG	05NOV96	240	06NOV96	241	2
00271	Oral	4	20 MG	07NOV96	242	08NOV96	243	2
00271	Oral	3	20 MG	09NOV96	244	10NOV96	245	2
00271	Oral	2	20 MG	11NOV96	246	13NOV96	248	3
00271	Oral	1	20 MG	14NOV96	249	20NOV96	255	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	255	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1984

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Clarithromycin	Biaxin	45, -20	24APR96	30APR96	500 MG	RESPIRATORY INFECTION
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	89, 25	07JUN96	07JUN96	X2 TABS	HEADACHE
	Caffeine	Excedrin	89, 25	07JUN96	07JUN96	X2 TABS	HEADACHE
	Paracetamol	Excedrin	89, 25	07JUN96	07JUN96	X2 TABS	HEADACHE
		Tylenol Extra Strength	-5, -69	06MAR96	17MAR96	2 TABS	UPPER RESPIRATORY TRACT INFECTION
			28, -37	07APR96	07APR96	2 TABS	HEADACHE
			63, -2	12MAY96	12MAY96	2 TABS	HEADACHE
			91, 27	09JUN96	09JUN96	X2 TABS	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	21, -44	31MAR96	31MAR96	200 MG	NECK PAIN
	Menthol	Vicks Cough Drop	42, -23	21APR96	21APR96		PHARYNGITIS
RESPIRATORY	Chlorphenamine Maleate	Triaminic Cough Syrup	-5, -69	06MAR96	06MAR96#	X1	RESPIRATORY INFECTION
	Menthol	Vicks Cough Drop	42, -23	21APR96	21APR96		PHARYNGITIS
			42, -23	21APR96	21APR96		PHARYNGITIS
	Phenylpropanolamine Hydrochloride	Triaminic Cough Syrup	-5, -69	06MAR96	06MAR96#	X1	RESPIRATORY INFECTION
	Salbutamol	Albuterol	-3722,-3786	01JAN86	.	1TAB DAY	ASTHMA
			-3722,-3786	01JAN86	.	1TAB DAY	ASTHMA
		Proventil Inhaler	-3722,-3786	01JAN86	.	4PUFFSX1-PRN	ASTHMA
			-3722,-3786	01JAN86	.	4PUFFSX1-PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	DECREASED ENERGY/TIRED	58, -7	Not Stated	40	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE (DAILY)	58, -7	6 Days	40		MIL	NO	PSR	Yes	No
Carciovascular System	Vasodilatation	FEELING HOT	-5, -69	61 Days	0		MIL	NO	PSR	No	No
Digestive System	Decreased Appetite	REDUCED APPETITE	8, -57	24 Days	20	CON	MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	27, -38	11 Days	20	CON	MIL	NO	PBU	No	No
Nervous System	Concentration Impaired	DECREASED CONCENTRATION	62, -3	4 Days	40	CON	MIL	NO	PSR	No	No
	Dizziness	COLD CLAMMY LIGHTHEADEDNESS [LIGHTHEADEDNESS]	26, -39	15 Mins	20	1	MIL	DCR	PSR	No	No
		LIGHTHEADED	24, -41	15 Mins	20	2	MIL	DCR	PSR	No	No
		LIGHTHEADED {WHEN STANDING}	62, -3	Not Stated	40	CON	MIL	NO	PSR	No	No
	Hypertonia	STIFF NECK	28, -37	30 Mins	20	3	MIL	NO	PBU	No	No
	Nervousness	INCREASED IRRITABILITY	63, -2	Not Stated	40	CON	MIL	NO	PSR	No	No
	Somnolence	SOMNOLENCE DAYTIME	5, -60	52 Days	20	CON	MIL	NO	PSR	No	No
	Tremor	SHAKY	65, 1	Not Stated	40	CON	MIL	NO	PSR	No	No
		SUBJECTIVE FEELINGS OF SHAKINESS	24, -41	14 Days	20	3	MIL	DCR	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT SWALLOWING	27, -38	11 Days	20	CON	MIL	NO	PBU	No	No
Skin and Appendages	Skin Disorder	COLD, CLAMMY LIGHTHEADEDNESS [COLD, CLAMMY]	26, -39	15 Mins	20	1	MIL	DCR	PSR	No	No
Special Senses	Conjunctivitis	DRY ITCHY EYES	28, -37	2 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25JAN96	-46,-110	0	98	76	68	96	70	72	170.00	63.5
BL	11MAR96	1, -64	0	98	74	68	96	70	70	172.00	
1	18MAR96	8, -57	20	132	78	82	116	78	94	175.00	
2	25MAR96	15, -50	20	115	73	74	126	84	86	174.00	
3	01APR96	22, -43	20	129	75	76	128	78	67	173.00	
4	08APR96	29, -36	20	135	73	69	125	66	80	172.00	
5	15APR96	36, -29	30	124	78	69	127	85	75	168.00	
6	22APR96	43, -22	40	133	78	76	129	78	73	168.00	
7	02MAY96	53, -12	40	126	76	67	116	76	75	164.00	
8	14MAY96	65, 1	40	92	66	73	123	87	87	163.00	
12	10JUN96	92, 28	40	130	76	76	126	84	78	168.00	
16	12JUL96	124, 60	40	120	70	76	110	80	92	167.00	
20	09AUG96	152, 88	40	98	75	80	90	60	112	162.00	
24	06SEP96	180, 116	40	105	80	80	90	70	100	160.00	
28	07OCT96	211, 147	40	105	75	72	95	80	92	162.00	
32	05NOV96	240, 176	30	120	80	80	120	80	84	164.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-46	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.5	L	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.9	.	.	.	30 - 70	%
				Lymphocytes	35.3	.	.	.	21 - 51	%
				Monocytes	3.8	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-46	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Hemoglobin	12	.	.	.	12 - 15.6	G/DL
				Hematocrit	34.5	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.2	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37	.	.	.	30 - 70	%
				Lymphocytes	49	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	65	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	180	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.8	.	.	.	30 - 70	%
				Lymphocytes	37.8	.	.	.	21 - 51	%
				Monocytes	3.8	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	263000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 14/CONTINUATION-WEEK 24	180	Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	101	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	240	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	69.8	.	.	.	30 - 70	%
				Lymphocytes	21	.	.	.	21 - 51	%
				Monocytes	2.6	.	.	.	0 - 10	%
				Eosinophils	6.1	H	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00271 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	240	Basophils	0.5	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	110	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	03APR96	1	10APR96	8	8
00272	Oral	2	100 MG	11APR96	9	17APR96	15	7
00272	Oral	3	150 MG	18APR96	16	26APR96	24	9
00272	Oral	4	200 MG	27APR96	25	30APR96	28	4
00272	Oral	4	200 MG	01MAY96	29	06MAY96	34	6
00272	Oral	4	200 MG	07MAY96	35	14MAY96	42	8
00272	Oral	4	200 MG	15MAY96	43	21MAY96	49	7
00272	Oral	4	200 MG	22MAY96	50	28MAY96	56	7
00142	Oral	4	200 MG	29MAY96	57	25JUN96	84	28
00142	Oral	4	200 MG	26JUN96	85	23JUL96	112	28
00142	Oral	4	200 MG	24JUL96	113	20AUG96	140	28
00142	Oral	4	200 MG	21AUG96	141	18SEP96	169	29

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	169	200	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-37, -93	26FEB96	19MAR96#	500MG/WK	HEADACHES
			8, -49	10APR96	10APR96	500 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	2, -55	Not Stated	50	CON	MIL	NO	PSR	No	No
Nervous System	Somnolence	DROWSINESS	113, 57	Not Stated	200	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19MAR96	-15, -71	0	106	62	60	100	68	66	120.00	61.0
BL	03APR96	1, -56	0	102	70	72	94	68	82	122.00	
1	10APR96	8, -49	50	102	72	78	96	64	96	120.00	
2	17APR96	15, -42	100	102	70	78	96	66	84	120.00	
3	26APR96	24, -33	150	102	70	84	98	68	108	122.00	
4	01MAY96	29, -28	200	98	64	90	102	64	102	123.00	
5	07MAY96	35, -22	200	116	72	90	98	66	96	125.00	
7	22MAY96	50, -7	200	110	78	108	100	80	116	127.00	
8	29MAY96	57, 1	200	110	75	100	110	80	108	128.00	
12	26JUN96	85, 29	200	112	78	90	106	78	102	131.00 H	
16	24JUL96	113, 57	200	118	96	96	100	58	110	135.00 H	
20	21AUG96	141, 85	200	112	76	108	114	80	138 H	141.00 H	
24	18SEP96	169, 113	200	168	72	72	116	60	96	145.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39	.	.	.	30 - 70	%
				Lymphocytes	48.9	.	.	.	21 - 51	%
				Monocytes	8.1	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	451000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.2	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	305	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	64	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-15	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.4	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	320000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	274	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	14	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.9	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37	L	.	-	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	31.9	.	.	.	30 - 70	%
				Lymphocytes	44.8	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	15.9	H	.	+	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.5	.	.	.	2.6 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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PATIENT ID: 329.008.00272 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	141	Alkaline Phosphatase	285	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	17MAY96	1	23MAY96	7	7
00273	Oral	2	100 MG	24MAY96	8	29MAY96	13	6
00273	Oral	3	150 MG	30MAY96	14	09JUN96	24	11
00273	Oral	4	200 MG	10JUN96	25	16JUN96	31	7
00273	Oral	4	200 MG	17JUN96	32	23JUN96	38	7
00273	Oral	5	250 MG	24JUN96	39	30JUN96	45	7
00273	Oral	6	300 MG	01JUL96	46	10JUL96	55	10
00273	Oral	6	300 MG	11JUL96	56	18JUL96	63	8
00153	Oral	6	300 MG	19JUL96	64	03SEP96	110	47
00153	Oral	6	300 MG	04SEP96	111	09SEP96	116	6

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	116	300	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
TEMPOROMANDIBULAR JOINT PAIN	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-37, -100	10APR96	.	(ALMOST DAILY) AS NEEDED	TMJ PAIN
MUSCULO-SKELETAL	Flurbiprofen	Ansaid	-58, -121	20MAR96	10APR96#	3 PILLS/DAY	TMJ PAIN

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Accidental Overdose	TRICYCLIC TOXICITY	116, 53	8 Days	300		SEV	STP	REL	No	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19APR96	-28, -91	0	120	85	80	120	85	92	152.00	72.0
BL	17MAY96	1, -63	0	120	80	96	105	83	102	153.00	
1	24MAY96	8, -56	100	110	85	112	105	82	136 H	150.00	
2	31MAY96	15, -49	150	112	84	92	108	85	100	150.00	
3	10JUN96	25, -39	200	100	80	96	100	80	112	147.00	
4	17JUN96	32, -32	200	110	85	96	100	85	108	145.00	
5	24JUN96	39, -25	250	110	80	100	110	80	108	145.00	
6	01JUL96	46, -18	300	124	79	104	131	81	104	140.00 L	
8	11JUL96	56, -8	300	112	82	106	110	80	120	138.00 L	
8	19JUL96	64, 1	300	105	85	96	100	80	100	140.00 L	
16	04SEP96	111, 48	300	110	85	104	110	80	112	140.00 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-28	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.1	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	427000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	263	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	3.1	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-28	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 1/UNSCHEDULED LAB 1	-10	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00273 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Basophils	1.1	.	.	.	0 - 2	%
				Platelets	341000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	251	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	60 - 110	MG/DL
				Globulin	3.9	H	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08MAY96	1	14MAY96	7	7
00275	Oral	2	20 MG	15MAY96	8	20MAY96	13	6
00275	Oral	3	20 MG	21MAY96	14	27MAY96	20	7
00275	Oral	4	20 MG	28MAY96	21	03JUN96	27	7
00275	Oral	5	30 MG	04JUN96	28	10JUN96	34	7
00275	Oral	5	30 MG	11JUN96	35	24JUN96	48	14
00275	Oral	6	40 MG	25JUN96	49	01JUL96	55	7
00163	Oral	5	30 MG	02JUL96	56	22JUL96	76	21
00163	Oral	5	30 MG	23JUL96	77	19AUG96	104	28
00163	Oral	5	30 MG	20AUG96	105	15SEP96	131	27
00163	Oral	5	30 MG	16SEP96	132	20OCT96	166	35
	Oral	5	30 MG	21OCT96	167	24NOV96	201	35
00163	Oral	5	30 MG	25NOV96	202	16DEC96	223	22

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	Yes	223	30		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Antibiotic Nos	Antibiotic {Nos}	49, -7	25JUN96	09JUL96		FOOT INFECTION
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-738, -793	01MAY94	.	PRN	ALLERGIES, INSOMNIA
			-1, -56	07MAY96	07MAY96#	50 MG	ALLERGY
			8, -48	15MAY96	.	50 MG	ALLERGY
			56, 1	02JUL96	.		ITCHINESS
			77, 22	23JUL96	24JUL96	50 MG	ALLERGIES
			132, 77	16SEP96	17SEP96	50 MG	ALLERGIES
			202, 147	25NOV96	26NOV96	50 MG	ALLERGIES
MUSCULO-SKELETAL	Ibuprofen	Advil	-493, -548	01JAN95	.	PRN	HEADACHES
			-1, -56	07MAY96	.		HEADACHES
			56, 1	02JUL96	.		ANKLE SPRAIN
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-738, -793	01MAY94	.	PRN	ALLERGIES, INSOMNIA
			-1, -56	07MAY96	07MAY96#	50 MG	ALLERGY
			8, -48	15MAY96	.	50 MG	ALLERGY
			56, 1	02JUL96	.		ITCHINESS
			77, 22	23JUL96	24JUL96	50 MG	ALLERGIES
			132, 77	16SEP96	17SEP96	50 MG	ALLERGIES
			202, 147	25NOV96	26NOV96	50 MG	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	1, -55	Not Stated	20	CON	MIL	NO	PSR	No	No
			75, 20	06:00 Hrs	30	1	MIL	NO	REL	No	No
			97, 42	9 Days	30	3	MIL	NO	REL	No	No
			119, 64	2 Days	30	3	MIL	NO	REL	No	No
			181, 126	26:00 Hrs	30	2	MIL	NO	REL	No	No
Nervous System	Dizziness	DIZZINESS	49, -7	9 Days	40	3	MIL	NO	REL	No	No
			73, 18	5 Days	30	3	MIL	NO	REL	No	No
			95, 40	3 Mins	30	1	MIL	NO	REL	No	No
			124, 69	3 Days	30	2	MIL	NO	REL	No	No
		LIGHTHEADEDNESS	29, -27	3 Days	30	2	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	30APR96	-8, -63	0	100	70	80	110	80	100	166.00	64.0
BL	07MAY96	-1, -56	0	100	60	100	110	70	76	166.00	
1	15MAY96	8, -48	20	110	80	80	105	80	100	164.00	
2	21MAY96	14, -42	20	110	82	100	90	65	76	163.00	
3	28MAY96	21, -35	20	100	72	88	100	80	96	167.00	
4	04JUN96	28, -28	30	108	72	66	98	70	90	170.00	
5	11JUN96	35, -21	30	104	72	66	96	72	88	170.00	
7	25JUN96	49, -7	40	98	70	72	96	70	88	165.00	
8	02JUL96	56, 1	30	110	62	72	94	60	90	165.00	
12	23JUL96	77, 22	30	110	70	78	90	62	108	163.00	
16	20AUG96	105, 50	30	104	74	74	86	70	96	158.00	
20	16SEP96	132, 77	30	100	74	72	92	68	96	154.00 L	
24	21OCT96	167, 112	30	60 L	72	76	88	68	86	154.00 L	
28	25NOV96	202, 147	30	98	88	78	94	56	90	154.00 L	
32	16DEC96	223, 168	30	98	64	90	92	60	112	154.00 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	231	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.1	.	.	.	30 - 70	%
				Lymphocytes	22.1	.	.	.	21 - 51	%
				Monocytes	12.4	H	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	266000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	216	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	132	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67	.	.	.	30 - 70	%
				Lymphocytes	23.1	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	247000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	219	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	132	Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	53	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	223	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.4	.	.	.	30 - 70	%
				Lymphocytes	35.9	.	.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.008.00275 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	223	Alkaline Phosphatase	240	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	10APR95	1	16APR95	7	7
00127	Oral	2	100 MG	17APR95	8	23APR95	14	7
00127	Oral	3	150 MG	24APR95	15	30APR95	21	7
00127	Oral	4	200 MG	01MAY95	22	08MAY95	29	8
00127	Oral	4	200 MG	09MAY95	30	14MAY95	35	6
00127	Oral	4	200 MG	15MAY95	36	26MAY95	47	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	No	No	47	200	Adverse event, including intercurrent illness	NONCOMPLIANT SECONDARY TO NAUSEA

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
INITIAL INSOMNIA	INSOMNIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
SEPARATION ANXIETY	STRESS REACTION	MENTAL DISORD	CUR	1995

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN WHEN TAKING MEDS	8, .	45 Days	100	CON	MIL	NO	PBU	No	No
	Headache	OCCASIONAL HEADACHE	3, .	Not Stated	50		MIL	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	15, .	38 Days	150		MOD	STP	REL	No	No
Nervous System	Dizziness	DIZZINESS	15, .	38 Days	150		MOD	NO	REL	No	No
	Insomnia	INITIAL INSOMNIA	8, .	45 Days	100	CON	MOD	NO	PSR	No	No
	Somnolence	DAYTIME DROWSINESS	3, .	Not Stated	50	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	03APR95	-7, .	0	104	66	62	105	55	68	79.90	58.0
BL	10APR95	1, .	0	114	54	75	.	.	.	79.70	
1	17APR95	8, .	100	112	61	78	119	53	91	80.90	
2	24APR95	15, .	150	111	62	74	111	63	83	78.20	
3	01MAY95	22, .	200	115	54	74	118	78	72	79.60	
4	08MAY95	29, .	200	127	52	79	111	82	89	77.60	
5	15MAY95	36, .	200	118	57	91	111	68	103	78.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	40.4	.	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	338000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	8 - 21	MG/DL
				Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 39	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	60 - 110	MG/DL
				Globulin	2.8	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00127 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11APR95	1	17APR95	7	7
00128	Oral	2	0 MG	18APR95	8	24APR95	14	7
00128	Oral	3	0 MG	25APR95	15	25APR95	15	1
	Oral	4	0 MG	26APR95	16	02MAY95	22	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	No	No	22	0	Adverse event, including intercurrent illness	RIGHT BBB

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
GENERALIZED ANXIETY DISORDER	NEUROSES	MENTAL DISORD	CUR	1994
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1993
ATTENTION DEFICIT DISORDER	MENTAL STATUS, IMPAIRED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Brompheniramine Maleate	Dimetapp	-830, .	01JAN93	.	4TABS PRN	SEASONAL ALLERGIES
	Phenylephrine Hydrochloride	Dimetapp	-830, .	01JAN93	.	4TABS PRN	SEASONAL ALLERGIES
	Phenylpropanolamine Hydrochloride	Dimetapp	-830, .	01JAN93	.	4TABS PRN	SEASONAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	8, .	Not Stated	0	CON	MIL	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05APR95	-6, .	0	121	65	91	84	74	101	114.88	62.2
BL	11APR95	1, .	0	115	61	98	122	54	114	111.60	
1	18APR95	8, .	0	123	66	98	107	68	96	111.50	
2	25APR95	15, .	0	115	53	85	114	68	90	112.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36.3	L	.	-	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3	.	.	.	30 - 70	%
				Lymphocytes	45.8	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	232000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	216	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00128 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00129 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11APR95	1	17APR95	7	7
00129	Oral	2	0 MG	18APR95	8	24APR95	14	7
00129	Oral	3	0 MG	25APR95	15	01MAY95	21	7
00129	Oral	4	0 MG	02MAY95	22	08MAY95	28	7
00129	Oral	5	0 MG	09MAY95	29	16MAY95	36	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	No	No	36	0	Lack of Efficacy	PATIENT DOING SOME WHAT WORSE-MOTHER ANXIOUS ABOUT INCREASE DEATH WISHES

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00129 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BROKEN COLLAR BONE	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1992

CUR = Current, PRV = Past

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	22MAR95	-20, .	0	115	42	68	108	50	79	187.80	69.3
BL	11APR95	1, .	0	131	53	64	130	49	68	189.50	
1	18APR95	8, .	0	131	53	58	137	89	64	188.70	
2	25APR95	15, .	0	115	54	64	123	57	64	186.70	
3	02MAY95	22, .	0	114	57	67	123	60	69	189.40	
4	09MAY95	29, .	0	106	40	59	108	56	75	187.50	
5	16MAY95	36, .	0	123	49	57	115	49	65	190.07	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00129 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.5	.	.	.	30 - 70	%
				Lymphocytes	33.2	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	141000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	127	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00129 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18APR95	1	24APR95	7	7
00130	Oral	2	20 MG	25APR95	8	01MAY95	14	7
00130	Oral	3	20 MG	02MAY95	15	08MAY95	21	7
00130	Oral	4	20 MG	09MAY95	22	15MAY95	28	7
00130	Oral	4	20 MG	16MAY95	29	22MAY95	35	7
00130	Oral	4	20 MG	23MAY95	36	29MAY95	42	7
00130	Oral	4	20 MG	30MAY95	43	05JUN95	49	7
00130	Oral	4	20 MG	06JUN95	50	12JUN95	56	7
00010	Oral	4	20 MG	13JUN95	57	06AUG95	111	55
00010	Oral	4	20 MG	07AUG95	112	18SEP95	154	43
00010	Oral	4	20 MG	19SEP95	155	02OCT95	168	14
00130	Oral	4	20 MG	03OCT95	169	04OCT95	170	2
00130	Oral	3	20 MG	05OCT95	171	06OCT95	172	2
00130	Oral	2	20 MG	07OCT95	173	09OCT95	175	3
00130	Oral	1	20 MG	10OCT95	176	16OCT95	182	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	182	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
NERVOUS STOMACH	STOMACH/DUODENUM DISORD	DIGESTIVE SYST	CUR	1989

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Atropine Sulfate	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
	Calcium Carbonate	Tums	149, 93	13SEP95	.	1TAB PRN	STOMACH ACHE
			149, 93	13SEP95	.	1TAB PRN	STOMACH ACHE
	Hyoscine Hydrobromide	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
	Hyoscyamine Sulfate	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
	Phenobarbital	Donnatal	-1568,-1624	01JAN91	18APR95	1-2TIMES PER WEEK	STOMACH PROBLEMS
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	140, 84	04SEP95	13SEP95	1500MG	SINUS INFECTION
	Amoxicillin Trihydrate	Amoxil	8, -49	25APR95	04MAY95	1500MG	SINUSITIS
CENTRAL NERVOUS SYSTEM	Nefazodone	Nefazodone	170, 114	04OCT95	.	100MG	DEPRESSION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	149, 93	Not Stated	20		MIL	NO	PBU	Yes	No
Digestive System	Nausea	NAUSEA	36, -21	3 Days	20	2	MIL	NO	PSR	No	No
Nervous System	Agitation	["HYPER"{AGITATION}]	32, -25	26 Days	20	3	MOD	NO	PSR	No	No
Respiratory System	Sinusitis	SINUS INFECTION	140, 84	10 Days	20	CON	MOD	NO	PBU	Yes	No
		SINUSITIS	8, -49	10 Days	20	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12APR95	-6, -62	0	139	58	57	130	70	74	146.30	66.3
BL	18APR95	1, -56	0	128	56	76	144	71	90	147.60	
1	25APR95	8, -49	20	135	60	64	137	69	94	145.00	
2	02MAY95	15, -42	20	128	55	52	131	65	54	145.80	
3	09MAY95	22, -35	20	130	53	65	137	64	86	145.80	
4	16MAY95	29, -28	20	133	67	59	122	61	76	145.09	
5	23MAY95	36, -21	20	130	61	72	131	62	102	145.10	
6	30MAY95	43, -14	20	130	64	64	122	63	88	147.60	
7	06JUN95	50, -7	20	129	64	66	130	72	82	148.62	
8	13JUN95	57, 1	20	130	60	79	138	76	93	151.10	
16	07AUG95	112, 56	20	.	.	.	138	73	85	162.70 H	
20	19SEP95	155, 99	20	137	60	65	137	66	71	165.30 H	
24	03OCT95	169, 113	20	139	66	59	123	76	67	162.40 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.1	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	223	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	22	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEC	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.8	.	.	.	30 - 70	%
				Lymphocytes	27.9	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Basophils	0.8	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	155	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	48	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00130 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	155	Monocytes	3	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	28000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	207	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEC		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	02MAY95	1	08MAY95	7	7
00131	Oral	2	20 MG	09MAY95	8	15MAY95	14	7
00131	Oral	3	20 MG	16MAY95	15	22MAY95	21	7
00131	Oral	4	20 MG	23MAY95	22	29MAY95	28	7
00131	Oral	4	20 MG	30MAY95	29	05JUN95	35	7
00131	Oral	4	20 MG	06JUN95	36	12JUN95	42	7
00131	Oral	4	20 MG	13JUN95	43	19JUN95	49	7
00131	Oral	4	20 MG	20JUN95	50	26JUN95	56	7
00011	Oral	4	20 MG	27JUN95	57	24JUL95	84	28
00011	Oral	4	20 MG	25JUL95	85	23AUG95	114	30
00011	Oral	4	20 MG	24AUG95	115	27AUG95	118	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	118	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
HEART MURMUR, GRADE 1, ASYMPTOMATIC	CARDIAC MURMURS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1984

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Docusate Sodium	Correctol	21, -36	22MAY95	22MAY95	2TABLETS	CONSTIPATION
	Yellow Phenolphthalein	Correctol	21, -36	22MAY95	22MAY95	2TABLETS	CONSTIPATION
DERMATOLOGICALS	Sulfur	Clearasil	29, -28	30MAY95	.	1GRAM	ACNE
	Triclosan	Clearasil	29, -28	30MAY95	.	1GRAM	ACNE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Constipation	CONSTIPATION	19, -38	3 Days	20	1	MOD	NO	PSR	Yes	No
Hemic and Lymphatic System	Thrombocythemia	INCREASED PLATELET COUNT	57, 1	29 Days	20	CON	MIL	NO	PBU	No	No
Skin and Appendages	Acne	ACNE-FACIAL	29, -28	Not Stated	20	CON	MOD	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26APR95	-6, -62	0	130	64	63	114	56	62	160.90	66.8
BL	02MAY95	1, -56	0	106	60	64	122	56	72	158.70	
1	09MAY95	8, -49	20	107	53	63	122	63	84	157.60	
2	16MAY95	15, -42	20	121	60	69	123	65	85	159.64	
3	23MAY95	22, -35	20	121	68	66	106	57	71	157.50	
4	30MAY95	29, -28	20	115	60	73	130	65	100	156.50	
5	06JUN95	36, -21	20	124	55	64	130	68	80	158.98	
6	13JUN95	43, -14	20	115	52	67	130	72	86	160.40	
7	20JUN95	50, -7	20	115	71	70	124	65	67	162.20	
8	27JUN95	57, 1	20	130	68	69	115	81	102	162.10	
12	25JUL95	85, 29	20	124	65	70	123	76	84	163.80	
16	24AUG95	115, 59	20	115	44	63	94	60	72	159.00	
20	26SEP95	148, 92#	0	106	63	75	107	56	83	155.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.4	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	374000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	103	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	120	H	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39.4	.	.	.	30 - 70	%
				Lymphocytes	46.2	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	410000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	100	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	85	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.9	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	2.9	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	381000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 13/CONTINUATION-WEEK 20	148 (30)	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	148 (30)	Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	33.8	.	.	.	30 - 70	%
				Lymphocytes	54.5	H	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	315000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00131 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	148	(30)	Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	23MAY95	1	29MAY95	7	7
00132	Oral	2	100 MG	30MAY95	8	05JUN95	14	7
00132	Oral	3	150 MG	06JUN95	15	12JUN95	21	7
00132	Oral	4	200 MG	13JUN95	22	19JUN95	28	7
00132	Oral	4	200 MG	20JUN95	29	26JUN95	35	7
00132	Oral	4	200 MG	27JUN95	36	04JUL95	43	8
00132	Oral	4	200 MG	05JUL95	44	10JUL95	49	6
00132	Oral	4	200 MG	11JUL95	50	18JUL95	57	8
00001	Oral	4	200 MG	19JUL95	58	23AUG95	93	36
00001	Oral	4	200 MG	24AUG95	94	14SEP95	115	22
00001	Oral	4	200 MG	15SEP95	116	23OCT95	154	39
00132	Oral	4	200 MG	24OCT95	155	24OCT95	155	1
00132	Oral	3	150 MG	25OCT95	156	26OCT95	157	2
00132	Oral	2	100 MG	27OCT95	158	29OCT95	160	3
00132	Oral	1	50 MG	30OCT95	161	05NOV95	167	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	167	50	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES(OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	27, -31	3 Days	200	CON	MIL	NO	UNR	No	No
Digestive System	Nausea	NAUSEA	27, -31	3 Days	200		MIL	NO	UNR	No	No
			94, 37	62 Days	200		MIL	NO	PSR	No	No
	Vomiting	VOMITING	28, -30	06:00 Hrs	200		MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	17MAY95	-6, -63	0	114	77	54	112	70	79	111.35	62.0
BL	23MAY95	1, -57	0	117	58	85	123	72	94	112.90	
1	30MAY95	8, -50	100	131	68	79	108	64	108	110.50	
2	06JUN95	15, -43	150	114	63	95	113	67	106	111.79	
3	13JUN95	22, -36	200	115	69	103	123	80	106	114.00	
4	20JUN95	29, -29	200	121	69	89	114	68	112	109.30	
5	27JUN95	36, -22	200	122	71	91	122	72	105	110.30	
6	05JUL95	44, -14	200	122	68	95	123	72	112	111.30	
7	11JUL95	50, -8	200	114	64	93	116	72	105	109.50	
8	19JUL95	58, 1	200	131	84	108	140	81	97	111.30	
12	24AUG95	94, 37	200	116	79	96	115	72	96	112.50	
16	15SEP95	116, 59	200	116	62	95	114	67	99	113.30	
20	24OCT95	155, 98	200	114	67	95	116	62	99	112.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.8	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1	.	.	.	30 - 70	%
				Lymphocytes	40.1	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	234	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.5	.	.	.	30 - 70	%
				Lymphocytes	35.5	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	7.2	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	255	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	155	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	41.7	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	244000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	267	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00132 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	155	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	13JUN95	1	19JUN95	7	7
00133	Oral	2	20 MG	20JUN95	8	26JUN95	14	7
00133	Oral	3	20 MG	27JUN95	15	04JUL95	22	8
00133	Oral	4	20 MG	05JUL95	23	10JUL95	28	6
00133	Oral	5	30 MG	11JUL95	29	17JUL95	35	7
00133	Oral	6	40 MG	18JUL95	36	27JUL95	45	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	45	40	Lost to follow-up	PT DECIDED TO STOP STUDY HERSELF NOT FOR LACK OF EFFICACY,PT WAS LOST TO FU

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
PREMENSTRUAL TENSION(OCCASIONAL)	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993
SINUS INFECTIONS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1985
FEVER OF UNKNOWN ORIGIN	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1993
STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	PRV	1985

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	28, .	10JUL95	.	2TBSP.PRN	LOOSE STOOLS
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	32, .	14JUL95	20JUL95	500MG	EXTRACTED WISDOM TOOTH
CENTRAL NERVOUS SYSTEM	Pain Reliever	Premenstrual Syndrome Pain Relief {Nos}	-893, .	01JAN93	.	500MG PRN	PREMENSTRUAL TENSION
	Paracetamol	Tylenol	-893, .	01JAN93	.	500MG PRN	HEADACHE
MUSCULO-SKELETAL	Etodolac	Lodine	32, .	14JUL95	17JUL95	200MG	EXTRACTED WIDSOM TEETH

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Diarrhea	LOOSE STOOLS	17, .	Not Stated	20		MOD	NO	PSR	Yes	No
	Nausea	NAUSEA	17, .	Not Stated	20	CON	MOD	NO	PSR	No	No
	Tooth Disorder	WISDOM TOOTH EXTRACTION {TOOTH DISORDER}	32, .	03:00 Hrs	30	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Sweating	SWEATING INCREASED	25, .	Not Stated	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07JUN95	-6, .	0	138	72	132	144	59	95	308.26	68.1
BL	13JUN95	1, .	0	144	98	105	149	85	114	308.80	
1	20JUN95	8, .	20	152	80	95	155	58	105	308.00	
2	27JUN95	15, .	20	145	55	88	145	79	97	307.80	
3	05JUL95	23, .	20	145	79	95	147	72	108	309.50	
4	11JUL95	29, .	30	138	76	80	138	83	87	308.30	
5	18JUL95	36, .	40	131	72	109	148	69	111	308.40	
6	27JUL95	45, .	40	148	72	91	146	62	109	308.90	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.4	.	.	.	30 - 70	%
				Lymphocytes	33.3	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	233000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	109	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00133 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	06JUL95	1	13JUL95	8	8
00134	Oral	2	100 MG	14JUL95	9	18JUL95	13	5
00134	Oral	3	150 MG	19JUL95	14	25JUL95	20	7
00134	Oral	4	200 MG	26JUL95	21	02AUG95	28	8
00134	Oral	4	200 MG	03AUG95	29	07AUG95	33	5
00134	Oral	4	200 MG	08AUG95	34	14AUG95	40	7
00134	Oral	4	200 MG	15AUG95	41	23AUG95	49	9
00134	Oral	4	200 MG	24AUG95	50	28AUG95	54	5
00134	Oral	3	150 MG	29AUG95	55	09SEP95	66	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	66	150	Adverse event, including intercurrent illness	PATIENT WITHDRAWN FOR TACHYCARDIA&INCREASED QT/QTC

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DERMATOLOGICAL FUNGUS	MYCOSES	INFECTIOUS/PARASITIC DIS	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1993
OCCASIONAL STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
SPRAINED ARM MUSCLES	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Ketoconazole	Nizoral	-1, .	05JUL95	10JUL95	200MG	FUNGUS
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	38, .	12AUG95	.	500MG PRN	HEADACHE
		Midol	-916, .	01JAN93	.	2TABLETS	MENSTRUAL CRAMPS
	Caffeine	Midol	-916, .	01JAN93	.	2TABLETS	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-916, .	01JAN93	.	2TABLETS	MENSTRUAL CRAMPS
DERMATOLOGICALS	Ketoconazole	Nizoral	-1, .	05JUL95	10JUL95	200MG	FUNGUS
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Triphasil	-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
			-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
	Levonorgestrel	Triphasil	-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
			-1282, .	01JAN92	.	1PILL PER DAY	BIRTH CONTROL
MUSCULO-SKELETAL	Naproxen	Naproxen	-34, .	02JUN95	09JUN95#	500MG PRN	SPRAINED MUSCLE
	Naproxen Sodium	Anaprox	-916, .	01JAN93	.	550MG PRN	MENSTRUAL CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	5, .	65 Days	50	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE(OCCASIONAL)	38, .	Not Stated	200		MIL	NO	PSR	Yes	No
Carciovascular System	Postural Hypotension	POSTURAL HYPOTENSION	37, .	33 Days	200	3	MOD	NO	PSR	No	No
	Qt Interval Prolonged	INCREASED QT/{CORRECTED}QTC RATIO	55, .	15 Days	150	CON	MOD	STP	REL	No	No
	Syncope	BLACKOUTS	37, .	33 Days	200	3	MOD	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	37, .	33 Days	200		MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	22, .	48 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	37, .	33 Days	200	CON	MOD	STP	REL	No	No
	Somnolence	HYPERSOMNOLENCE	5, .	65 Days	50	CON	MOD	NO	PSR	No	No
Skin and Appendages	Sweating	INCREASED SWEATING	22, .	48 Days	200	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	28JUN95	-8, .	0	114	60	76	115	76	93	122.50	66.0
BL	06JUL95	1, .	0	122	68	93	128	73	119	122.50	
1	14JUL95	9, .	100	114	56	95	106	72	111	122.70	
2	19JUL95	14, .	150	122	72	101	122	75	105	124.70	
3	26JUL95	21, .	200	114	76	93	121	84	112	122.20	
4	03AUG95	29, .	200	115	76	98	122	72	114	123.90	
5	08AUG95	34, .	200	122	76	115	115	80	117	123.50	
6	15AUG95	41, .	200	122	90	108	131	84	108	124.00	
7	24AUG95	50, .	200	136	81	88	129	82	101	124.20	
8	29AUG95	55, .	150	115	69	94	104	88	115	122.80	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	4.9	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	325000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	77	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.6	.	.	.	30 - 70	%
				Lymphocytes	34.9	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	363000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	86	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00134 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	02OCT95	1	08OCT95	7	7
00135	Oral	2	0 MG	09OCT95	8	15OCT95	14	7
00135	Oral	3	0 MG	16OCT95	15	22OCT95	21	7
00135	Oral	4	0 MG	23OCT95	22	29OCT95	28	7
00135	Oral	5	0 MG	30OCT95	29	05NOV95	35	7
00135	Oral	4	0 MG	06NOV95	36	19NOV95	49	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	49	0	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
DYSMENORRHEA{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
HYPOTHYROID	HYPOTHYROIDISM	ENDOCR/METAB/IMMUNITY DISORD	CUR	1992
MENSTRUAL CRAMPS{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
PARTIAL THYROIDECTOMY	OPERATION, ENDOCR	OPERATIONS	PRV	1991

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Amitriptyline Hydrochloride	Elavil	-9,	.	23SEP95	24SEP95#	25MG	DEPRESSION
	Paroxetine	Paxil	36,	.	06NOV95	.	10MG	DEPRESSION
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	-274,	.	01JAN95	.	220MG PRN	HEADACHES
SYSTEMIC HORMONAL	Levothyroxine Sodium	Synthroid	-1370,	.	01JAN92	.	150MG	HYPOTHYROID

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	29, .	21 Days	0	CON	MIL	NO	PSR	No	No
Digestive System	Diarrhea	DIARRHEA	20, .	1 Days	0	CON	MIL	NO	UNR	No	No
	Nausea	NAUSEA	20, .	2 Days	0	CON	MIL	NO	UNR	No	No
	Vomiting	VOMITING	20, .	2 Days	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25SEP95	-7, .	0	113	74	89	122	60	100	133.60	71.0
BL	02OCT95	1, .	0	113	63	78	.	.	.	131.60	
1	09OCT95	8, .	0	118	56	83	124	59	91	132.70	
2	16OCT95	15, .	0	119	60	80	121	70	88	131.70	
3	23OCT95	22, .	0	123	56	86	122	56	88	133.90	
4	30OCT95	29, .	0	122	64	74	122	56	80	132.40	
5	06NOV95	36, .	0	107	82	86	123	68	105	133.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.8	.	.	.	30 - 70	%
				Lymphocytes	23.4	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00135 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03OCT95	1	09OCT95	7	7
00136	Oral	2	0 MG	10OCT95	8	16OCT95	14	7
00136	Oral	3	0 MG	17OCT95	15	23OCT95	21	7
00136	Oral	4	0 MG	24OCT95	22	02NOV95	31	10
00136	Oral	5	0 MG	03NOV95	32	06NOV95	35	4
00136	Oral	5	0 MG	07NOV95	36	13NOV95	42	7
00136	Oral	5	0 MG	14NOV95	43	20NOV95	49	7
00136	Oral	5	0 MG	21NOV95	50	27NOV95	56	7
00136	Oral	4	0 MG	28NOV95	57	11DEC95	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	70	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1992
SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1995
SPRAINED LEFT ANKLE	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	-1005,	.	01JAN93	.	2 TABS PRN	MENSTRUAL CRAMPS
	Caffeine	Midol	-1005,	.	01JAN93	.	2 TABS PRN	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-1005,	.	01JAN93	.	2 TABS PRN	MENSTRUAL CRAMPS
MUSCULO-SKELETAL	Ibuprofen	Advil	-275,	.	01JAN95	.	750 MG PRN	OCCASSIONAL HEADACHE
RESPIRATORY	Dexbrompheniramine Maleate	Drixoral	-275,	.	01JAN95	.	500 PRN	SINUS CONGESTION
	Pseudoephedrine Sulfate	Drixoral	-275,	.	01JAN95	.	500 PRN	SINUS CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	33, .	11 Days	0	3	MIL	NO	PBU	Yes	No
Metabolic and Nutritional Disorders	Thirst	INCREASE IN THIRST	8, .	15 Days	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Contact Dermatitis	CONTACT DERMATITIS LOWER AND UPPER HIP	8, .	15 Days	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26SEP95	-7, .	0	131	56	109	105	72	115	287.60	66.5
BL	03OCT95	1, .	0	119	76	102	124	66	115	299.60	
1	10OCT95	8, .	0	132	57	81	84 L	63	114	296.40	
2	17OCT95	15, .	0	124	48 L	90	102	73	117	288.90	
3	24OCT95	22, .	0	101	50	86	114	56	115	292.80	
4	03NOV95	32, .	0	109	54	54	117	67	86		
5	07NOV95	36, .	0	133	80	66	131	50	103	294.00	
6	14NOV95	43, .	0	124	60	84	109	55	111	287.40	
7	21NOV95	50, .	0	116	62	74	110	82	100	293.80	
8	28NOV95	57, .	0	125	57	86	105	49	96	296.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61	.	.	.	30 - 70	%
				Lymphocytes	25.1	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	346000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	130	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	34.7	L	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.1	H	.	.	30 - 70	%
				Lymphocytes	19	L	.	.	21 - 51	%
				Monocytes	3.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	119	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00136 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	10OCT95	1	16OCT95	7	7
00137	Oral	2	100 MG	17OCT95	8	23OCT95	14	7
00137	Oral	3	150 MG	24OCT95	15	30OCT95	21	7
00137	Oral	4	200 MG	31OCT95	22	06NOV95	28	7
00137	Oral	4	200 MG	07NOV95	29	13NOV95	35	7
00137	Oral	4	200 MG	14NOV95	36	20NOV95	42	7
00137	Oral	4	200 MG	21NOV95	43	27NOV95	49	7
00137	Oral	4	200 MG	28NOV95	50	04DEC95	56	7
	Oral	3	150 MG	05DEC95	57	16DEC95	68	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	No	68	150		TEAM FELT THAT DUE TO CONTINUING ADHD SYMPTOMS PATIENT NEEDED TREATMENT WITH STIMULANT

* Relative to Start of Study Medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	36, .	22 Days	200	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	39, .	4 Days	200		MIL	NO	PSR	No	No
Nervous System	Somnolence	SOMNOLENCE	16, .	42 Days	150	CON	MOD	NO	PSR	No	No
Urogenital System	Urinary Frequency	INCREASED URINATION	8, .	8 Days	100	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

					Sitting			Standing				
Week	Visit Date	Relative Days *		Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	03OCT95	-7,	.	0	101	53	100	111	64	115	87.30	62.0
BL	10OCT95	1,	.	0	99	54	85	98	57	101	88.30	
1	17OCT95	8,	.	100	114	60	98	106	60	101	86.50	
2	24OCT95	15,	.	150	120	72	105	109	64	114	85.70	
3	31OCT95	22,	.	200	111	60	88	102	63	.	84.80	
4	07NOV95	29,	.	200	93	50	108	84	52	117	85.10	
5	14NOV95	36,	.	200	106	56	101	91	56	126	85.60	
6	21NOV95	43,	.	200	118	69	102	98	54	114	86.00	
7	28NOV95	50,	.	200	99	60	112	98	52	111	84.90	
8	05DEC95	57,	.	150	130	59	111	103	56	119	85.90	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7	.	.	.	30 - 70	%
				Lymphocytes	29.6	.	.	.	21 - 51	%
				Monocytes	2.8	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	310000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	426	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.7	L	.	-	41 - 50	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	67.7	.	.	.	30 - 70	%
				Lymphocytes	24.5	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	288000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	367	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00137 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00138 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	10OCT95	1	13OCT95	4	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	4	20	Other reason	PATIENT WITHDREW CONSENT

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00138 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
OCCASIONAL STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02OCT95	-8, .	0	114	64	76	107	71	84	116.50	65.5
BL	10OCT95	1, .	0	122	61	83	115	65	98	117.70	
1	17OCT95	8, .	20	104	54	70	107	71	85	117.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00138 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	12.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	4.8	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	296000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	149	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00138 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	31OCT95	1	06NOV95	7	7
00169	Oral	2	0 MG	07NOV95	8	13NOV95	14	7
00169	Oral	3	0 MG	14NOV95	15	20NOV95	21	7
00169	Oral	4	0 MG	21NOV95	22	27NOV95	28	7
00169	Oral	4	0 MG	28NOV95	29	04DEC95	35	7
00169	Oral	4	0 MG	05DEC95	36	11DEC95	42	7
00169	Oral	4	0 MG	12DEC95	43	18DEC95	49	7
00169	Oral	4	0 MG	19DEC95	50	27DEC95	58	9
00098	Oral	4	0 MG	04JAN96	66	22JAN96	84	19
00169	Oral	4	0 MG	23JAN96	85	23JAN96	85	1
00169	Oral	3	0 MG	24JAN96	86	25JAN96	87	2
00169	Oral	2	0 MG	26JAN96	88	28JAN96	90	3
00169	Oral	1	0 MG	29JAN96	91	04FEB96	97	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	97	0	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Permethrin	Elimite	36, -30	05DEC95	05DEC95	5 %	SCABIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	SCABIES	34, -32	13 Days	0	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	SLIGHT DIZZINESS WHEN TAKING MEDS	50, -16	Not Stated	0	CON	MOD	NO	PSR	No	No
	Insomnia	MILD INITIAL INSOMNIA	43, -23	Not Stated	0	CON	MIL	NO	PSR	No	No
	Manic Reaction	HYPOMANIA	64, -2	Not Stated	0	CON	SEV	STP	REL	No	No
	Somnolence	DAYTIME SLEEPINESS	23, -43	17 Days	0		MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25OCT95	-6, -71	0	110	57	70	110	69	67	80.90	56.0
BL	31OCT95	1, -65	0	108	52	94	111	57	98	80.20	
1	07NOV95	8, -58	0	92	42	74	99	45	90	80.40	
2	14NOV95	15, -51	0	113	63	86	110	56	106	81.90	
3	21NOV95	22, -44	0	110	53	80	106	53	79	83.40	
4	28NOV95	29, -37	0	106	56	102	107	57	106	83.00	
5	05DEC95	36, -30	0	119	54	74	112	61	75	83.30	
6	12DEC95	43, -23	0	99	45	86	98	46	97	83.10	
7	19DEC95	50, -16	0	108	57	84	99	57	95	84.10	
8	27DEC95	58, -8	0	95	53	76	98	52	93	82.50	
12	23JAN96	85, 20	0	122	68	108	107	44	111	86.20 H	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.2	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.4	.	.	.	30 - 70	%
				Lymphocytes	32.2	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	274000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	203	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	30 - 70	%
				Lymphocytes	35.1	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	4.3	.	.	.	0 - 5	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	267000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.6	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	210	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00169 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07NOV95	1	13NOV95	7	7
00170	Oral	2	20 MG	14NOV95	8	20NOV95	14	7
00170	Oral	3	20 MG	21NOV95	15	27NOV95	21	7
00170	Oral	4	20 MG	28NOV95	22	04DEC95	28	7
00170	Oral	5	30 MG	05DEC95	29	11DEC95	35	7
00170	Oral	6	40 MG	12DEC95	36	20DEC95	44	9
00170	Oral	6	40 MG	21DEC95	45	28DEC95	52	8
00170	Oral	5	30 MG	29DEC95	53	02JAN96	57	5
00102	Oral	5	30 MG	03JAN96	58	28JAN96	83	26
00102	Oral	5	30 MG	29JAN96	84	25FEB96	111	28
00102	Oral	5	30 MG	26FEB96	112	31MAR96	146	35
00102	Oral	5	30 MG	01APR96	147	21APR96	167	21
00102	Oral	5	30 MG	22APR96	168	22MAY96	198	31
00102	Oral	5	30 MG	23MAY96	199	24JUN96	231	33
00358	Oral	4	20 MG	25JUN96	232	26JUN96	233	2
00358	Oral	3	20 MG	27JUN96	234	28JUN96	235	2
00358	Oral	2	20 MG	29JUN96	236	01JUL96	238	3
00358	Oral	1	20 MG	02JUL96	239	08JUL96	245	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	Yes	245	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BILATERAL LEG PAIN:MUSCULAR ORIGIN	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SCOLIOSIS	DEFORMITY, ACQUIRED	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Maalox Liquid	238, 181	01JUL96	.	8-16 TSP	NAUSEA
	Magnesium Hydroxide	Maalox Liquid	238, 181	01JUL96	.	8-16 TSP	NAUSEA
MUSCULO-SKELETAL	Ibuprofen	Motrin	246, 189	09JUL96	.	400 MG	DYSMENORRHEA
RESPIRATORY	Dimenhydrinate	Dramamine	238, 181	01JUL96	.	100 MG	NAUSEA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	234, 177	11 Days	20	CON	MOD	NO	PSR	No	Yes
Digestive System	Constipation	CONSTIPATION	244, 187	Not Stated	20	CON	MIL	NO	UNR	No	No
	Decreased Appetite	LOSS OF APPETITE	3, -55	43 Days	20	CON	MIL	NO	PSR	No	No
			45, -13	14 Days	40	CON	MOD	DCR	PSR	No	No
	Increased Appetite	INCREASED APPETITE	147, 90	85 Days	30	CON	MIL	NO	PSR	No	No
			237, 180	9 Days	20	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	234, 177	12 Days	20	CON	SEV	NO	REL	Yes	Yes
	Vomiting	VOMITING	238, 181	6 Days	20	CON	SEV	NO	REL	Yes	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS	45, -13	14 Days	40	CON	MIL	NO	PBU	No	No
Nervous System	Agitation	AGITATION	246, 189	12:00 Hrs	20	CON	MOD	NO	PSR	No	Yes
	Insomnia	MIDDLE INSOMNIA	17, -41	6 Days	20	CON	MIL	NO	PSR	No	No
			22, -36	37 Days	20	CON	MOD	NO	PSR	No	No
	Somnolence	DROWSY	234, 177	11 Days	20	CON	MOD	NO	PSR	No	Yes
		SLEEPINESS WHEN TAKING EVENING MEDS	45, -13	14 Days	40	CON	MOD	NO	PSR	No	No
	Tremor	SHAKY TREMORS	234, 177	2 Days	20	CON	MOD	NO	PSR	No	Yes
Urogenital System	Dysmenorrhea	DYSMENORRHEA	244, 187	Not Stated	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26OCT95	-12, -69	0	135	86	112	126	86	115	101.60	65.5
1	14NOV95	8, -50	20	130	68	112	146	96	133	101.60	
2	21NOV95	15, -43	20	128	79	114	124	80	126	101.10	
3	28NOV95	22, -36	20	128	90	109	114	79	109	100.30	
4	05DEC95	29, -29	30	129	83	115	126	91	119	100.90	
5	12DEC95	36, -22	40	106	70	97	116	68	108	100.60	
6	21DEC95	45, -13	40	107	68	84	100	73	90	98.80	
7	29DEC95	53, -5	30	124	90	108	116	84	105	100.60	
8	03JAN96	58, 1	30	130	80	125	124	81	125	101.50	
12	29JAN96	84, 27	30	105	65	105	99	57	100	103.40	
16	26FEB96	112, 55	30	114	52	106	114	49 L	108	105.90	
20	01APR96	147, 90	30	93	76	78	115	60	102	106.30	
24	22APR96	168, 111	30	114	72	93	128	67	98	109.00 H	
28	23MAY96	199, 142	30	113	96	74	111	74	99	113.40 H	
32	24JUN96	231, 174	30	128	82	99	131	85	99	114.60 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	301000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	141	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	114	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
			-5	Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.5	.	.	.	30 - 70	%
				Lymphocytes	26.4	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	2.9	H	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	6	.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.4	H	.	.	30 - 70	%
				Lymphocytes	18.7	L	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	271000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	147	Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	122	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	231	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.9	.	.	.	30 - 70	%
				Lymphocytes	48.3	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16/CONTINUATION-WEEK 32	231	Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	125	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	45	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	61	H	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 17/DOWN TITRATION	247 (2)	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.3	.	.	.	30 - 70	%
				Lymphocytes	38.6	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00170 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 17/DOWN TITRATION	247 (2)	Monocytes	3.5	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	216000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	115	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	62	L	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	07NOV95	1	14NOV95	8	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	8	50	Adverse event, including intercurrent illness	MACULAR RASH

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGY TO IODINE	ADVERSE EFF/OTHER DRUG	EXT CAUSES OF INJURY/POISONING	CUR	1994
PREGNANCY	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1994
SEXUAL ASSAULT{STATUS POST,NO POST-TRAUMATIC STRESS DISORDER SYNDROME}	RAPE	EXT CAUSES OF INJURY/POISONING	PRV	1992
SUICIDE ATTEMPT{NOT IN CURRENT EPISODE}	SUICIDE	EXT CAUSES OF INJURY/POISONING	PRV	1994
WEIGHT LOSS{52LBS.-PLANNED}	WEIGHT LOSS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1995
{CHILDBIRTH}	PREGNANCY, COMPLICATIONS	COMPLIC OF PREGNANCY/BIRTH	PRV	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Triphasil	1, .	07NOV95	.	1TAB	BIRTH CONTROL
			1, .	07NOV95	.	1TAB	BIRTH CONTROL
	Levonorgestrel	Triphasil	1, .	07NOV95	.	1TAB	BIRTH CONTROL
			1, .	07NOV95	.	1TAB	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory System	Pharyngitis	SORE THROAT	8, .	Not Stated	50	CON	MIL	NO	PBU	No	No
	Sinusitis	SINUS CONGESTION	8, .	Not Stated	50	CON	MIL	NO	PBU	No	No
Skin and Appendages	Maculopapular Rash	RASH{FINE MACULAR ON FACE,INSIDE ELBOWS,BACK}	4, .	Not Stated	50	CON	SEV	STP	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	31OCT95	-7, .	0	131	69	79	135	74	109	200.60	62.0
BL	07NOV95	1, .	0	116	60	98	116	59	97	201.90	
1	14NOV95	8, .	50	122	71	93	115	74	105	199.30	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.1	.	.	.	35 - 46	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1	.	.	.	30 - 70	%
				Lymphocytes	22.1	.	.	.	21 - 51	%
				Monocytes	2.7	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	404000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	128	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00171 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	13NOV95	1	19NOV95	7	7
00172	Oral	2	100 MG	20NOV95	8	26NOV95	14	7
00172	Oral	3	150 MG	27NOV95	15	03DEC95	21	7
00172	Oral	4	200 MG	04DEC95	22	10DEC95	28	7
00172	Oral	4	200 MG	11DEC95	29	20DEC95	38	10
00172	Oral	4	200 MG	21DEC95	39	26DEC95	44	6
00172	Oral	4	200 MG	27DEC95	45	02JAN96	51	7
00172	Oral	4	200 MG	03JAN96	52	08JAN96	57	6
00097	Oral	4	200 MG	09JAN96	58	06FEB96	86	29
00097	Oral	4	200 MG	07FEB96	87	03MAR96	112	26
00097	Oral	4	200 MG	04MAR96	113	31MAR96	140	28
00097	Oral	4	200 MG	01APR96	141	28APR96	168	28
00097	Oral	4	200 MG	29APR96	169	09JUN96	210	42
00097	Oral	4	200 MG	10JUN96	211	07JUL96	238	28
00360	Oral	4	200 MG	08JUL96	239	08JUL96	239	1
00360	Oral	3	150 MG	09JUL96	240	10JUL96	241	2
00360	Oral	2	100 MG	11JUL96	242	13JUL96	244	3
00360	Oral	1	50 MG	14JUL96	245	20JUL96	251	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	251	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-681, -738	01JAN94	.	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Tachycardia	TACHYCARDIA	2, -56	14 Days	50	2	MIL	NO	PBU	No	No
Digestive System	Diarrhea	DIARRHEA	249, 192	2 Days	50	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	23, -35	231 Days	200	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	249, 192	2 Days	50	CON	MIL	NO	PBU	No	No
Nervous System	Abnormal Dreams	NIGHTMARES	36, -22	52 Days	200		MOD	NO	PSR	No	No
	Dizziness	DIZZINESS	21, -37	233 Days	150	CON	MOD	NO	PSR	No	No
	Insomnia	INITIAL INSOMNIA	211, 154	29 Days	200	CON	MIL	NO	PBU	No	No
	Somnolence	SOMNOLENCE	17, -41	6 Days	150	CON	MOD	NO	PSR	No	No
	Thinking Abnormal	RACING THOUGHTS	40, -18	13 Days	200		MIL	NO	PBU	No	No
Special Senses	Tinnitus	RINGING IN EARS	21, -37	30 Days	150		MIL	NO	PSR	No	No
Urogenital System	Urinary Retention	URINARY RETENTION	58, 1	8 Days	200	CON	MOD	NO	PBU	No	No
	Urination Impaired	HARD TO INITIATE URINATION	58, 1	8 Days	200	CON	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06NOV95	-7, -64	0	125	71	100	147	76	115	126.50	64.0
BL	13NOV95	1, -57	0	129	63	84	124	73	109	126.50	
1	20NOV95	8, -50	100	122	70	129 H	115	57	137	123.60	
2	27NOV95	15, -43	150	98	66	101	104	58	92	123.00	
3	04DEC95	22, -36	200	126	81	92	121	69	96	125.00	
4	11DEC95	29, -29	200	102	53	88	129	67	100	122.50	
5	21DEC95	39, -19	200	117	67	108	108	56	.	121.40	
6	27DEC95	45, -13	200	131	81	104	112	47 L	108	121.90	
7	03JAN96	52, -6	200	115	61	102	102	56	110	121.70	
8	09JAN96	58, 1	200	101	76	102	85 L	33 L	108	121.50	
12	07FEB96	87, 30	200	99	49	104	91	37 L	108	122.80	
16	04MAR96	113, 56	200	107	53	109	118	57	114	121.20	
20	01APR96	141, 84	200	123	65	120	108	41 L	120	125.10	
24	29APR96	169, 112	200	123	74	92	114	79	104	123.30	
28	10JUN96	211, 154	200	123	77	112	106	68	115	122.40	
32	08JUL96	239, 182	200	114	64	114	91	41 L	90	121.90	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7	.	.	.	30 - 70	%
				Lymphocytes	36.6	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2.3	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Intent-to-Treat Population

PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.6	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.7	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.1	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	4.8	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	141	Alkaline Phosphatase	127	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	239	Hemoglobin	12.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.3	.	.	.	30 - 70	%
				Lymphocytes	42.9	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	267000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.009.00172 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 16/CONTINUATION-WEEK 32	239	Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	121	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	20NOV95	1	26NOV95	7	7
00173	Oral	2	20 MG	27NOV95	8	03DEC95	14	7
00173	Oral	3	20 MG	04DEC95	15	10DEC95	21	7
00173	Oral	4	20 MG	11DEC95	22	17DEC95	28	7
00173	Oral	5	30 MG	18DEC95	29	28DEC95	39	11
00173	Oral	5	30 MG	29DEC95	40	07JAN96	49	10
00173	Oral	4	20 MG	08JAN96	50	14JAN96	56	7
00173	Oral	4	20 MG	15JAN96	57	21JAN96	63	7
00108	Oral	4	20 MG	22JAN96	64	26FEB96	99	36
00173	Oral	4	20 MG	27FEB96	100	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	100	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
STOMACH ACHE	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
UPPER RESPIRATORY TRACT INFECTION	UPPER RESP INFECT, ACUTE	RESPIRATORY SYST DIS	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Chlorphenamine Maleate	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
	Dextromethorphan Hydrobromide	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
	Paracetamol	Tylenol	-19, -82	01NOV95	.	650MG PRN	UPPER RESP. TRACT INFECTION
		Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
	Pseudoephedrine Hydrochloride	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
			-19, -82	01NOV95	.	2TABS PRN	URI
	Dextromethorphan Hydrobromide	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
			-19, -82	01NOV95	.	2TABS PRN	URI
	Paracetamol	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
			-19, -82	01NOV95	.	2TABS PRN	URI
	Pseudoephedrine Hydrochloride	Tylenol Cold {Medicine}	-19, -82	01NOV95	.	2TABS PRN	URI
			-19, -82	01NOV95	.	2TABS PRN	URI

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	43, -21	Not Stated	30	CON	MOD	NO	PSR	No	No
Nervous System	Insomnia	INSOMNIA	57, -7	Not Stated	20	CON	MOD	NO	PSR	No	No
	Nervousness	RESTLESSNESS	40, -24	18 Days	30	CON	MOD	DCR	PSR	No	No
	Somnolence	INCREASED DAYTIME SLEEPINESS SOMNOLENCE	24, -40	Not Stated	20	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08NOV95	-12, -75	0	131	68	84	129	68	86	145.80	64.2
BL	20NOV95	1, -63	0	133	80	85	131	73	96	142.60	
1	27NOV95	8, -56	20	130	64	80	132	67	84	147.10	
2	04DEC95	15, -49	20	110	67	66	123	64	74	142.90	
3	11DEC95	22, -42	20	117	59	80	115	69	83	144.60	
4	18DEC95	29, -35	30	121	60	75	122	68	80	145.60	
6	29DEC95	40, -24	30	131	65	87	122	56	88	144.30	
7	08JAN96	50, -14	20	124	57	98	131	68	96	139.00	
8	15JAN96	57, -7	20	131	69	88	122	74	94	140.10	
8	22JAN96	64, 1	20	114	61	80	116	66	87	141.60	
12	26FEB96	99, 36	20	100	50	80	124	61	85	139.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-12	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	33	.	.	.	30 - 70	%
				Lymphocytes	46	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	8	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	382	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEC		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	36	.	.	.	30 - 70	%
				Lymphocytes	57	H	.	.	21 - 51	%
				Monocytes	0	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	293000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00173 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Blood Urea Nitrogen	7	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	289	H	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21NOV95	1	27NOV95	7	7
00174	Oral	2	0 MG	28NOV95	8	04DEC95	14	7
00174	Oral	3	0 MG	05DEC95	15	11DEC95	21	7
00174	Oral	4	0 MG	12DEC95	22	18DEC95	28	7
00174	Oral	5	0 MG	19DEC95	29	26DEC95	36	8
00174	Oral	5	0 MG	27DEC95	37	01JAN96	42	6
00174	Oral	5	0 MG	02JAN96	43	08JAN96	49	7
00174	Oral	5	0 MG	09JAN96	50	16JAN96	57	8
00107	Oral	5	0 MG	17JAN96	58	30JAN96	71	14
00174	Oral	4	0 MG	31JAN96	72	01FEB96	73	2
00174	Oral	3	0 MG	02FEB96	74	03FEB96	75	2
00174	Oral	2	0 MG	04FEB96	76	06FEB96	78	3
00174	Oral	1	0 MG	07FEB96	79	13FEB96	85	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	85	0	Lack of Efficacy	PT.HAD RELAPSE-NEEDED TX

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES{SEASONAL}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
MILD OBESITY	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
TEMPOROMANDIBULAR JOINT SYNDROME	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	13, -45	03DEC95	07DEC95	2TBS.PRN	FLU
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	-689, -746	01JAN94	.	500 MG PRN	HEADACHES
			13, -45	03DEC95	07DEC95	500MG	FLU
	Caffeine	Excedrin	-689, -746	01JAN94	.	500 MG PRN	HEADACHES
			13, -45	03DEC95	07DEC95	500MG	FLU
	Paracetamol	Excedrin	-689, -746	01JAN94	.	500 MG PRN	HEADACHES
			13, -45	03DEC95	07DEC95	500MG	FLU
MUSCULO-SKELETAL	Oxaprozin	Daypro	-13, -70	08NOV95	.	600MG PRN	TMJ
RESPIRATORY	Dexbrompheniramine Maleate	Drixoral	-385, -442	01NOV94	.	2TABS PRN	ALLERGIES
	Pseudoephedrine Sulfate	Drixoral	-385, -442	01NOV94	.	2TABS PRN	ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	13, -45	Not Stated	0		MOD	NO	PSR	Yes	No
	Infection	FLU{STOMACH ACHE}	13, -45	5 Days	0	CON	MIL	NO	UNR	Yes	No
Digestive System	Constipation	CONSTIPATION	20, -38	Not Stated	0		MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14NOV95	-7, -64	0	115	60	64	123	85	98	219.20	65.5
BL	21NOV95	1, -57	0	132	74	91	124	66	105	219.60	
1	28NOV95	8, -50	0	125	77	101	135	72	111	222.40	
2	05DEC95	15, -43	0	145	89	84	158	84	105	218.90	
3	12DEC95	22, -36	0	135	66	81	136	71	100	223.00	
4	19DEC95	29, -29	0	129	79	106	137	67	114	222.40	
5	27DEC95	37, -21	0	145	88	105	138	72	126	224.00	
6	02JAN96	43, -15	0	123	68	80	147	78	86	224.10	
7	09JAN96	50, -8	0	136	83	104	150	85	109	222.40	
8	17JAN96	58, 1	0	138	83	108	149	76	104	220.40	
12	31JAN96	72, 15	0	114	68	95	122	70	105	221.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.4	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	56	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	30 - 70	%
				Lymphocytes	34	.	.	.	21 - 51	%
				Monocytes	3.8	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	304000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	62	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00174 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28NOV95	1	04DEC95	7	7
00193	Oral	2	20 MG	05DEC95	8	11DEC95	14	7
00193	Oral	3	20 MG	12DEC95	15	18DEC95	21	7
00193	Oral	4	20 MG	19DEC95	22	26DEC95	29	8
00193	Oral	5	30 MG	27DEC95	30	04JAN96	38	9
00193	Oral	5	30 MG	05JAN96	39	08JAN96	42	4
00193	Oral	5	30 MG	09JAN96	43	15JAN96	49	7
00193	Oral	5	30 MG	16JAN96	50	23JAN96	57	8
	Oral	1	20 MG	24JAN96	58	06FEB96	71	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	71	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Excedrin	-331, .	01JAN95	.	500PRN	HEADACHE
	Caffeine	Excedrin	-331, .	01JAN95	.	500PRN	HEADACHE
	Paracetamol	Excedrin	-331, .	01JAN95	.	500PRN	HEADACHE
MUSCULO-SKELETAL	Eucalyptus Oil	Hall'S Cough Drops	15, .	12DEC95	27DEC95	1PRN	URI
	Ibuprofen	Ibuprofen	15, .	12DEC95	27DEC95	200MG PRN	URI
	Menthol	Hall'S Cough Drops	15, .	12DEC95	27DEC95	1PRN	URI
RESPIRATORY	Dextromethorphan Hydrobromide	Nyquil	15, .	12DEC95	27DEC95	1TBS PRN	URI
	Doxylamine Succinate	Nyquil	15, .	12DEC95	27DEC95	1TBS PRN	URI
	Eucalyptus Oil	Hall'S Cough Drops	15, .	12DEC95	27DEC95	1PRN	URI
	Menthol	Hall'S Cough Drops	15, .	12DEC95	27DEC95	1PRN	URI
	Paracetamol	Nyquil	15, .	12DEC95	27DEC95	1TBS PRN	URI
	Pseudoephedrine Hydrochloride	Nyquil	15, .	12DEC95	27DEC95	1TBS PRN	URI

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Nervousness	RESTLESSNESS	4, .	12 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD SYNDROME (URI) {UPPER RESPIRATORY INFECTION}	13, .	18 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21NOV95	-7, .	0	121	63	89	127	65	101	131.90	63.8
BL	28NOV95	1, .	0	111	51	90	130	64	100	134.60	
1	05DEC95	8, .	20	127	64	80	129	63	79	132.40	
2	12DEC95	15, .	20	115	57	76	114	57	93	132.90	
3	19DEC95	22, .	20	105	65	91	117	65	119	133.20	
4	27DEC95	30, .	30	123	57	95	122	60	103	136.10	
5	05JAN96	39, .	30	109	46	91	99	52	103	134.00	
6	09JAN96	43, .	30	123	53	94	122	60	108	139.00	
7	16JAN96	50, .	30	114	52	93	122	62	72	137.50	
8	24JAN96	58, .	20	114	64	103	134	69	105	139.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.6	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	14	H	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.6	H	.	.	30 - 70	%
				Lymphocytes	16.7	L	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	324000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	173	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	12.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.5	.	.	.	30 - 70	%
				Lymphocytes	25.5	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	26.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	162	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00193 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05DEC95	1	11DEC95	7	7
00194	Oral	2	100 MG	12DEC95	8	18DEC95	14	7
00194	Oral	3	150 MG	19DEC95	15	26DEC95	22	8
00194	Oral	4	200 MG	27DEC95	23	01JAN96	28	6
00194	Oral	4	200 MG	02JAN96	29	08JAN96	35	7
00194	Oral	4	200 MG	09JAN96	36	15JAN96	42	7
00194	Oral	4	200 MG	16JAN96	43	22JAN96	49	7
00194	Oral	4	200 MG	23JAN96	50	29JAN96	56	7
00105	Oral	4	200 MG	30JAN96	57	26FEB96	84	28
00105	Oral	4	200 MG	27FEB96	85	01APR96	119	35
00105	Oral	4	200 MG	02APR96	120	29APR96	147	28
00105	Oral	4	200 MG	30APR96	148	04JUN96	183	36
00194	Oral	4	200 MG	05JUN96	184	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	184	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES TO MILK	ALLERGIC REACTION, FOOD	INJURY/POISONING	CUR	1993
ANKLE PAIN{SECONDARY TO SURGICAL CORRECTION RIGHT FOOT{CLUB)}	OPERATION, MUSCLE/TENDON	OPERATIONS	CUR	1984
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MYALGIA{UNSPECIFIED}	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Cimetidine	Tagamet	28, -29	01JAN96	.	200MG	STOMACH ACHE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-703, -759	01JAN94	.	250MG PRN	ANKLE PAIN
		Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI
	Pseudoephedrine Hydrochloride	Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI
RESPIRATORY	Cough Syrup/Med	Cough Syrup {Nos}	29, -28	02JAN96	16JAN96	2TBL PRN	UPPER RESPIRATORY TRACT INFECTION
	Paracetamol	Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI
	Pseudoephedrine Hydrochloride	Tylenol Sinus	29, -28	02JAN96	16JAN96	750MG	URI

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	15, -42	181 Days	150	CON	MOD	NO	REL	Yes	No
Digestive System	Nausea	NAUSEA	43, -14	153 Days	200	CON	MOD	STP	PSR	No	No
Nervous System	Abnormal Dreams	INCREASED DREAMING	3, -54	34 Days	50		MOD	NO	PSR	No	No
		NIGHTMARES	3, -54	13 Days	50	1	MOD	NO	PSR	No	No
	Insomnia	INITIAL INSOMNIA	85, 29	64 Days	200	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD SYNDROME UPPER RESPIRATORY TRACT INFECTION(URI)	29, -28	15 Days	200	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Sweating	NIGHT SWEATS	120, 64	76 Days	200	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	28NOV95	-7, -63	0	109	58	66	98	69	68	90.40	56.8
BL	05DEC95	1, -56	0	116	55	77	95	62	88	91.40	
1	12DEC95	8, -49	100	105	53	88	104	54	83	90.20	
2	19DEC95	15, -42	150	112	69	95	118	62	89	90.20	
3	27DEC95	23, -34	200	114	65	98	108	62	111	91.30	
4	02JAN96	29, -28	200	116	80	117	138	73	119	90.00	
5	09JAN96	36, -21	200	109	57	105	106	62	109	91.00	
6	16JAN96	43, -14	200	114	68	106	116	66	102	90.80	
7	23JAN96	50, -7	200	107	62	106	100	56	108	91.10	
8	30JAN96	57, 1	200	106	57	98	113	62	102	89.90	
12	27FEB96	85, 29	200	93	48	97	114	48	87	89.90	
16	02APR96	120, 64	200	95	60	88	97	65	87	87.00	
20	30APR96	148, 92	200	106	53	81	111	52	83	86.70	
24	04JUN96	183, 127	200	104	56	99	117	53	100	87.40	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	36	L	.	-	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.3	.	.	.	30 - 70	%
				Lymphocytes	34.4	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	316000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.3	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	244	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	125	H	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	35.9	L	.	-	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.1	.	.	.	30 - 70	%
				Lymphocytes	32.7	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	284000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	78	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.1	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	259	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	12.8	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	28.6	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	4.9	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	289000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	239	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00194 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	148	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	15DEC95	1	18DEC95	4	4
00195	Oral	2	100 MG	19DEC95	5	26DEC95	12	8
00195	Oral	3	150 MG	27DEC95	13	01JAN96	18	6
00195	Oral	4	200 MG	02JAN96	19	07JAN96	24	6
	Oral	3	150 MG	08JAN96	25	19JAN96	36	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	36	150	Adverse event, including intercurrent illness	CARDIAC ARRHYTHYMIA(PVC'S)

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1991
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Codeine Phosphate	Tylenol Number 3	-14, .	01DEC95	02DEC95#	650MG	HEADACHE
	Paracetamol	Tylenol	-1809, .	01JAN91	.	650MG PRN	HEADACHE
		Tylenol Number 3	-14, .	01DEC95	02DEC95#	650MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Advil	-1809, .	01JAN91	.	200MG PRN	HEADACHE
	Naproxen Sodium	Anaprox	-713, .	01JAN94	.	275MG PRN	MENSTRUAL CRAMPS
RESPIRATORY	Salbutamol	Proventil	-348, .	01JAN95	.	2PUFFS PRN	SEASONAL ALLERGIES
			-348, .	01JAN95	.	2PUFFS PRN	SEASONAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chest Pain	CHEST PAIN	21, .	19 Days	200	2	MOD	NO	PSR	No	No
	Headache	HEAD PAIN	19, .	21 Days	200	20	MOD	NO	PSR	No	No
Carciovascular System	Extrasystoles	CARIDAC ARRHYTHMIA [PREMATURE VENTRICULAR CONTRACTIONS]	25, .	15 Days	150	CON	MOD	STP	REL	No	No
	Vasodilatation	FACIAL FLUSHING	11, .	29 Days	100	CON	MOD	NO	PSR	No	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS	13, .	13 Days	150	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	21, .	19 Days	200	CON	MOD	NO	PSR	No	No
Skin and Appendages	Sweating	SWEATING	11, .	29 Days	100	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06DEC95	-9, .	0	115	65	72	122	71	86	112.40	64.0
BL	15DEC95	1, .	0	123	58	63	107	63	77	112.30	
1	19DEC95	5, .	100	116	47	65	107	60	86	112.80	
2	27DEC95	13, .	150	106	65	79	115	54	79	110.70	
3	02JAN96	19, .	200	115	57	98	106	62	129 H	111.20	
3	08JAN96	25, .	150	140	85	96	139	73	125 H		

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	38.8	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	220000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	96	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	61	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00195 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-9	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 2/ELIGIBILITY	-1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	13	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18DEC95	1	26DEC95	9	9
00196	Oral	2	20 MG	27DEC95	10	01JAN96	15	6
00196	Oral	3	20 MG	02JAN96	16	07JAN96	21	6
00196	Oral	4	20 MG	08JAN96	22	14JAN96	28	7
00196	Oral	5	30 MG	15JAN96	29	21JAN96	35	7
00196	Oral	5	30 MG	22JAN96	36	28JAN96	42	7
00196	Oral	5	30 MG	29JAN96	43	04FEB96	49	7
00196	Oral	5	30 MG	05FEB96	50	11FEB96	56	7
00196	Oral	4	20 MG	12FEB96	57	25FEB96	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	70	20	Other reason	PATIENT WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES TO ASPIRIN	ADVERSE EFF/ANALGESIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
ALLERGIES TO SULFA DRUGS	ADVERSE EFF/ANTI-INFECT	EXT CAUSES OF INJURY/POISONING	CUR	1995
ANEMIA	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1995
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1993
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
MENSTRUAL CRAMPS{OCCASIONAL}	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
OBESITY{MILD}	OBESITY	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Dihydroxyaluminum Sodium Carbonate	Rolaids	10, .	27DEC95	.	2TABS PRN	HEARTBURN
	Famotidine	Pepcid Ac	10, .	27DEC95	.	75MG	HEARTBURN
ANTIINFECTIVES,SYSTEMIC	Cefixime	Cefixime	56, .	11FEB96	.	400MG	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-716, .	01JAN94	.	975MG	HEADACHES
		Tylenol Sinus	55, .	10FEB96	.	975MG	SINUS INFECTION
	Pseudoephedrine Hydrochloride	Tylenol Sinus	55, .	10FEB96	.	975MG	SINUS INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-716, .	01JAN94	.	800MG PRN	HEADACHES
RESPIRATORY	Carbinoxamine Maleate	Rondec Dm	56, .	11FEB96	.	4TABS	SINUS INFECTION
	Dextromethorphan Hydrobromide	Rondec Dm	56, .	11FEB96	.	4TABS	SINUS INFECTION
	Guaifenesin	Entex	54, .	09FEB96	09FEB96	4TABS	SINUS INFECTION
	Paracetamol	Tylenol Sinus	55, .	10FEB96	.	975MG	SINUS INFECTION
	Phenylephrine Hydrochloride	Entex	54, .	09FEB96	09FEB96	4TABS	SINUS INFECTION
	Phenylpropanolamine Hydrochloride	Entex	54, .	09FEB96	09FEB96	4TABS	SINUS INFECTION
	Prednisone	Prednisone	56, .	11FEB96	.	5MG QD	ASTHMA
	Pseudoephedrine Hydrochloride	Rondec Dm	56, .	11FEB96	.	4TABS	SINUS INFECTION
		Tylenol Sinus	55, .	10FEB96	.	975MG	SINUS INFECTION
	Salbutamol	Albuterol	-1081, .	01JAN93	.	2TSP PRN	ASTHMA
			-1081, .	01JAN93	.	2TSP PRN	ASTHMA
		Albuterol Inhaler	-1081, .	01JAN93	.	2PUFFS PRN	ASTHMA
			-1081, .	01JAN93	.	2PUFFS PRN	ASTHMA
SYSTEMIC HORMONAL	Prednisone	Prednisone	56, .	11FEB96	.	5MG QD	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Constipation	CONSTIPATION	3, .	Not Stated	20	7	MIL	NO	PBU	No	No
	Decreased Appetite	DECREASED APPETITE	2, .	21 Days	20	CON	MIL	NO	PBU	No	No
	Dry Mouth	DRY MOUTH	17, .	6 Days	20	CON	MIL	NO	PSR	No	No
	Dyspepsia	HEARTBURN	41, .	Not Stated	30	CON	MIL	NO	PBU	Yes	No
	Nausea	NAUSEA	2, .	21 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Insomnia	INSOMNIA (INITIAL)	2, .	21 Days	20	CON	MIL	NO	PBU	No	No
Respiratory System	Asthma	ASTHMA	43, .	Not Stated	30	CON	SEV	NO	UNR	Yes	No
	Sinusitis	SINUS INFECTION	43, .	Not Stated	30	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11DEC95	-7, .	0	148	85	102	146	76	106	237.00	65.0
BL	18DEC95	1, .	0	137	75	90	138	71	91	232.40	
1	27DEC95	10, .	20	146	80	90	138	77	100	231.00	
2	02JAN96	16, .	20	144	79	75	140	79	86	233.80	
3	08JAN96	22, .	20	153	87	88	153	87	98	237.90	
4	15JAN96	29, .	30	146	80	87	146	80	90	237.50	
5	22JAN96	36, .	30	137	83	74	129	85	85	235.90	
6	29JAN96	43, .	30	138	77	91	139	66	94	236.00	
7	05FEB96	50, .	30	137	72	95	150	90	96	239.50	
8	12FEB96	57, .	20	117	66	100	114	60	102	234.10	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	10.9	L	.	.	12 - 15.6	G/DL
				Hematocrit	33.1	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.1	.	.	.	30 - 70	%
				Lymphocytes	22.9	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	1.4	.	.	.	0 - 2	%
				Platelets	386000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	130	H	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	11.5	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.1	L	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	16.7	H	.	+	3.8 - 10.8	THOU/MCL
				Neutrophil Bands	5	.	.	.	0 - 8	%
				Segmented Neutrophils	89	H	.	.	40 - 75	%
				Lymphocytes	5	L	.	.	16 - 46	%
				Monocytes	1	.	.	.	0 - 12	%
				Eosinophils	0	.	.	.	0 - 7	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	417000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.1	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00196 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	25	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.1	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	123	H	.	.	70 - 115	MG/DL
				Globulin	4.9	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	29DEC95	1	01JAN96	4	4
00197	Oral	2	0 MG	02JAN96	5	07JAN96	10	6
00197	Oral	3	0 MG	08JAN96	11	15JAN96	18	8
00197	Oral	4	0 MG	16JAN96	19	22JAN96	25	7
00197	Oral	4	0 MG	23JAN96	26	29JAN96	32	7
00197	Oral	4	0 MG	30JAN96	33	05FEB96	39	7
00197	Oral	4	0 MG	06FEB96	40	12FEB96	46	7
00197	Oral	4	0 MG	13FEB96	47	20FEB96	54	8
00139	Oral	4	0 MG	21FEB96	55	18MAR96	81	27
00139	Oral	4	0 MG	19MAR96	82	22APR96	116	35
00139	Oral	4	0 MG	23APR96	117	20MAY96	144	28
00139	Oral	4	0 MG	21MAY96	145	24JUN96	179	35
00139	Oral	4	0 MG	25JUN96	180	15JUL96	200	21
00139	Oral	4	0 MG	16JUL96	201	19AUG96	235	35
00197	Oral	4	0 MG	20AUG96	236	20AUG96	236	1
00197	Oral	3	0 MG	21AUG96	237	22AUG96	238	2
00197	Oral	2	0 MG	23AUG96	239	25AUG96	241	3
00197	Oral	1	0 MG	26AUG96	242	01SEP96	248	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	Yes	248	0		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
STOMACH PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Famotidine	Pepcid	-58, -112	01NOV95	.	20MG PRN	STOMACH PAIN
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	174, 120	19JUN96	23JUN96	1000 MG	SCALP LACERATIONS
	Clavulanic Acid	Augmentin	174, 120	19JUN96	23JUN96	1000 MG	SCALP LACERATIONS
MUSCULO-SKELETAL	Ibuprofen	Advil	-362, -416	01JAN95	.	200MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Trauma	SCALP LACERATIONS (TOP OF HEAD)	172, 118	2 Days	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	236, 182	4 Days	0		MOD	NO	UNR	No	No
	Vomiting	VOMITING	236, 182	4 Days	0	3	MIL	NO	UNR	No	No
Nervous System	Dizziness	DIZZY	21, -34	1 Days	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20DEC95	-9, -63	0	118	54	88	110	59	115	99.40	58.0
BL	29DEC95	1, -54	0	106	49	86	124	60	95	97.80	
1	02JAN96	5, -50	0	92	40	72	101	55	86	98.60	
1	08JAN96	11, -44	0	102	50	79	107	50	96	100.00	
3	16JAN96	19, -36	0	100	38	71	97	49	81	99.60	
4	23JAN96	26, -29	0	94	43	81	100	46	83	101.60	
5	30JAN96	33, -22	0	115	68	81	116	49	105	100.30	
6	06FEB96	40, -15	0	82	47	96	86 L	53	100	99.70	
7	13FEB96	47, -8	0	89	40	75	90	52	84	98.80	
8	20FEB96	54, -1	0	90	47	91	98	52	120	99.10	
12	19MAR96	82, 28	0	100	49	83	107	42	95	100.00	
16	23APR96	117, 63	0	99	53	71	99	57	94	99.60	
20	21MAY96	145, 91	0	97	63	76	83 L	61	90	102.30	
24	25JUN96	180, 126	0	114	61	98	112	63	112	106.94 H	
28	16JUL96	201, 147	0	106	53	93	105	52	100	107.40 H	
32	20AUG96	236, 182	0	103	44	89	98	62	84	109.20 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	38.2	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	155	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-9	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	38.4	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	8 - 21	MG/DL
				Creatinine	0.7	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.6	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	134	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	5.7 - 8.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	54	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
		VISIT 13/CONTINUATION-WEEK 20	145	Hemoglobin	13	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	37.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.6	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	7.2	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	231000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	123	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	145	Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	236	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.4	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.5	.	.	.	30 - 70	%
				Lymphocytes	43.8	.	.	.	21 - 51	%
				Monocytes	7.3	.	.	.	0 - 10	%
				Eosinophils	4.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	147	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00197 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 16/CONTINUATION-WEEK 32	236	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Bacteria		3	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	HISPANIC

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	02JAN96	1	07JAN96	6	6
00198	Oral	2	0 MG	08JAN96	7	15JAN96	14	8
00198	Oral	3	0 MG	16JAN96	15	22JAN96	21	7
00198	Oral	4	0 MG	23JAN96	22	29JAN96	28	7
00198	Oral	4	0 MG	30JAN96	29	05FEB96	35	7
00198	Oral	4	0 MG	06FEB96	36	12FEB96	42	7
00198	Oral	4	0 MG	13FEB96	43	19FEB96	49	7
00198	Oral	4	0 MG	20FEB96	50	26FEB96	56	7
	Oral	3	0 MG	27FEB96	57	09MAR96	68	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	68	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGY TO CODEINE	ADVERSE EFF/ANALGESIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
OTITIS MEDIA BILATERAL{PROBABLE}	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
UPPER RESPIRATORY TRACT INFECTION(FLU)	INFLUENZA	RESPIRATORY SYST DIS	CUR	1994
GRAVIDA 1,PARA 0,ABORTION {PREGNANCY}	PREGNANCY	FAMILY/PERSONAL HISTORY	PRV	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Tetanus Toxoid	Tetanus {Toxoid}	48,	.	18FEB96	18FEB96	1CC	VACCINATION(FACIAL CUTS)
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-366,	.	01JAN95	.	650MG PRN	HEADACHE
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Triphasil	-1096,	.	01JAN93	.	1PILL	BIRTH CONTROL
			-1096,	.	01JAN93	.	1PILL	BIRTH CONTROL
	Levonorgestrel	Triphasil	-1096,	.	01JAN93	.	1PILL	BIRTH CONTROL
			-1096,	.	01JAN93	.	1PILL	BIRTH CONTROL
RESPIRATORY	Guaifenesin	Robitussin	-366,	.	01JAN95	.	2TBLS	FLU SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	2, .	Not Stated	0	CON	MOD	NO	PSR	No	No
	Trauma	FACIAL CUTS {LEFT CHEEK}	48, .	1 Days	0	CON	MOD	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	7, .	13 Days	0	CON	MIL	NO	PSR	No	No
Nervous System	Abnormal Dreams	NIGHTMARE	2, .	7 Days	0	6	MOD	NO	PSR	No	No
	Nervousness	RESTLESSNESS	15, .	8 Days	0	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19DEC95	-14, .	0	116	66	86	123	68	94	103.00	61.5
BL	02JAN96	1, .	0	112	63	91	115	66	95	103.90	
1	08JAN96	7, .	0	113	67	91	108	65	93	102.80	
2	16JAN96	15, .	0	107	57	81	105	59	88	105.60	
3	23JAN96	22, .	0	108	65	80	115	64	81	105.90	
4	30JAN96	29, .	0	131	65	94	124	64	115	104.50	
5	06FEB96	36, .	0	97	50	86	106	48	105	104.60	
6	13FEB96	43, .	0	132	70	91	126	75	90	105.10	
7	20FEB96	50, .	0	99	52	76	99	53	97	105.00	
8	27FEB96	57, .	0	106	59	86	106	57	88	105.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	34.1	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	44	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-14	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	3.9 - 5.2	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	40 - 75	%
				Lymphocytes	35.1	.	.	.	16 - 46	%
				Monocytes	6	.	.	.	0 - 12	%
				Eosinophils	5.1	.	.	.	0 - 7	%
				Basophils	1.5	.	.	.	0 - 2	%
				Platelets	183000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	44	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00198 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	16JAN96	1	22JAN96	7	7
00199	Oral	2	100 MG	23JAN96	8	28JAN96	13	6
00199	Oral	3	150 MG	29JAN96	14	06FEB96	22	9
00199	Oral	4	200 MG	07FEB96	23	13FEB96	29	7
00199	Oral	4	200 MG	14FEB96	30	20FEB96	36	7
00199	Oral	5	250 MG	21FEB96	37	27FEB96	43	7
00199	Oral	5	250 MG	28FEB96	44	05MAR96	50	7
00199	Oral	5	250 MG	06MAR96	51	12MAR96	57	7
	Oral	4	200 MG	13MAR96	58	26MAR96	71	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	71	200	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGY TO CECLOR	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	1995
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MUSCULAR NECK PAIN	MYALGIA	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES	58, .	Not Stated	200	5	MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	9, .	15 Days	100	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	2, .	42 Days	50	CON	MOD	NO	PSR	No	No
			44, .	15 Days	250	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	2, .	Not Stated	50	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	10JAN96	-6, .	0	130	65	73	136	81	96	160.30	66.0
BL	16JAN96	1, .	0	114	61	69	106	56	88	158.90	
1	23JAN96	8, .	100	138	59	95	107	69	108	160.50	
2	29JAN96	14, .	150	111	61	88	103	53	100	158.90	
3	07FEB96	23, .	200	123	49	109	91	54	114	159.80	
4	14FEB96	30, .	200	114	50	101	98	41	105	158.10	
5	21FEB96	37, .	250	114	61	95	105	58	98	156.10	
6	28FEB96	44, .	250	137	76	96	112	64	105	157.70	
7	06MAR96	51, .	250	100	62	86	98	48	94	158.20	
8	13MAR96	58, .	200	122	72	96	90	55	105	155.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	12.3	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63.2	.	.	.	30 - 70	%
				Lymphocytes	28.6	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	1.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	148000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.7	.	.	.	30 - 70	%
				Lymphocytes	30	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	0.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00199 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	58	Alkaline Phosphatase	65	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	23JAN96	1	01FEB96	10	10
00200	Oral	2	0 MG	02FEB96	11	05FEB96	14	4
00200	Oral	3	0 MG	06FEB96	15	12FEB96	21	7
00200	Oral	4	0 MG	13FEB96	22	19FEB96	28	7
00200	Oral	4	0 MG	20FEB96	29	27FEB96	36	8
00200	Oral	4	0 MG	28FEB96	37	07MAR96	45	9
	Oral	3	0 MG	08MAR96	46	19MAR96	57	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	No	No	57	0	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANEMIC	ANEMIA, OTHER	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
{COMMON} COLD	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Diphenhydramine Hydrochloride	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
	Paracetamol	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
		Tylenol	-752, .	01JAN94	.	500MG	HEADACHE
	Pseudoephedrine Hydrochloride	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
			-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
	Paracetamol	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
			-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
	Pseudoephedrine Hydrochloride	Benadryl Cold	-22, .	01JAN96	05JAN96#	2TAB PRN	COLD
			-22, .	01JAN96	05JAN96#	2TAB PRN	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Av Block	SINUS ARRHYTHMIA(MOBITZ I)	15, .	43 Days	0	2	MIL	NO	PBU	No	No
Digestive System	Nausea	NAUSEA	29, .	9 Days	0	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Thirst	INCREASE IN THIRST	21, .	3 Days	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Rash	NON PAPULAR RASH (UPPER TORSO AND BACK)	57, .	Not Stated	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	17JAN96	-6, .	0	115	76	70	121	79	74	118.20	62.0
BL	23JAN96	1, .	0	122	72	81	.	.	.	121.40	
1	02FEB96	11, .	0	110	60	79	114	59	78	119.30	
2	06FEB96	15, .	0	110	80	91	123	69	106	123.00	
3	13FEB96	22, .	0	100	62	105	122	60	101	120.20	
4	20FEB96	29, .	0	122	83	84	107	69	105	119.90	
5	28FEB96	37, .	0	107	56	86	112	77	95	120.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	11.4	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72	H	.	.	30 - 70	%
				Lymphocytes	19.4	L	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	313000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	23.5	L	.	.	25 - 35	PG
				Mean Corpuscle Volume	72	L	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	37	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00200 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	06FEB96	1	12FEB96	7	7
00201	Oral	2	20 MG	13FEB96	8	19FEB96	14	7
00201	Oral	3	20 MG	20FEB96	15	27FEB96	22	8
00201	Oral	4	20 MG	28FEB96	23	04MAR96	28	6
00201	Oral	4	20 MG	05MAR96	29	11MAR96	35	7
00201	Oral	4	20 MG	12MAR96	36	18MAR96	42	7
00201	Oral	4	20 MG	19MAR96	43	25MAR96	49	7
00201	Oral	5	30 MG	26MAR96	50	01APR96	56	7
	Oral	4	20 MG	02APR96	57	04APR96	59	3

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	No	59	20	Adverse event, including intercurrent illness	PHYSICIAN DISCRETIONS DUE TO IRREGULAR PARANOID BEHAVIOR

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
FEVER	PYREXIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
STREP THROAT	INFECTION, BACTERIAL	INFECTIOUS/PARASITIC DIS	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	-9, .	28JAN96	06FEB96	750MG	STREP THROAT
			56, .	01APR96	.	750 MG	TONSILLITIS
	Clavulanic Acid	Augmentin	-9, .	28JAN96	06FEB96	750MG	STREP THROAT
			56, .	01APR96	.	750 MG	TONSILLITIS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-9, .	28JAN96	.	650 PRN	FEVER
RESPIRATORY	Hydrocodone Bitartrate	Codimal Dh	56, .	01APR96	.	2 TSP. PRN	TONSILLITIS
	Mepyramine Maleate	Codimal Dh	56, .	01APR96	.	2 TSP. PRN	TONSILLITIS
	Phenylephrine Hydrochloride	Codimal Dh	56, .	01APR96	.	2 TSP. PRN	TONSILLITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	TONSILLITIS {STREP PHARYNGITIS}	56, .	Not Stated	30	CON	MIL	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	31, .	1 Days	20	CON	MIL	NO	PBU	No	No
	Vomiting	VOMITING	31, .	1 Days	20		MIL	NO	UNR	No	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN {11LBS}[WEIGHT GAIN]	57, .	Not Stated	20	CON	MOD	NO	PSR	No	No
Nervous System	Agitation	AGITATION	58, .	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	Hostility	AGGRESSIVE ASSAULTIVE BEHAVIOR	58, .	Not Stated	20	CON	SEV	STP	PSR	Yes	Yes
	Insomnia	INITIAL INSOMNIA	23, .	Not Stated	20	CON	MOD	NO	PSR	No	No
	Paranoid Reaction	PARANOIA	58, .	Not Stated	20	CON	MOD	STP	PSR	No	Yes
	Somnolence	SOMNOLENCE	50, .	Not Stated	30	CON	MIL	NO	PSR	No	No
Respiratory System	Rhinitis	NASAL CONGESTION	62, .	3 Days	20	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	31JAN96	-6, .	0	106	51	85	122	67	110	151.80	67.0
BL	06FEB96	1, .	0	127	53	87	130	95	112	150.80	
1	13FEB96	8, .	20	130	69	85	158	74	102	151.40	
2	20FEB96	15, .	20	124	57	86	120	61	97	152.40	
3	28FEB96	23, .	20	118	59	93	121	65	108	153.90	
4	05MAR96	29, .	20	131	63	101	114	64	105	154.30	
5	12MAR96	36, .	20	131	80	90	129	65	103	158.90	
6	19MAR96	43, .	20	125	78	100	131	85	106	157.20	
7	26MAR96	50, .	30	124	49	90	122	68	97	158.40	
8	02APR96	57, .	20	136	59	109	121	77	106	163.80 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.1	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	9.9	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	180000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	208	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.2	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	10.2	H	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	1.6	.	.	.	0 - 2	%
				Platelets	163000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	18	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	214	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	29	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00201 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	100	.	.	.	70 - 115	MG/DL
				Globulin	4.3	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	20FEB96	1	26FEB96	7	7
00202	Oral	2	0 MG	27FEB96	8	07MAR96	17	10
00202	Oral	3	0 MG	08MAR96	18	18MAR96	28	11
00202	Oral	4	0 MG	19MAR96	29	26MAR96	36	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	36	0	Protocol violation, including non-compliance	PATIENT WAS NON-COMPLIANT DUE TO POSITIVE DRUG SCREEN

* Relative to Start of Study Medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
SEASONAL ALLERGY	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Metacycline	Metacycline	-415, .	01JAN95	.	1TAB	SEASONAL ALLERGY
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	-50, .	01JAN96	.	2TABS PRN	MENSTRUAL CRAMPS
	Caffeine	Midol	-50, .	01JAN96	.	2TABS PRN	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-50, .	01JAN96	.	2TABS PRN	MENSTRUAL CRAMPS
	Paracetamol	Tylenol	-415, .	01JAN95	.	650 PRN	HEADACHES
GU SYSTEM/SEX HORMONES	Mestranol	Ortho Novum	-50, .	01JAN96	.	1PILL	BIRTH CONTROL
			-50, .	01JAN96	.	1PILL	BIRTH CONTROL
	Norethisterone	Ortho Novum	-50, .	01JAN96	.	1PILL	BIRTH CONTROL
			-50, .	01JAN96	.	1PILL	BIRTH CONTROL

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHES IN AM	18, .	12 Days	0	CON	MOD	NO	PSR	No	No
		STOMACH CRAMPS(VIRAL)	3, .	3 Days	0	CON	MIL	NO	PBU	No	No
Digestive System	Diarrhea	DIARRHEA(VIRAL)	3, .	3 Days	0	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14FEB96	-6, .	0	101	65	83	107	71	93	103.80	62.0
BL	20FEB96	1, .	0	114	75	88	102	59	98	105.30	
1	27FEB96	8, .	0	100	50	86	106	60	90	103.70	
2	08MAR96	18, .	0	107	56	86	113	66	102	104.80	
4	19MAR96	29, .	0	110	71	79	122	75	84	105.50	
5	26MAR96	36, .	0	130	78	108	135	67	100	103.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	273000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00202 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	36	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	04MAR96	1	10MAR96	7	7
00203	Oral	2	100 MG	11MAR96	8	18MAR96	15	8
00203	Oral	3	150 MG	19MAR96	16	26MAR96	23	8
	Oral	2	100 MG	27MAR96	24	05APR96	33	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	No	No	33	100	Adverse event, including intercurrent illness	BORDERLINE PROLONGED QT-QTC 1ST DEGREE AV BLOCK

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
LEFT AXIS DEVIATION	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-63, .	01JAN96	.	600MG	SEASONAL ALLERGIES
RESPIRATORY	Hydrocodone Bitartrate	Codimal Dh	-63, .	01JAN96	.	1/2TAB	SEASONAL ALLERGIES
	Mepyramine Maleate	Codimal Dh	-63, .	01JAN96	.	1/2TAB	SEASONAL ALLERGIES
	Phenylephrine Hydrochloride	Codimal Dh	-63, .	01JAN96	.	1/2TAB	SEASONAL ALLERGIES
VARIOUS	Allergenic Extract, Nos	Allergy Shots	-793, .	01JAN94	.	1X	SEASONAL ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Av Block	1ST DEGREE AV BLOCK	23, .	Not Stated	150	CON	MOD	STP	REL	No	No
	Palpitation	PALPITATIONS	21, .	Not Stated	150	CON	MOD	NO	PSR	No	No
	Qt Interval Prolonged	PROLONGED QT-QUANTITATIVE TIP CULTURES	23, .	Not Stated	150	CON	MOD	STP	REL	No	No
	Vasodilatation	HOT FLASHES(FACIAL FLUSHING)	21, .	Not Stated	150	CON	MOD	NO	PSR	No	No
Digestive System	Nausea	NAUSEA WHEN TAKING PM MEDS	2, .	Not Stated	50	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Thirst	INCREASED THIRST	21, .	Not Stated	150	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	28FEB96	-5, .	0	95	65	103	103	49	109	85.80	57.5
BL	04MAR96	1, .	0	115	68	77	107	71	103	85.00	
1	11MAR96	8, .	100	108	61	100	110	65	105	84.00	
2	19MAR96	16, .	150	113	58	105	99	58	106	84.70	
3	26MAR96	23, .	150	110	55	104	109	54	109	84.67	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.6	.	.	.	30 - 70	%
				Lymphocytes	39.8	.	.	.	21 - 51	%
				Monocytes	8.9	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	295000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	8 - 21	MG/DL
				Creatinine	0.6	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	227	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.4	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	60 - 110	MG/DL
				Globulin	2.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00203 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	19MAR96	1	25MAR96	7	7
00204	Oral	2	20 MG	26MAR96	8	01APR96	14	7
00204	Oral	3	20 MG	02APR96	15	08APR96	21	7
00204	Oral	4	20 MG	09APR96	22	15APR96	28	7
00204	Oral	4	20 MG	16APR96	29	22APR96	35	7
00204	Oral	4	20 MG	23APR96	36	29APR96	42	7
00204	Oral	4	20 MG	30APR96	43	06MAY96	49	7
00204	Oral	4	20 MG	07MAY96	50	13MAY96	56	7
00149	Oral	4	20 MG	14MAY96	57	10JUN96	84	28
00149	Oral	4	20 MG	11JUN96	85	08JUL96	112	28
00149	Oral	4	20 MG	09JUL96	113	12AUG96	147	35
00149	Oral	4	20 MG	13AUG96	148	09SEP96	175	28
00149	Oral	4	20 MG	10SEP96	176	14OCT96	210	35
00149	Oral	4	20 MG	15OCT96	211	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	211	20	Lost to follow-up	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ATTENTION DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1986
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
WEIGHT GAIN	WEIGHT GAIN	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1996

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Methylphenidate Hydrochloride	Ritalin	-808, -864	01JAN94	01MAR96#	20MG SR	ATTENTION DEFICIT HYPERACTIVITY DISORDER
	Paracetamol	Tylenol	-808, -864	01JAN94	.	675MG PRN	OCCASIONAL HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	8, -49	22 Days	20	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	13MAR96	-6, -62	0	108	59	93	102	64	98	113.20	63.0
BL	19MAR96	1, -56	0	105	64	87	105	51	89	117.10	
1	26MAR96	8, -49	20	145	73	89	136	96	100	115.80	
2	02APR96	15, -42	20	110	56	80	111	63	83	114.40	
3	09APR96	22, -35	20	106	53	74	97	56	84	115.90	
4	16APR96	29, -28	20	116	58	88	123	58	102	116.60	
5	23APR96	36, -21	20	115	50	78	109	62	89	118.10	
6	30APR96	43, -14	20	123	50	86	104	67	86	119.70	
7	07MAY96	50, -7	20	122	63	93	122	59	98	120.10	
8	14MAY96	57, 1	20	114	61	80	114	63	80	117.90	
12	11JUN96	85, 29	20	115	62	93	108	67	102	119.90	
16	09JUL96	113, 57	20	119	57	91	115	67	105	121.60	
20	13AUG96	148, 92	20	118	57	86	120	68	101	123.00	
24	10SEP96	176, 120	20	118	58	90	105	66	106	126.10 H	
28	14OCT96	210, 154	20	120	57	74	126	55	91	129.00 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	31	.	.	.	30 - 70	%
				Lymphocytes	53	H	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	339	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 39	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	3.2	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	36.4	.	.	.	30 - 70	%
				Lymphocytes	51.7	H	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	293000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.1	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	319	.	.	.	44 - 400	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	122	H	.	.	60 - 110	MG/DL
				Globulin	2.9	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	34	.	.	.	30 - 70	%
				Lymphocytes	51	.	.	.	21 - 51	%
				Monocytes	11	H	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	255000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00204 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 13/CONTINUATION-WEEK 20	148	Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	4.5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	329	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 39	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	60 - 110	MG/DL
				Globulin	3.3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	18DEC96	1	22DEC96	5	5
00235	Oral	2	20 MG	23DEC96	6	29DEC96	12	7
00235	Oral	3	20 MG	30DEC96	13	05JAN97	19	7
00235	Oral	4	20 MG	06JAN97	20	14JAN97	28	9
00235	Oral	4	20 MG	15JAN97	29	19JAN97	33	5
00235	Oral	4	20 MG	20JAN97	34	26JAN97	40	7
00235	Oral	4	20 MG	27JAN97	41	02FEB97	47	7
00235	Oral	4	20 MG	03FEB97	48	09FEB97	54	7
00109	Oral	4	20 MG	10FEB97	55	17MAR97	90	36
00109	Oral	4	20 MG	17MAR97	90	13APR97	117	28
00235	Oral	4	20 MG	14APR97	118	14APR97	118	1
00235	Oral	3	20 MG	15APR97	119	16APR97	120	2
00235	Oral	2	20 MG	17APR97	121	19APR97	123	3
00235	Oral	1	20 MG	20APR97	124	26APR97	130	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	12	Yes	No	130	20	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
FLU SYMPTOMS	INFLUENZA	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Minocycline	Minocycline	-33, -87	15NOV96	.	100MG	ACNE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol (Liquid)	-11, -65	07DEC96	07DEC96#	2 TEASPOONS	FLU SYMPTOMS
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Ortho Novum 1/35-28	40, -15	26JAN97	.	1 PILL	BIRTH CONTROL
	Norethisterone	Ortho Novum 1/35-28	40, -15	26JAN97	.	1 PILL	BIRTH CONTROL
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-11, -65	07DEC96	07DEC96#	200 MG PRN	FLU SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	90, 36	29 Days	20	CON	MIL	NO	PSR	No	No
Cardiovascular System	Arrhythmia	SINUS ARRHYTHMIA (PER EKG)	90, 36	Not Stated	20	CON	MIL	NO	UNR	No	No
	Tachycardia	ELEVATED PULSE	20, -35	36 Days	20	CON	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	13, -42	43 Days	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	41, -14	50 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Insomnia	INSOMNIA (INITIAL)	48, -7	8 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	10DEC96	-8, -62	0	119	66	82	107	70	109	121.70	65.0
BL	17DEC96	-1, -55	0	112	66	86	98	65	109	121.60	
1	23DEC96	6, -49	20	111	67	80	116	66	82	123.60	
2	30DEC96	13, -42	20	104	59	76	110	63	74	122.20	
3	06JAN97	20, -35	20	122	63	95	112	54	135	121.50	
4	15JAN97	29, -26	20	99	57	93	106	61	100	119.40	
5	20JAN97	34, -21	20	138	91	102	121	55	125	120.20	
6	27JAN97	41, -14	20	114	60	97	104	66	133	118.00	
7	03FEB97	48, -7	20	107	57	81	112	58	105	119.80	
8	10FEB97	55, 1	20	121	60	86	112	70	117	122.20	
12	17MAR97	90, 36	20	130	65	106	120	77	109	123.30	
16	14APR97	118, 64	20	145	82	86	135	78	115	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	41	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.2	.	.	.	30 - 70	%
				Lymphocytes	33.9	.	.	.	21 - 51	%
				Monocytes	9.9	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	103	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 39	U/L
				Total Bilirubin	1.9	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	59	L	.	.	60 - 110	MG/DL
				Globulin	3	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG			.	.		
				Urine Blood - Dipstick NEG			.	.		
				Urine Red Blood Cells/HPF NEG			.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-1	Glucose - Random	83	.	.	.	60 - 110	MG/DL
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEC		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	55	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00235 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	F	VISIT 10/ACUTE PHASE-WEEK 8	55	Segmented Neutrophils	73.2	H	.	.	30 - 70	%
				Lymphocytes	14.6	L	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	196000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	76	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	30DEC96	1	05JAN97	7	7
00236	Oral	2	100 MG	06JAN97	8	14JAN97	16	9
00236	Oral	3	150 MG	15JAN97	17	19JAN97	21	5
00236	Oral	4	200 MG	20JAN97	22	26JAN97	28	7
	Oral	4	200 MG	27JAN97	29	08FEB97	41	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	41	200	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1996
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Midol	-168, .	15JUL96	.	1 TAB PRN	MENSTRUAL CRAMPS
	Caffeine	Midol	-168, .	15JUL96	.	1 TAB PRN	MENSTRUAL CRAMPS
	Cinnamedrine Hydrochloride	Midol	-168, .	15JUL96	.	1 TAB PRN	MENSTRUAL CRAMPS
	Paracetamol	Tylenol	-45, .	15NOV96	.	250 MG PRN	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Dizziness	DIZZINESS	22, .	Not Stated	200	CON	MOD	STP	REL	No	No
	Insomnia	MIDDLE INSOMNIA	17, .	6 Days	150	CON	MIL	NO	PSR	No	No
	Somnolence	DAYTIME SEDATION	22, .	Not Stated	200	CON	MOD	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	17DEC96	-13, .	0	136	72	87	124	56	94	146.90	63.1
BL	30DEC96	1, .	0	113	44	75	103	57	86	147.30	
1	06JAN97	8, .	100	115	57	98	100	52	121 H	144.30	
2	15JAN97	17, .	150	115	66	90	121	71	106	141.50	
3	20JAN97	22, .	200	131	74	109	108	58	133 H	143.30	
4	27JAN97	29, .	200	130	69	84	114	63	103	137.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.3	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	265000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	183	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00236 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-13	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11NOV96	1	19NOV96	9	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	No	No	9	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ACNE	SKIN/SUBCUT DISORD, OTHER	SKIN/SUBCUTANEOUS TISSUE DIS	P&C	
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	P&C	
SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	P&C	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Isotretinoin	Accutane	.,	.	.		ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04NOV96	-7, .	0	124	58	66	114	64	75	149.50	68.0
BL	11NOV96	1, .	0	113	63	96	111	51	103	146.60	
1	18NOV96	8, .	0	115	57	84	107	64	98	148.80	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.6	.	.	.	30 - 70	%
				Lymphocytes	46.1	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	5.2	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	213	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	102	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00237 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	12NOV96	1	18NOV96	7	7
00238	Oral	2	0 MG	19NOV96	8	25NOV96	14	7
00238	Oral	3	0 MG	26NOV96	15	02DEC96	21	7
00238	Oral	4	0 MG	03DEC96	22	09DEC96	28	7
00238	Oral	4	0 MG	10DEC96	29	16DEC96	35	7
00238	Oral	4	0 MG	17DEC96	36	22DEC96	41	6
00238	Oral	4	0 MG	23DEC96	42	30DEC96	49	8
00238	Oral	4	0 MG	31DEC96	50	06JAN97	56	7
	Oral	4	0 MG	07JAN97	57	19JAN97	69	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	69	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-681, .	01JAN95	.	325MG PRN	HEADACHES
			50, .	31DEC96	.	250 MG	HEADACHE
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	38, .	19DEC96	31DEC96	60 MG	CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	INCREASE HEADACHE	22, .	Not Stated	0	CON	MOD	NO	PSR	Yes	No
Cardiovascular System	Av Block	SERIAL INCREASE PR INTERVAL	15, .	15 Days	0	CON	MIL	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	22, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Nervous System	Abnormal Dreams	VIVID DREAMING	15, .	8 Days	0	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	42, .	9 Days	0	CON	MIL	NO	UNR	Yes	No
	Pharyngitis	SORE THROAT	42, .	9 Days	0	CON	MIL	NO	UNR	Yes	No
	Rhinitis	CONGESTION {NOSE}	42, .	9 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	28OCT96	-15, .	0	115	60	83	106	55	100	112.20	66.5
BL	12NOV96	1, .	0	107	53	88	106	52	97	113.60	
1	19NOV96	8, .	0	106	48	74	112	62	95	114.80	
2	26NOV96	15, .	0	108	47	74	99	57	86	115.00	
3	03DEC96	22, .	0	99	42	78	105	47	88	115.80	
4	10DEC96	29, .	0	107	49	72	105	54	78	114.50	
5	17DEC96	36, .	0	112	51	82	115	59	100	112.80	
6	23DEC96	42, .	0	97	45	76	108	47	88	114.40	
7	31DEC96	50, .	0	111	54	77	109	58	86	115.00	
8	07JAN97	57, .	0	104	56	72	110	52	87	112.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	14.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	31.3	.	.	.	21 - 51	%
				Monocytes	6.4	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	104	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	6	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	2.8	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	88	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00238 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19NOV96	1	24NOV96	6	6
00239	Oral	2	100 MG	25NOV96	7	01DEC96	13	7
00239	Oral	3	150 MG	02DEC96	14	08DEC96	20	7
00239	Oral	4	200 MG	09DEC96	21	15DEC96	27	7
00239	Oral	4	200 MG	16DEC96	28	22DEC96	34	7
00239	Oral	4	200 MG	23DEC96	35	29DEC96	41	7
00239	Oral	4	200 MG	30DEC96	42	05JAN97	48	7
00239	Oral	4	200 MG	06JAN97	49	14JAN97	57	9
00183	Oral	4	200 MG	15JAN97	58	17FEB97	91	34
00183	Oral	4	200 MG	18FEB97	92	16MAR97	118	27
00183	Oral	4	200 MG	17MAR97	119	13APR97	146	28
00183	Oral	4	200 MG	14APR97	147	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	147	200	Protocol violation, including non-compliance	PT. STOPPED MEDS ON OWN.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MIGRAINES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1991
SINUS ARRHYTHMIA	ARRHYTHMIA	CIRCULATORY SYST	CUR	1996
SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	CUR	1996
DRUG ALLERGY - PENICILLIN	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	P&C	1995
MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995

CUR = Current, PRV = Past

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PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
		Excedrin	92, 35	18FEB97	17MAR97		HEADACHE
	Caffeine	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
		Excedrin	92, 35	18FEB97	17MAR97		HEADACHE
	Citric Acid	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
	Paracetamol	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
		Excedrin	92, 35	18FEB97	17MAR97		HEADACHE
	Sodium Bicarbonate	Actron	-263, -320	01MAR96	.	2TABS PRN	MIGRAINE
DERMATOLOGICALS	Clobetasol Propionate	Temovate Emollient Cream	119, 62	17MAR97	.	1 APPLICATION PRN	DRY FINGERTIPS
	Promethazine Hydrochloride	Phenergan	41, -17	29DEC96	29DEC96	25 MG	VOMITING
RESPIRATORY	Dexbrompheniramine Maleate	Drixoral	92, 35	18FEB97	17MAR97		SINUS CONGESTION
	Promethazine Hydrochloride	Phenergan	41, -17	29DEC96	29DEC96	25 MG	VOMITING
	Pseudoephedrine Sulfate	Drixoral	92, 35	18FEB97	17MAR97		SINUS CONGESTION
SYSTEMIC HORMONAL	Melatonin	Melatonin	42, -16	30DEC96	.	1TAB	INSOMNIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	92, 35	Not Stated	200	CON	MIL	NO	PSR	No	No
Cardiovascular System	Bradycardia	SINUS BRADYCARDIA PER EKG	175, 118	Not Stated	0	CON	MIL	NO	PBU	No	No
	Tachycardia	ELEVATED PULSE	7, -51	141 Days	100	CON	MIL	NO	REL	No	No
Digestive System	Dry Mouth	DRY MOUTH	21, -37	8 Days	200	CON	MIL	NO	PSR	No	No
			49, -9	10 Days	200	CON	MIL	NO	PSR	No	No
	Dysphagia	DIFFICULTY SWALLOWING PILL	28, -30	8 Days	200	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	38, -20	5 Days	200	CON	MOD	NO	PBU	No	No
	Vomiting	VOMITING	38, -20	5 Days	200	CON	MOD	NO	PBU	Yes	No
Nervous System	Insomnia	MIDDLE INSOMNIA	42, -16	8 Days	200	CON	MIL	NO	PSR	Yes	No
	Somnolence	DAYTIME SOMNOLENCE	21, -37	22 Days	200	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	HEAD COLD	49, -9	10 Days	200	CON	MIL	NO	UNR	No	No
	Sinusitis	SINUS CONGESTION	92, 35	28 Days	200	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Dry Skin	DRY FINGERTIPS	119, 62	Not Stated	200	CON	MIL	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	11NOV96	-8, -65	0	122	60	54	113	62	53	148.90	65.5
BL	18NOV96	-1, -58	0	114	60	53	123	57	74	149.40	
1	25NOV96	7, -51	100	115	61	88	106	63	96	147.70	
2	02DEC96	14, -44	150	115	69	85	112	60	109	146.80	
3	09DEC96	21, -37	200	124	74	94	107	68	117	147.70	
4	16DEC96	28, -30	200	121	66	86	113	58	115	149.10	
5	23DEC96	35, -23	200	126	77	106	121	77	121 H	149.50	
6	30DEC96	42, -16	200	113	75	100	115	73	102	143.40	
7	06JAN97	49, -9	200	121	59	108	119	81	131 H	146.50	
8	15JAN97	58, 1	200	120	74	68	131	82	91	143.40	
12	18FEB97	92, 35	200	115	55	80	106	64	97	144.90	
16	17MAR97	119, 62	200	114	52	65	105	54	80	149.80	
20	14APR97	147, 90	200	126	62	64	122	66	65	144.40	
24	12MAY97	175, 118#	0	114	65	59	115	65	71	153.60	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	31	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	67000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	43	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.7	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	5	.	.	+		
				Urine Bacteria	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.3	.	.	.	30 - 70	%
				Lymphocytes	28.5	.	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	58		Alkaline Phosphatase	42	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	4	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	108	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Amphetamines	NEG		.	.	.	
					Urine Barbiturates	NEG		.	.	.	
					Urine Benzodiazepines	NEG		.	.	.	
					Urine Cannabinoids	NEG		.	.	.	
					Urine Cocaine	NEG		.	.	.	
					Urine Methadone	NEG		.	.	.	
					Urine Methaqualone	NEG		.	.	.	
					Urine Opiates	NEG		.	.	.	
					Urine Phencyclidine	NEG		.	.	.	
					Urine Propoxyphene	NEG		.	.	.	
		VISIT 13/CONTINUATION-WEEK 20	147	(1)	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
					Hematocrit	39.2	.	.	.	35 - 46	%
					Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	70.7	H	.	.	30 - 70	%
					Lymphocytes	22.2	.	.	.	21 - 51	%
					Monocytes	5.2	.	.	.	0 - 10	%
					Eosinophils	1	.	.	.	0 - 5	%
					Basophils	1	.	.	.	0 - 2	%
					Platelets	191000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	28.4	.	.	.	25 - 35	PG

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00239 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	147 (1)	Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	37	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	54	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	14JAN97	1	20JAN97	7	7
00240	Oral	2	20 MG	21JAN97	8	27JAN97	14	7
00240	Oral	3	20 MG	28JAN97	15	03FEB97	21	7
00240	Oral	4	20 MG	04FEB97	22	10FEB97	28	7
00240	Oral	4	20 MG	11FEB97	29	17FEB97	35	7
00240	Oral	5	30 MG	18FEB97	36	25FEB97	43	8
00240	Oral	5	30 MG	25FEB97	43	04MAR97	50	8
	Oral	5	30 MG	04MAR97	50	05MAR97	51	2

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	51	30	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SLEEP DISTURBANCE	DISTURBANCE, SLEEP, UNSPEC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1984

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-13, .	01JAN97	.	400 MG PRN	HEADACHES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Concentration Impaired	ATTENTION DEFICIT HYPERACTIVITY DISORDER	72, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No
	Depression	WORSENING OF DEPRESSION	48, .	Not Stated	30	CON	SEV	STP	UNR	Yes	Yes
	Insomnia	WORSENING OF SLEEP DISTURBANCE	51, .	Not Stated	30	CON	SEV	NO	PSR	Yes	Yes
Respiratory System	Sinusitis	SINUS CONGESTION	29, .	14 Days	20	CON	MIL	NO	UNR	No	No
Skin and Appendages	Rash	BILATERAL ERYTHEMATOUS EYELIDS	29, .	8 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	03JAN97	-11, .	0	120	84	85	124	82	91	168.00	67.7
BL	10JAN97	-4, .	0	138	65	80	128	74	93	171.40	
1	21JAN97	8, .	20	122	56	67	112	66	73	172.50	
2	28JAN97	15, .	20	108	57	76	114	64	81	168.10	
3	04FEB97	22, .	20	127	64	71	123	71	88	171.80	
4	11FEB97	29, .	20	117	46	72	114	68	81	167.40	
5	18FEB97	36, .	30	123	58	88	115	65	103	173.80	
6	25FEB97	43, .	30	129	64	89	121	71	106	173.00	
7	04MAR97	50, .	30	121	63	85	112	66	96	173.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-11	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.9	.	.	.	30 - 70	%
				Lymphocytes	29.5	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	298000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	193	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00240 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-11	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	17FEB97	1	23FEB97	7	7
00262	Oral	2	100 MG	24FEB97	8	02MAR97	14	7
00262	Oral	3	150 MG	03MAR97	15	06MAR97	18	4
00262	Oral	4	200 MG	07MAR97	19	16MAR97	28	10
00262	Oral	4	200 MG	17MAR97	29	23MAR97	35	7
00262	Oral	4	200 MG	24MAR97	36	30MAR97	42	7
00262	Oral	4	200 MG	31MAR97	43	06APR97	49	7
00262	Oral	4	200 MG	07APR97	50	14APR97	57	8
	Oral	4	200 MG	14APR97	57	26APR97	69	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	69	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ENCOPRETIC	PSYCHOGENIC PHYSIOL DYSFUNC	MENTAL DISORD	CUR	1993
EYE INFECTION (LEFT AND RIGHT EYE)	EYE DISORD, OTHER	NERVOUS SYST/SENSE ORGAN DIS	CUR	1997
OCCASIONAL HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
CHRONIC EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1986
TUBES IN EARS	OPERATION, EAR	OPERATIONS	PRV	1986

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	40, .	28MAR97	28MAR97	500 MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	27, .	15MAR97	15MAR97	1 TAB	COUGH
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	27, .	15MAR97	15MAR97	1 TAB	COUGH
SENSORY ORGANS	Sulfacetamide Sodium	Sulfacetamide Sodium	-7, .	10FEB97	07APR97	15 ML	EYE INFECTION (LEFT AND RIGHT EYE)

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Av Block	INCREASED PR INTERVAL (PER EKG)	19, .	11 Days	200	CON	MIL	NO	PSR	No	No
	Heart Malformation	POSSIBLE RIGHT ATRIAL ENLARGEMENT (PER EKG)	29, .	15 Days	200	CON	MIL	NO	PSR	No	No
	Postural Hypotension	MILD OTHOSTATIC STATE (1X) (DUE TO BLOOD DRAW) {ORTHOSTATIC HYPOTENSION}	57, .	5 Mins	200	CON	MIL	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	8, .	64 Days	100	CON	MIL	NO	REL	No	No
Nervous System	Somnolence	DAYTIME SOMNOLENCE	8, .	8 Days	100	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	27, .	2 Days	200	CON	MIL	NO	PBU	Yes	No
Special Senses	Ear Pain	EARACHE	15, .	5 Days	150	CON	MIL	NO	PBU	No	No
	Eye Disorder	EYE INFECTION (LEFT AND RIGHT EYE)	-7, .	57 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

					Sitting			Standing				
Week	Visit Date	Relative Days *		Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	07FEB97	-10,	.	0	122	69	54	134	75	68	145.40	62.3
BL	17FEB97	1,	.	0	126	83	74	131	79	84	145.90	
1	24FEB97	8,	.	100	129	63	77	120	70	112	141.20	
2	03MAR97	15,	.	150	130	85	91	120	72	119	143.60	
3	07MAR97	19,	.	200	131	75	90	113	63	119	141.90	
4	17MAR97	29,	.	200	127	85	103	119	65	129 H	139.20	
5	24MAR97	36,	.	200	147	91	106	147	84	112	136.70	
6	31MAR97	43,	.	200	143	83	96	122	74	117	136.90	
7	07APR97	50,	.	200	139	81	108	116	76	121 H	134.50 L	
8	14APR97	57,	.	200	139	74	102	116	79	114	135.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	32	.	.	.	30 - 70	%
				Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	399	.	.	+	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	3.9	.	.	.	0 - 10	%
				Eosinophils	8.1	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	285	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00262 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	01NOV96	1	07NOV96	7	7
00264	Oral	2	100 MG	08NOV96	8	10NOV96	10	3
00264	Oral	3	150 MG	11NOV96	11	17NOV96	17	7
00264	Oral	4	200 MG	18NOV96	18	24NOV96	24	7
00264	Oral	4	200 MG	25NOV96	25	01DEC96	31	7
00264	Oral	4	200 MG	02DEC96	32	10DEC96	40	9
00264	Oral	4	200 MG	11DEC96	41	15DEC96	45	5
00264	Oral	4	200 MG	16DEC96	46	22DEC96	52	7
	Oral	4	200 MG	23DEC96	53	04JAN97	65	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	65	200	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
ASTHMA - NO PROBLEMS FOR 2 YRS	ASTHMA	RESPIRATORY SYST DIS	PRV	1991

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-732, .	31OCT94	.	325MG PRN	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE
	Pseudoephedrine Hydrochloride	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE
RESPIRATORY	Ibuprofen	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE
	Pseudoephedrine Hydrochloride	Coadvil	-732, .	31OCT94	.	400MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Electrocardiogram Abnormal	NONSPECIFIC T-WAVE ABNORMALITY (PER EKG) BASELINE ARTIFACT	53, .	Not Stated	200	CON	MIL	NO	PSR	No	No
	Tachycardia	INCREASED HEART RATE	11, .	Not Stated	150	CON	MIL	NO	PSR	No	No
		SINUS TACHYCARDIA	53, .	Not Stated	200	CON	MIL	NO	PSR	No	No
Nervous System	Agitation	AGITATION	11, .	8 Days	150	CON	MOD	NO	PSR	No	No
	Insomnia	DECREASED SLEEP (INITIAL, MIDDLE)	41, .	6 Days	200	CON	MIL	NO	PSR	No	No
	Somnolence	DAYTIME SOMNOLENCE	8, .	25 Days	100	CON	MOD	NO	PSR	No	No
			46, .	Not Stated	200	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

					Sitting			Standing				
Week	Visit Date	Relative Days *		Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	25OCT96	-7,	.	0	138	73	71	129	82	83	171.00	62.5
BL	01NOV96	1,	.	0	109	72	102	122	66	82	171.00	
1	08NOV96	8,	.	100	121	79	108	.	.	.	170.30	
1	11NOV96	11,	.	150	145	80	105	126	87	140 H		
2	18NOV96	18,	.	200	130	88	104	130	68	133 H	168.00	
3	25NOV96	25,	.	200	145	88	117	120	73	145 H	168.00	
4	02DEC96	32,	.	200	137	76	115	104	57	137 H	169.40	
6	11DEC96	41,	.	200	135	86	126	123	61	150 H	165.80	
6	16DEC96	46,	.	200	144	91	137 H	125	72	140 H	169.60	
7	23DEC96	53,	.	200	128	66	131	115	55	148 H	169.10	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.7	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	1.3	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	354000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	25	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	44.3	.	.	.	30 - 70	%
				Lymphocytes	42	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	287000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	53	Hemoglobin	13	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00264 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	53	Segmented Neutrophils	67.2	.	.	.	30 - 70	%
				Lymphocytes	26	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	1.6	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	314000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	96	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21JAN97	1	27JAN97	7	7
00276	Oral	2	0 MG	28JAN97	8	03FEB97	14	7
00276	Oral	3	0 MG	04FEB97	15	10FEB97	21	7
00276	Oral	4	0 MG	11FEB97	22	17FEB97	28	7
00276	Oral	5	0 MG	18FEB97	29	24FEB97	35	7
00276	Oral	5	0 MG	25FEB97	36	03MAR97	42	7
00276	Oral	6	0 MG	04MAR97	43	12MAR97	51	9
00276	Oral	6	0 MG	13MAR97	52	17MAR97	56	5
	Oral	5	0 MG	18MAR97	57	01APR97	71	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	71	0	Lack of Efficacy	ALTHOUGH IMPROVED REMAINS SYMPTOMATIC

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
EARLY REPOLARIZATION {EKG}	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997
HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
STOMACH ACHES	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1997

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Loperamide Hydrochloride	Imodium	70, .	31MAR97	31MAR97	1 TAB PRN	STOMACH VIRUS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-386, .	01JAN96	.	500 MG PRN	OCCASIONAL HEADACHE
			-314, .	13MAR96	.	500 MG PRN	SORE THROAT
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	53, .	14MAR97	14MAR97	440 MG	SORE THROAT
RESPIRATORY	Guaifenesin	Robitussin	51, .	12MAR97	18MAR97	1 TSP PRN	SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Fever	FEVER	52, .	6 Days	0	CON	MIL	NO	PBU	Yes	No
	Headache	HEADACHES	15, .	15 Days	0	CON	MIL	NO	PSR	No	No
	Infection	STOMACH VIRUS	70, .	2 Days	0	CON	MIL	NO	PSR	Yes	No
Digestive System	Decreased Appetite	DECREASED APPETITE	57, .	Not Stated	0	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	15, .	29 Days	0	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Weight Loss	WEIGHT LOSS	52, .	20 Days	0	CON	MIL	NO	PSR	No	No
Respiratory System	Pharyngitis	SORE THROAT	31, .	12:00 Hrs	0	CON	MIL	NO	PBU	No	No
			52, .	6 Days	0	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	17JAN97	-4, .	0	123	39	77	116	64	101	127.40	66.6
BL	21JAN97	1, .	0	115	59	85	.	.	.	128.60	
1	28JAN97	8, .	0	116	58	78	109	54	90	125.10	
2	04FEB97	15, .	0	115	56	85	114	64	93	127.00	
3	11FEB97	22, .	0	112	43	73	119	49	100	126.50	
4	18FEB97	29, .	0	122	64	91	115	59	97	129.00	
5	25FEB97	36, .	0	123	61	80	121	49	95	128.10	
6	04MAR97	43, .	0	121	62	91	107	70	111	128.10	
7	13MAR97	52, .	0	125	67	82	112	68	101	123.70	
8	18MAR97	57, .	0	105	49	76	107	57	98	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	1	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.6	.	.	.	30 - 70	%
				Lymphocytes	44.4	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	261000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	77	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.5	.	.	.	30 - 70	%
				Lymphocytes	34.3	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	1.2	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	210000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	140	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	58	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	36	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00276 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	19MAR96	1	25MAR96	7	7
00301	Oral	2	100 MG	26MAR96	8	04APR96	17	10
00301	Oral	3	150 MG	05APR96	18	11APR96	24	7
00301	Oral	4	200 MG	12APR96	25	15APR96	28	4
00301	Oral	4	200 MG	16APR96	29	22APR96	35	7
00301	Oral	4	200 MG	23APR96	36	29APR96	42	7
00301	Oral	4	200 MG	30APR96	43	06MAY96	49	7
00301	Oral	4	200 MG	07MAY96	50	13MAY96	56	7
00140	Oral	4	200 MG	14MAY96	57	10JUN96	84	28
00301	Oral	4	200 MG	11JUN96	85	11JUN96	85	1
00301	Oral	3	150 MG	12JUN96	86	13JUN96	87	2
00301	Oral	2	100 MG	14JUN96	88	16JUN96	90	3
00301	Oral	1	50 MG	17JUN96	91	23JUN96	97	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	97	50	Other reason	WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1983
HEADACHES{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
ASTHMA ATTACKS{HOSPITALIZED}	ASTHMA	RESPIRATORY SYST DIS	PRV	1990
BROKEN LEFT ARM{X2}	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1988
BROKEN RIGHT ARM	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CARDIOVASCULAR	Theophylline	Theo-Dur	-443, -499	01JAN95	.	600MGI	ASTHMA
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-443, -499	01JAN95	.	375MG PRN	HEADACHES
RESPIRATORY	Orciprenaline Sulfate	Alupent	-808, -864	01JAN94	.	2PUFFS PRN	ASTHMA
	Theophylline	Theo-Dur	-443, -499	01JAN95	.	600MGI	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	INCREASED SWEATING(VIRAL SYNDROME)	22, -35	20 Mins	150	CON	MIL	NO	PBU	No	No
		NAUSEA(VIRAL SYNDROME)	22, -35	1 Days	150	CON	MIL	NO	PBU	No	No
		VOMITING(VIRAL SYNDOME)	22, -35	1 Days	150	CON	MIL	NO	PBU	No	No
Carciovascular System	Tachycardia	INCREASE IN PULSE(SECONDARY TO ALUPENT)	36, -21	15 Mins	200	CON	MOD	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	22, -35	1 Days	150	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	06MAR96	-13, -69	0	91	45	79	108	59	101	127.00	80.0
BL	19MAR96	1, -56	0	93	45	75	95	57	75	129.00	
1	26MAR96	8, -49	100	91	44	84	114	49	72	129.50	
2	05APR96	18, -39	150	105	59	77	107	65	89	125.20	
3	12APR96	25, -32	200	106	52	90	99	61	108	126.50	
4	16APR96	29, -28	200	116	63	74	108	58	90	125.70	
5	23APR96	36, -21	200	124	70	114	107	59	126 H	124.80	
6	30APR96	43, -14	200	97	46	83	93	62	95	127.40	
7	07MAY96	50, -7	200	101	53	86	115	62	92	128.60	
8	14MAY96	57, 1	200	99	52	66	105	57	88	127.10	
12	11JUN96	85, 29	200	107	56	66	107	75	78	129.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-6	Neutrophil Bands	1	L	.	.	4 - 12	%
				Segmented Neutrophils	57	.	.	.	30 - 70	%
				Lymphocytes	25	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	2	.	.	.	0 - 2	%
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	229	H	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	75	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEC		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.4	.	.	.	30 - 70	%
				Lymphocytes	32.5	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	8.7	H	.	.	0 - 5	%
				Basophils	2.5	H	.	.	0 - 2	%
				Platelets	272000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	13.1	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.6	.	.	.	30 - 70	%
				Lymphocytes	34	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	245000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00301 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	171	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	27MAR96	1	02APR96	7	7
00302	Oral	2	0 MG	03APR96	8	10APR96	15	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	No	No	15	0	Adverse event, including intercurrent illness	PATIENT WAS WITHDRAWN DUE TO MACULOPAPULAR RASH,SINUS BRADYCARDIA WITH ARRHYTHMIA AND JUNCTIONAL ESCAPE PATTERN

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ABDOMINAL CYST-SURGERY	OPERATION, OTHER ABDOM	OPERATIONS	PRV	1990
TENDONITIS	RHEUMATIC DISORD	MUSCULOSKEL/CONNECT TISSUE DIS	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-86, .	01JAN96	20MAR96#	500MG	TENDONITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Nodal Arrhythmia	JUNCTIONAL ESCAPE PATTERN(EKG)	8, .	Not Stated	0	CON	MIL	NO	PSR	No	No
Skin and Appendages	Maculopapular Rash	RASH ON WRIST ELBOWS,ANKLE,(MACULOPAPULAR)	8, .	Not Stated	0	CON	MOD	STP	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20MAR96	-7, .	0	145	51	56	147	50	77	157.10	68.0
BL	27MAR96	1, .	0	138	59	85	130	44	85	158.20	
1	03APR96	8, .	0	122	50	64	123	43	84	157.10	
2	10APR96	15, .	0	123	50	66	115	50	60	158.60	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.7	.	.	.	30 - 70	%
				Lymphocytes	35.4	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	11.4	H	.	+	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	212000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	108	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00302 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	02APR96	1	08APR96	7	7
00303	Oral	2	20 MG	09APR96	8	15APR96	14	7
00303	Oral	3	20 MG	16APR96	15	22APR96	21	7
00303	Oral	4	20 MG	23APR96	22	29APR96	28	7
00303	Oral	4	20 MG	30APR96	29	06MAY96	35	7
00303	Oral	4	20 MG	07MAY96	36	13MAY96	42	7
00303	Oral	4	20 MG	14MAY96	43	21MAY96	50	8
00303	Oral	4	20 MG	22MAY96	51	27MAY96	56	6
00155	Oral	4	20 MG	28MAY96	57	24JUN96	84	28
00155	Oral	4	20 MG	25JUN96	85	29JUL96	119	35
00155	Oral	4	20 MG	30JUL96	120	26AUG96	147	28
00155	Oral	4	20 MG	27AUG96	148	24SEP96	176	29
00155	Oral	4	20 MG	25SEP96	177	29OCT96	211	35
00155	Oral	4	20 MG	30OCT96	212	09DEC96	252	41
00303	Oral	4	20 MG	10DEC96	253	10DEC96	253	1
00303	Oral	3	20 MG	11DEC96	254	12DEC96	255	2
00303	Oral	2	20 MG	13DEC96	256	15DEC96	258	3
00303	Oral	1	20 MG	16DEC96	259	22DEC96	265	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	Yes	265	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
SINUS INFECTION	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Clarithromycin	Biaxin	-32, -88	01MAR96	.	500MG	SINUS INFECTION
CENTRAL NERVOUS SYSTEM	Chlorphenamine Maleate	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Fluoxetine	Prozac	-23, -79	10MAR96	17MAR96#	10MG	DEPRESSION
	Paracetamol	Tylenol	-32, -88	01MAR96	.	650 PRN	SINUS INFECTION
		Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	23, -34	24APR96	24APR96	20MG	NASAL CONGESTION
MUSCULO-SKELETAL	Ibuprofen	Advil	-822, -878	01JAN94	.	200MG	OCCASIONAL HEADACHE
RESPIRATORY	Chlorphenamine Maleate	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
			-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Dextromethorphan Hydrobromide	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
			-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Diphenhydramine Hydrochloride	Benadryl	23, -34	24APR96	24APR96	20MG	NASAL CONGESTION
	Paracetamol	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
			-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
	Pseudoephedrine Hydrochloride	Tylenol Cold And Flu	-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION
			-32, -88	01MAR96	.	300MG PRN	SINUS INFECTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Allergic Reaction	SEASONAL ALLERGIES	28, -29	1 Days	20	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25MAR96	-8, -64	0	116	66	59	123	71	54	166.20	71.0
BL	02APR96	1, -56	0	108	59	68	122	58	76	166.90	
1	09APR96	8, -49	20	116	56	62	121	45	65	166.20	
2	16APR96	15, -42	20	122	57	61	121	60	64	165.00	
3	23APR96	22, -35	20	123	57	62	120	48	66	165.00	
4	30APR96	29, -28	20	130	58	61	125	51	59	165.60	
5	07MAY96	36, -21	20	130	58	62	121	63	60	165.00	
6	14MAY96	43, -14	20	115	50	62	123	61	64	167.00	
7	22MAY96	51, -6	20	115	65	72	123	65	72	166.90	
8	28MAY96	57, 1	20	107	49	49	107	46	56	164.90	
12	25JUN96	85, 29	20	138	69	75	133	65	72	166.26	
16	30JUL96	120, 64	20	109	47	62	116	59	68	170.67	
20	27AUG96	148, 92	20	122	52	64	128	58	70	169.60	
24	25SEP96	177, 121	20	122	59	68	121	67	68	169.30	
32	30OCT96	212, 156	20	116	58	67	117	71	72	170.20	
32	10DEC96	253, 197	20	127	60	67	118	60	76	172.80	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.3	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	11.8	H	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	167000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	64	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.1	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.7	.	.	.	30 - 70	%
				Lymphocytes	35.5	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	177000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	42.6	.	.	.	30 - 70	%
				Lymphocytes	40.6	.	.	.	21 - 51	%
				Monocytes	10.7	H	.	.	0 - 10	%
				Eosinophils	5.6	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	177000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	148	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	253	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.9	.	.	.	30 - 70	%
				Lymphocytes	31.4	.	.	.	21 - 51	%
				Monocytes	7.5	.	.	.	0 - 10	%
				Eosinophils	5.4	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	30000	L	.	-	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 16/CONTINUATION-WEEK 32	253	Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	56	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
		VISIT 16/UNSCHEDULED LAB 1	256	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	6.9	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00303 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 16/UNSCHEDULED LAB 1	256	Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	09APR96	1	15APR96	7	7
00304	Oral	2	20 MG	16APR96	8	22APR96	14	7
00304	Oral	3	20 MG	23APR96	15	29APR96	21	7
00304	Oral	4	20 MG	30APR96	22	06MAY96	28	7
00304	Oral	5	30 MG	07MAY96	29	13MAY96	35	7
00304	Oral	5	30 MG	14MAY96	36	20MAY96	42	7
00304	Oral	5	30 MG	21MAY96	43	27MAY96	49	7
00304	Oral	5	30 MG	28MAY96	50	03JUN96	56	7
00159	Oral	5	30 MG	04JUN96	57	01JUL96	84	28
00159	Oral	5	30 MG	02JUL96	85	29JUL96	112	28
00159	Oral	5	30 MG	30JUL96	113	26AUG96	140	28
00159	Oral	5	30 MG	27AUG96	141	22SEP96	167	27
00159	Oral	5	30 MG	23SEP96	168	21OCT96	196	29
00304	Oral	4	20 MG	22OCT96	197	23OCT96	198	2
00304	Oral	3	20 MG	24OCT96	199	24OCT96	199	1
00304	Oral	2	20 MG	25OCT96	200	28OCT96	203	4
00304	Oral	1	20 MG	29OCT96	204	04NOV96	210	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	210	20	Other reason	PATIENT WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE{OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	-464, -520	01JAN95	.	400MG	OCCASIONAL HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE{WORSENING FROM BASELINE}	43, -14	8 Days	30	CON	MOD	NO	PSR	No	No
Carciovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	43, -14	30 Mins	30	CON	MIL	NO	PSR	No	No
Metabolic and Nutritional Disorders	Weight Gain	WEIGHT GAIN {10 LBS}[WEIGHT GAIN]	113, 57	Not Stated	30	CON	MIL	NO	PSR	No	No
Nervous System	Somnolence	DAYTIME SLEEPINESS	36, -21	15 Days	30	CON	MOD	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	03APR96	-6, -62	0	122	56	73	131	65	70	201.00	67.0
BL	09APR96	1, -56	0	118	59	80	121	52	82	200.80	
1	16APR96	8, -49	20	138	60	72	139	57	73	199.90	
2	23APR96	15, -42	20	138	59	74	145	63	86	195.90	
3	30APR96	22, -35	20	140	70	90	145	83	102	198.10	
4	07MAY96	29, -28	30	132	71	91	139	73	100	197.20	
5	14MAY96	36, -21	30	137	60	100	139	74	102	195.20	
6	21MAY96	43, -14	30	138	65	91	68 L	56	109	198.70	
7	28MAY96	50, -7	30	137	64	69	120	59	79	200.70	
8	04JUN96	57, 1	30	130	64	99	128	60	102	198.70	
12	02JUL96	85, 29	30	131	64	70	120	67	75	202.20	
16	30JUL96	113, 57	30	113	52	78	120	54	98	213.00	
20	27AUG96	141, 85	30	129	61	88	142	61	96	207.20	
24	23SEP96	168, 112	30	118	57	88	91	56	89	207.40	
28	21OCT96	196, 140	30	140	54	70	139	60	73	210.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.8	.	.	.	30 - 70	%
				Lymphocytes	39.8	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	217000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	143	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	24	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	17.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.6	.	.	.	30 - 70	%
				Lymphocytes	31	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	7.7	H	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	230000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	165	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	110	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	16.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.9	.	.	.	41 - 50	%
				Red Blood Cell Count	5.5	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68	.	.	.	30 - 70	%
				Lymphocytes	23.8	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	153	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00304 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	141	Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	07MAY96	1	13MAY96	7	7
00305	Oral	2	100 MG	14MAY96	8	20MAY96	14	7
00305	Oral	3	150 MG	21MAY96	15	27MAY96	21	7
00305	Oral	4	200 MG	28MAY96	22	03JUN96	28	7
00305	Oral	4	200 MG	04JUN96	29	10JUN96	35	7
00305	Oral	4	200 MG	11JUN96	36	18JUN96	43	8
00305	Oral	4	200 MG	19JUN96	44	24JUN96	49	6
00305	Oral	4	200 MG	25JUN96	50	02JUL96	57	8
00151	Oral	4	200 MG	03JUL96	58	05AUG96	91	34
00151	Oral	4	200 MG	06AUG96	92	26AUG96	112	21
00151	Oral	4	200 MG	27AUG96	113	23SEP96	140	28
00151	Oral	4	200 MG	24SEP96	141	28OCT96	175	35
00151	Oral	4	200 MG	29OCT96	176	02DEC96	210	35
00151	Oral	4	200 MG	03DEC96	211	09JAN97	248	38
00305	Oral	4	200 MG	10JAN97	249	10JAN97	249	1
00305	Oral	3	150 MG	11JAN97	250	12JAN97	251	2
00305	Oral	2	100 MG	13JAN97	252	15JAN97	254	3
00305	Oral	1	50 MG	16JAN97	255	22JAN97	261	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	Yes	261	50		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Loperamide Hydrochloride	Imodium A-D	57, -1	02JUL96	02JUL96	4 MG	NAUSEA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Electrocardiogram Abnormal	POSITIVE/NEGATIVE RIGHT AXIS DEVIATION (EKG)	249, 192	19 Days	200	CON	MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	8, -50	22 Days	100	CON	MOD	NO	PSR	No	No
			58, 1	35 Days	200	CON	MIL	NO	PSR	No	No
			126, 69	142 Days	200	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	8, -50	15 Days	100	CON	MOD	NO	PSR	No	No
			22, -36	23 Days	200	CON	MIL	NO	PSR	No	No
			57, -1	1 Days	200	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS	8, -50	15 Days	100	CON	MOD	NO	PSR	No	No
			22, -36	71 Days	200	CON	MIL	NO	PSR	No	No
			126, 69	142 Days	200	CON	MIL	NO	PSR	No	No
Special Senses	Abnormal Vision	BLURRED VISION	58, 1	35 Days	200	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	01MAY96	-6, -63	0	114	53	80	111	66	105	136.50	72.3
BL	07MAY96	1, -57	0	108	54	86	107	53	89	135.90	
1	14MAY96	8, -50	100	107	65	92	108	69	98	135.10	
2	21MAY96	15, -43	150	96	54	94	99	37	98	133.80	
3	28MAY96	22, -36	200	123	62	96	106	64	96	133.70	
4	04JUN96	29, -29	200	126	76	100	93	47	132 H	135.60	
5	11JUN96	36, -22	200	123	72	96	98	38	.	135.60	
6	19JUN96	44, -14	200	115	65	96	103	53	120	133.90	
7	25JUN96	50, -8	200	120	74	100	114	60	135 H	134.06	
8	03JUL96	58, 1	200	105	60	115	95	53	140 H	134.50	
12	06AUG96	92, 35	200	113	61	96	99	46	120	136.30	
16	27AUG96	113, 56	200	114	56	89	105	55	123 H	134.30	
20	24SEP96	141, 84	200	103	57	91	90	53	117	132.80	
24	29OCT96	176, 119	200	115	65	88	100	50	126 H	137.00	
28	03DEC96	211, 154	200	115	62	100	105	71	121 H	138.60	
32	10JAN97	249, 192	200	122	65	98	106	68	125 H	137.40	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.5	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	200	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	29	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEC	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	58	Hemoglobin	15.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.7	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.3	.	.	.	30 - 70	%
				Lymphocytes	30	.	.	.	21 - 51	%
				Monocytes	12.2	H	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	58	Basophils	0.5	.	.	.	0 - 2	%
				Platelets	154000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	225	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
		VISIT 13/CONTINUATION-WEEK 20	141	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4	.	.	.	30 - 70	%
				Lymphocytes	39	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	141	Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	164000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	200	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	1.4	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	249	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00305 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	249	Hematocrit	44.3	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58	.	.	.	30 - 70	%
				Lymphocytes	33.6	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	0.7	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	162000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	195	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	70	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	11JUN96	1	17JUN96	7	7
00306	Oral	2	0 MG	18JUN96	8	24JUN96	14	7
00306	Oral	3	0 MG	25JUN96	15	01JUL96	21	7
00306	Oral	4	0 MG	02JUL96	22	08JUL96	28	7
00306	Oral	4	0 MG	09JUL96	29	15JUL96	35	7
00306	Oral	4	0 MG	16JUL96	36	22JUL96	42	7
00306	Oral	4	0 MG	23JUL96	43	29JUL96	49	7
00306	Oral	5	0 MG	30JUL96	50	05AUG96	56	7
	Oral	5	0 MG	06AUG96	57	19AUG96	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	70	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
NON MALIGNANT LUMP REMOVED FROM(LEFT)BREAST	OPERATION, BREAST	OPERATIONS	PRV	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
BLOOD/BLOOD FORM ORGANS	Ferrous Sulfate	Feosol Liquid	44, .	24JUL96	.	4 TSP.	ANEMIA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Vasodilatation	HOT FLASHES	22, .	50 Days	0	CON	MIL	NO	PSR	No	No
Hemic and Lymphatic System	Anemia	ANEMIA	-8, .	Not Stated	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	03JUN96	-8, .	0	106	60	57	99	53	89	115.40	64.0
BL	11JUN96	1, .	0	115	49	70	117	70	98	120.30	
1	18JUN96	8, .	0	94	53	99	98	58	96	118.50	
2	25JUN96	15, .	0	140	90	90	131	76	87	116.20	
3	02JUL96	22, .	0	117	59	79	118	72	93	118.40	
4	09JUL96	29, .	0	114	66	78	92	60	100	117.60	
5	16JUL96	36, .	0	104	55	85	114	58	94	117.20	
6	23JUL96	43, .	0	110	55	79	107	67	98	118.60	
7	30JUL96	50, .	0	98	45	76	93	58	95	119.40	
8	06AUG96	57, .	0	105	40	91	94	44 L	96	118.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	36	.	.	.	30 - 70	%
				Lymphocytes	60	H	.	.	21 - 51	%
				Monocytes	4	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	120	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-8	Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-5	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.6	.	.	.	30 - 70	%
				Lymphocytes	30.3	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	11.8	L	.	.	12 - 15.6	G/DL
				Hematocrit	34.9	L	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.5	.	.	.	30 - 70	%
				Lymphocytes	30.3	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	3.6	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	242000	.	.	.	130000 - 400000	PER CUMM

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00306 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	114	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	04NOV96	1	14NOV96	11	11
00312	Oral	2	0 MG	15NOV96	12	17NOV96	14	3
00312	Oral	3	0 MG	18NOV96	15	01DEC96	28	14
00312	Oral	4	0 MG	02DEC96	29	08DEC96	35	7
00312	Oral	4	0 MG	09DEC96	36	15DEC96	42	7
00312	Oral	4	0 MG	16DEC96	43	26DEC96	53	11
00312	Oral	4	0 MG	27DEC96	54	29DEC96	56	3
00312	Oral	5	0 MG	30DEC96	57	06JAN97	64	8
	Oral	5	0 MG	06JAN97	64	20JAN97	78	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	78	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES TO ERYTHROCIN	ADVERSE EFF/ANTIBIOTIC	EXT CAUSES OF INJURY/POISONING	CUR	
OCCASIONAL HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
SINUS ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996
STOMACH ULCER	ULCER, GASTRIC	DIGESTIVE SYST	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ranitidine Hydrochloride	Zantac	-308, .	01JAN96	.	300 MG PRN	STOMACH ULCER
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Tri-Levlen	-1038, .	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
			-1038, .	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
	Levonorgestrel	Tri-Levlen	-1038, .	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
			-1038, .	01JAN94	.	1 TAB DAILY	BIRTH CONTROL
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	-673, .	01JAN95	.	400 MG PRN	OCCASIONAL HEADACHE
RESPIRATORY	Guaifenesin	Entex	-308, .	01JAN96	.	4 TABS	SINUS ALLERGIES
	Loratadine	Claritin	-308, .	01JAN96	.	10 MG	SINUS ALLERGIES
	Phenylephrine Hydrochloride	Entex	-308, .	01JAN96	.	4 TABS	SINUS ALLERGIES
	Phenylpropanolamine Hydrochloride	Entex	-308, .	01JAN96	.	4 TABS	SINUS ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHES	64, .	15 Days	0	CON	MIL	NO	PBU	No	No
	Headache	INCREASE IN HEADACHES	54, .	Not Stated	0		MOD	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	30OCT96	-5, .	0	129	66	89	119	83	102	152.40	58.0
BL	04NOV96	1, .	0	103	54	.	109	56	.	151.70	
2	15NOV96	12, .	0	106	67	81	122	68	87	154.60	
2	18NOV96	15, .	0	106	78	100	112	50	106	153.30	
4	02DEC96	29, .	0	129	61	94	127	61	97	157.30	
5	09DEC96	36, .	0	121	57	96	120	62	103	156.70	
6	16DEC96	43, .	0	126	65	83	117	70	97	156.80	
8	27DEC96	54, .	0	111	61	82	114	68	68	160.00	
8	30DEC96	57, .	0	126	66	91	121	73	97	154.60	
8	06JAN97	64, .	0	122	64	88	128	46	102	159.40	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.2	.	.	.	30 - 70	%
				Lymphocytes	31.3	.	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	6.8	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	421000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-5	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	5.5	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	419000	H	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	59	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00312 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28OCT96	1	03NOV96	7	7
00324	Oral	2	20 MG	04NOV96	8	10NOV96	14	7
00324	Oral	3	20 MG	11NOV96	15	17NOV96	21	7
00324	Oral	4	20 MG	18NOV96	22	24NOV96	28	7
00324	Oral	4	20 MG	25NOV96	29	01DEC96	35	7
00324	Oral	4	20 MG	02DEC96	36	08DEC96	42	7
00324	Oral	4	20 MG	09DEC96	43	15DEC96	49	7
00324	Oral	4	20 MG	16DEC96	50	26DEC96	60	11
	Oral	4	20 MG	27DEC96	61	08JAN97	73	13

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	73	20	Adverse event, including intercurrent illness	RASH DEVELOPED BETWEEN WEEK 7 & 8

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES (OCCASIONAL)	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SEASONAL ALLERGIES	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	
SINUS CONGESTION	UPPER RESP DISORD, OTHER	RESPIRATORY SYST DIS	CUR	1996
UNCONSCIOUS AT AGE 1 - HIT HEAD IN FALL	COMA AND STUPOR	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1984

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol Extra Strength	-88, .	01AUG96	.	500 MG PRN	OCCASIONAL HEADACHES
		Tylenol Sinus	-88, .	01AUG96	.	1 TAB PRN	SINUS CONGESTION
	Pseudoephedrine Hydrochloride	Tylenol Sinus	-88, .	01AUG96	.	1 TAB PRN	SINUS CONGESTION
MUSCULO-SKELETAL	Ibuprofen	Advil	-88, .	01AUG96	.	200 MG PRN	OCCASSIONAL HEADACHES
RESPIRATORY	Paracetamol	Tylenol Sinus	-88, .	01AUG96	.	1 TAB PRN	SINUS CONGESTION
	Pseudoephedrine Hydrochloride	Sudafed	-88, .	01AUG96	.	120 MG PRN	SINUS CONGESTION
		Tylenol Sinus	-88, .	01AUG96	.	1 TAB PRN	SINUS CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Decreased Appetite	DECREASED APPETITE	50, .	31 Days	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	2, .	21 Days	20	CON	MIL	NO	PSR	No	No
Nervous System	Abnormal Dreams	INCREASED DREAMING	29, .	Not Stated	20	CON	MIL	NO	PSR	No	No
		NIGHTMARES	15, .	15 Days	20	CON	MIL	NO	PSR	No	No
	Insomnia	INSOMNIA	15, .	8 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Respiratory Disorder	COLD {SYMPTOMS}	43, .	8 Days	20	CON	MIL	NO	UNR	No	No
Skin and Appendages	Rash	RASH	61, .	20 Days	20	CON	MOD	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	21OCT96	-7, .	0	126	59	88	116	62	98	127.70	61.0
BL	28OCT96	1, .	0	130	64	82	131	75	85	126.30	
1	04NOV96	8, .	20	116	69	78	115	55	86	125.10	
2	11NOV96	15, .	20	114	66	86	127	66	83	126.50	
3	18NOV96	22, .	20	114	64	77	106	67	80	123.40	
4	25NOV96	29, .	20	119	59	89	77 L	55	94	124.80	
5	02DEC96	36, .	20	115	65	85	107	73	100	127.30	
6	09DEC96	43, .	20	114	72	85	106	57	86	124.90	
7	16DEC96	50, .	20	122	73	88	108	61	84	123.20	
8	27DEC96	61, .	20	115	62	86	132	68	89	124.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.9	.	.	.	30 - 70	%
				Lymphocytes	29.1	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	328000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	33.8	.	.	.	21 - 51	%
				Monocytes	9.6	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	305000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	75	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00324 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	61	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	65	L	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	27AUG96	1	02SEP96	7	7
00325	Oral	2	100 MG	03SEP96	8	08SEP96	13	6
00325	Oral	3	150 MG	09SEP96	14	15SEP96	20	7
00325	Oral	4	200 MG	16SEP96	21	22SEP96	27	7
00325	Oral	4	200 MG	23SEP96	28	29SEP96	34	7
00325	Oral	4	200 MG	30SEP96	35	09OCT96	44	10
00325	Oral	4	200 MG	10OCT96	45	13OCT96	48	4
00325	Oral	4	200 MG	14OCT96	49	20OCT96	55	7
00166	Oral	4	200 MG	21OCT96	56	17NOV96	83	28
00166	Oral	4	200 MG	18NOV96	84	15DEC96	111	28
00325	Oral	4	200 MG	16DEC96	112	16DEC96	112	1
00325	Oral	3	150 MG	17DEC96	113	18DEC96	114	2
00325	Oral	2	100 MG	19DEC96	115	21DEC96	117	3
00325	Oral	1	50 MG	22DEC96	118	28DEC96	124	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	124	50	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
HEADACHE {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1990
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1995
NAUSEA {STOMACH UPSET}	DYSPEPSIA	DIGESTIVE SYST	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Ranitidine Hydrochloride	Zantac	-604, -659	01JAN95	.	2TABS PRN	STOMACH UPSET
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol Extra Strength	-604, -659	01JAN95	.	1TAB PRN	MENSTRUAL CRAMPS
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	45, -11	10OCT96	.	150 MG	NASAL CONGESTION
	Dofamium Chloride	Desogen	27, -29	22SEP96	.	1 TAB DAILY	BIRTH CONTROL
MUSCULO-SKELETAL	Ketoprofen	Orudis Kt	-2430,-2485	01JAN90	.	2CAPS PRN	OCCASIONAL HEADACHE
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	45, -11	10OCT96	.	150 MG	NASAL CONGESTION
	Salbutamol	Ventolin Inhaler	-2430,-2485	01JAN90	.	2PUFFS PRN	ASTHMA
			-2430,-2485	01JAN90	.	2PUFFS PRN	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Chills	CHILLS	45, -11	40 Days	200	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHES	45, -11	40 Days	200	CON	MOD	NO	PBU	Yes	No
Carciovascular System	Syncope	DIZZINESS WITH SYNCOPE	6, -50	1 Days	50	CON	MIL	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	58, 3	27 Days	200		MOD	NO	PSR	No	No
Digestive System	Dry Mouth	DRY MOUTH	28, -28	8 Days	200	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	11, -45	11 Days	100	CON	MIL	NO	PSR	No	No
			28, -28	8 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Abnormal Dreams	INCREASED DREAMING	35, -21	11 Days	200	CON	MIL	NO	PSR	No	No
	Dizziness	DIZZINESS	6, -50	16 Days	50	CON	MOD	NO	PSR	No	No
			22, -34	Not Stated	200	CON	MIL	NO	PSR	No	No
Respiratory System	Cough Increased	COUGH	45, -11	40 Days	200	CON	MOD	NO	UNR	Yes	No
	Dyspnea	SHORTNESS OF BREATH	6, -50	16 Days	50	CON	MIL	NO	PSR	No	No
	Rhinitis	NASAL CONGESTION	45, -11	40 Days	200	CON	MOD	NO	UNR	Yes	No
Special Senses	Keratoconjunctivitis	IRRITATION IN EYES (DRY EYES)	14, -42	8 Days	150	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21AUG96	-6, -61	0	103	53	72	106	45	90	118.63	67.0
BL	27AUG96	1, -55	0	108	53	65	96	55	97	116.00	
1	03SEP96	8, -48	100	107	73	88	94	57	108	114.80	
2	09SEP96	14, -42	150	113	67	109	100	65	114	114.44	
3	16SEP96	21, -35	200	102	53	93	90	.	115	120.39	
4	23SEP96	28, -28	200	112	56	103	99	51	131 H	115.32	
5	30SEP96	35, -21	200	123	61	74	101	61	114	116.30	
6	10OCT96	45, -11	200	121	63	93	107	59	119	117.40	
7	14OCT96	49, -7	200	149	70	94	118	60	123	117.80	
8	21OCT96	56, 1	200	130	68	93	128	58	119	117.20	
12	18NOV96	84, 29	200	131	67	89	113	74	125	118.90	
16	16DEC96	112, 57	200	113	60	87	92	47	131 H	118.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.2	.	.	.	30 - 70	%
				Lymphocytes	40.1	.	.	.	21 - 51	%
				Monocytes	9.3	.	.	.	0 - 10	%
				Eosinophils	2.4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-6	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.3	.	.	.	30 - 70	%
				Lymphocytes	32.2	.	.	.	21 - 51	%
				Monocytes	8.8	.	.	.	0 - 10	%
				Eosinophils	0.5	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	313000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 12/CONTINUATION-WEEK 16	112	Hemoglobin	14	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	44.2	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	0.3	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	340000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00325 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 12/CONTINUATION-WEEK 16	112	Alkaline Phosphatase	64	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	4.4	H	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	05SEP96	1	08SEP96	4	4
00326	Oral	2	100 MG	09SEP96	5	15SEP96	11	7
00326	Oral	3	150 MG	16SEP96	12	22SEP96	18	7
00326	Oral	4	200 MG	23SEP96	19	29SEP96	25	7
00326	Oral	4	200 MG	30SEP96	26	06OCT96	32	7
00326	Oral	4	200 MG	07OCT96	33	16OCT96	42	10
00326	Oral	4	200 MG	17OCT96	43	23OCT96	49	7
00326	Oral	4	200 MG	24OCT96	50	27OCT96	53	4
00167	Oral	4	200 MG	28OCT96	54	24NOV96	81	28
00167	Oral	4	200 MG	25NOV96	82	15DEC96	102	21
00326	Oral	4	200 MG	16DEC96	103	16DEC96	103	1
00326	Oral	3	150 MG	17DEC96	104	18DEC96	105	2
00326	Oral	2	100 MG	19DEC96	106	21DEC96	108	3
00326	Oral	1	50 MG	22DEC96	109	28DEC96	115	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	115	50	Lack of Efficacy	THIS WAS PATIENTS ACTUD LAST VISIT TO CLINIC PATIENT WAS GIVEN DOWN TITRATION MEDS, FINISHED ON 28 DEC 96 BUT DID NOT RETURN TO CLINIC - MAILED MED PACKET TO US

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
COLD SYMPTOMS	NASOPHARYNGITIS, ACUTE	RESPIRATORY SYST DIS	PRV	1996

CUR = Current, PRV = Past

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Dextromethorphan Hydrobromide	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS
	Doxylamine Succinate	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS
	Paracetamol	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS
	Pseudoephedrine Hydrochloride	Nyquil	-24, -77	12AUG96	15AUG96#	6 TBS.	COLD SYMPTOMS

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Tachycardia	TACHYCARDIA	26, -28	Not Stated	200	CON	MIL	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	40, -14	4 Days	200	CON	MIL	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	40, -14	4 Days	200	CON	MIL	NO	PSR	No	No
	Hyperkinesia	AKATHISIA	26, -28	18 Days	200	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26AUG96	-10, -63	0	139	64	93	143	74	98	227.10	68.0
BL	05SEP96	1, -53	0	152	81	91	158	87	108	227.70	
1	09SEP96	5, -49	100	139	58	88	124	69	98	226.50	
2	16SEP96	12, -42	150	136	63	88	95	70	98	223.60	
3	23SEP96	19, -35	200	139	78	98	138	76	105	223.50	
4	30SEP96	26, -28	200	125	65	111	105	57	126	222.00	
5	07OCT96	33, -21	200	139	72	108	129	86	121	221.50	
6	17OCT96	43, -11	200	141	67	98	124	51	112	215.30	
7	24OCT96	50, -4	200	152	76	96	134	55	125	218.90	
8	28OCT96	54, 1	200	139	70	106	123	86	105	215.50	
12	25NOV96	82, 29	200	146	74	112	85 L	74	126	213.00	
16	16DEC96	103, 50	200	.	.	.	.	.	.	211.10 L	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.3	.	.	.	30 - 70	%
				Lymphocytes	35.7	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	3.7	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	248000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	181	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	78	H	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	54	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.4	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	27.7	.	.	.	21 - 51	%
				Monocytes	4.4	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	234000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	54	Alanine Aminotransferase	34	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	120	H	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 12/CONTINUATION-WEEK 16	103	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.8	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.3	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	3.8	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	237000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	134	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	26	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00326 TREATMENT GROUP: IMIPRAMINE

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Oriental

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16SEP96	1	22SEP96	7	7
00327	Oral	2	0 MG	23SEP96	8	29SEP96	14	7
00327	Oral	3	0 MG	30SEP96	15	06OCT96	21	7
00327	Oral	4	0 MG	07OCT96	22	13OCT96	28	7
00327	Oral	5	0 MG	14OCT96	29	20OCT96	35	7
	Oral	5	0 MG	21OCT96	36	04NOV96	50	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	No	No	50	0	Lack of Efficacy	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
INSECT BITES	INJURY, SUPERFICIAL	INJURY/POISONING	CUR	1996
MENSTRUAL CRAMPS	GENITAL FEMALE DISORD, OTHER	GENITOURINARY SYST DIS	CUR	1994
SINUS ALLERGIES {CONGESTION}	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1996
STOMACHACHE {OCCASIONAL}	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Aluminium Hydroxide	Mylanta Double Strength	-624, .	01JAN95	.	800 MG PRN	STOMACHE
	Dicycloverine	Dicyclomine	-624, .	01JAN95	.	20 MG PRN	STOMACH ACHE
	Dimeticone, Activated	Mylanta Double Strength	-624, .	01JAN95	.	800 MG PRN	STOMACHE
	Magnesium Hydroxide	Mylanta Double Strength	-624, .	01JAN95	.	800 MG PRN	STOMACHE
	Ranitidine Hydrochloride	Zantac	-624, .	01JAN95	.	150 MG PRN	STOMACH ACHE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-989, .	01JAN94	.	1000 MG PRN	OCCASIONAL HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-259, .	01JAN96	.	25 MG PRN	INSECT BITES
MUSCULO-SKELETAL	Ibuprofen	Midol Ib	-989, .	01JAN94	.	400 MG PRN	MENSTRUAL CRAMPS
RESPIRATORY	Chlorphenamine Maleate	Codimal La	-259, .	01JAN96	.	24 MG PRN	SINUS ALLERGIES CONGESTION
	Diphenhydramine Hydrochloride	Benadryl	-259, .	01JAN96	.	25 MG PRN	INSECT BITES
	Pseudoephedrine Hydrochloride	Codimal La	-259, .	01JAN96	.	24 MG PRN	SINUS ALLERGIES CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	09SEP96	-7, .	0	111	56	93	109	49	101	90.80	60.1
BL	16SEP96	1, .	0	88	50	87	94	47	93	94.40	
1	23SEP96	8, .	0	88	45	93	96	53	106	89.90	
2	30SEP96	15, .	0	98	43	93	109	68	106	90.70	
3	07OCT96	22, .	0	96	46	91	92	66	112	90.40	
4	14OCT96	29, .	0	118	53	84	118	57	94	92.10	
5	21OCT96	36, .	0	99	50	79	104	55	89	91.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	42	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.6	.	.	.	30 - 70	%
				Lymphocytes	27.6	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	224000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 7/ACUTE PHASE-WEEK 5	36	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.6	.	.	.	30 - 70	%
				Lymphocytes	28.5	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	239000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	91	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00327 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 7/ACUTE PHASE-WEEK 5	36	Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00328 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07OCT96	1	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	1	20	Other reason	WITHDREW CONSENT

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00328 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BIVENTRICULAR HYPERTROPHY	CARDIOMEGALY	CIRCULATORY SYST	CUR	1996
HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
STOMACH ACHES {OCCASIONAL}	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	30SEP96	-7, .	0	123	67	70	112	85	79	85.30	59.5
BL	07OCT96	1, .	0	111	68	71	112	76	86	86.60	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00328 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)		Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.9	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35	.	.	.	30 - 70	%
				Lymphocytes	56	H	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	197000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	398	.	.	+	44 - 400	U/L
				Aspartate Aminotransferase	27	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00328 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)		Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	09OCT96	1	15OCT96	7	7
00329	Oral	2	20 MG	16OCT96	8	22OCT96	14	7
00329	Oral	3	20 MG	23OCT96	15	28OCT96	20	6
00329	Oral	4	20 MG	29OCT96	21	04NOV96	27	7
00329	Oral	4	20 MG	05NOV96	28	11NOV96	34	7
00329	Oral	4	20 MG	12NOV96	35	18NOV96	41	7
00329	Oral	5	30 MG	19NOV96	42	25NOV96	48	7
00329	Oral	5	30 MG	26NOV96	49	02DEC96	55	7
	Oral	5	30 MG	03DEC96	56	17DEC96	70	15

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	No	70	30	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {OCCASIONAL}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
REPOLARIZATION ON ECG {EARLY}	CARDIOVAS FUNCTIONS/ECG, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
SINUS BRADYCARDIA {MARKED}	BRADYCARDIA	CIRCULATORY SYST	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-647, .	01JAN95	.	500 MG PRN	HEADACHE OCCASIONAL

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Nervous System	Depression	WORSENING OF DEPRESSION	35, .	22 Days	20	CON	MOD	NO	PBU	No	No
	Dizziness	DIZZINESS IN AM	6, .	10 Days	20	CON	MIL	NO	REL	No	No
	Somnolence	SLEEPINESS IN AM	6, .	16 Days	20	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

					Sitting			Standing				
Week	Visit Date	Relative Days *		Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	01OCT96	-8,	.	0	108	62	59	101	67	65	122.30	66.1
BL	09OCT96	1,	.	0	119	56	64	128	62	88	121.60	
1	16OCT96	8,	.	20	123	58	57	122	60	67	120.70	
2	23OCT96	15,	.	20	126	57	66	125	64	71	120.30	
3	29OCT96	21,	.	20	123	57	54	129	71	58	123.50	
4	05NOV96	28,	.	20	124	65	73	114	63	97	119.10	
5	12NOV96	35,	.	20	107	58	50	107	64	62	121.70	
6	19NOV96	42,	.	30	130	64	64	133	63	80	122.20	
7	26NOV96	49,	.	30	114	61	54	115	61	66	120.50	
8	03DEC96	56,	.	30	115	58	62	121	60	66	120.90	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Hemoglobin	16.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	49.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.2	.	.	.	30 - 70	%
				Lymphocytes	34.5	.	.	.	21 - 51	%
				Monocytes	3.5	.	.	.	0 - 10	%
				Eosinophils	6.4	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	207000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	346	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	118	H	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-8	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.8	.	.	.	30 - 70	%
				Lymphocytes	32.6	.	.	.	21 - 51	%
				Monocytes	4.6	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	213000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	298	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00329 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEC	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21OCT96	1	27OCT96	7	7
00330	Oral	2	0 MG	28OCT96	8	04NOV96	15	8

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	No	No	15	0	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ATTENTION-DEFICIT HYPERACTIVITY DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1996
BROKEN EAR DRUM	EAR/MASTOID DISORD	NERVOUS SYST/SENSE ORGAN DIS	CUR	1996
POSSIBLE VENTRICULAR HYPERTROPHY	CARDIOMEGALY	CIRCULATORY SYST	CUR	1996
SINUS ARRHYTHMIA	ARRHYTHMIA	CIRCULATORY SYST	CUR	1996
SINUS BRADYCARDIA	BRADYCARDIA	CIRCULATORY SYST	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Augmentin	-20, .	01OCT96	.	750 MG	BROKEN EAR DRUM
	Clavulanic Acid	Augmentin	-20, .	01OCT96	.	750 MG	BROKEN EAR DRUM
CENTRAL NERVOUS SYSTEM	Pemoline Magnesium	Cylert	-13, .	08OCT96	08OCT96#	37.5 MG	ADHD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Bradycardia	SINUS BRADYCARDIA	8, .	8 Days	0	CON	MIL	NO	PSR	No	No
	Heart Malformation	POSSIBLE LEFT VENTRICULAR HYPERTROPHY	8, .	8 Days	0	CON	MIL	NO	PSR	No	No
	Supraventricular Extrasystoles	OCCASIONAL PREMATURE ATRIAL COMPLEXES	8, .	8 Days	0	CON	MIL	NO	PSR	No	No
Digestive System	Nausea	NAUSEA	1, .	Not Stated	0	CON	MOD	STP	REL	No	No
	Vomiting	VOMITING	12, .	2 Days	0	2	MIL	STP	PSR	No	No
Nervous System	Dizziness	DIZZINESS	1, .	Not Stated	0	CON	MOD	STP	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	15OCT96	-6, .	0	117	79	68	106	88	70	93.50	59.0
BL	21OCT96	1, .	0	106	68	65	120	71	80	94.00	
1	28OCT96	8, .	0	115	72	68	106	71	73	96.80	
2	04NOV96	15, .	0	112	66	62	106	72	72	96.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.1	L	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	11.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1	.	.	.	30 - 70	%
				Lymphocytes	26.3	.	.	.	21 - 51	%
				Monocytes	7.7	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	340000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	8 - 21	MG/DL
				Creatinine	1	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	3.2	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	184	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 39	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	60 - 110	MG/DL
				Globulin	3.7	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.009.00330 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
00182	Oral	3	20 MG	19DEC95	1	11JAN96	24	24
00182	Oral	4	20 MG	12JAN96	25	18JAN96	31	7
00182	Oral	4	20 MG	19JAN96	32	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	No	No	32	20	Lost to follow-up	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	10, .	28DEC95	28DEC95	325	HEADACHE
	Cannabis	Marijuana	-1448, .	01JAN92	.		ILLICIT USE
	Paracetamol	Tylenol	-7, .	12DEC95	12DEC95#	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	10, .	1 Days	20	CON	MIL	NO	PSR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	05DEC95	-14, .	0	.	.	.	.	.	.	137.50	71.0
BL	19DEC95	1, .	0	110	80	68	112	87	84	140.50	
3	12JAN96	25, .	20	118	72	72	122	82	84	135.50	
4	19JAN96	32, .	20	118	75	66	124	70	74	130.00 L	
SC	12DEC97	725, .#	0	118	70	82	118	75	94		

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Hemoglobin	15.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	9.7	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	73.5	.	.	.	40 - 75	%
				Lymphocytes	16	.	.	.	16 - 46	%
				Monocytes	6.7	.	.	.	0 - 12	%
				Eosinophils	2.7	.	.	.	0 - 7	%
				Basophils	1.2	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	71	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-14	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEC		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 5/ACUTE PHASE-WEEK 3	25	Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	POS		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00182 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 5/ACUTE PHASE-WEEK 3	25	Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03DEC95	1	11DEC95	9	9
00183	Oral	2	0 MG	12DEC95	10	19DEC95	17	8
00183	Oral	3	0 MG	20DEC95	18	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	18	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
INCREASED CREATININE	CREATININE, INCREASED	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
INCREASED URINE NITROGEN	URINE, ABN, OTHER	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
ASTHMATIC REACTION{BRIEF}	ASTHMA	RESPIRATORY SYST DIS	PRV	1994
SEIZURE{UNKNOWN ETIOLOGY 1X}	CONVULSIONS	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1989

CUR = Current, PRV = Past

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	21NOV95	-12, .	0	112	78	68	105	80	80	150.20	71.0
BL	28NOV95	-5, .	0	100	60	65	100	50	72	155.50	
1	05DEC95	3, .	0	125	75	68	110	70	82	154.00	
1	12DEC95	10, .	0	115	70	72	98	65	92	153.50	
2	19DEC95	17, .	0	122	78	68	108	68	92	158.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.8	L	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	37	.	.	.	30 - 70	%
				Lymphocytes	51	.	.	.	21 - 51	%
				Monocytes	5.2	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	107	H	.	+	7 - 25	MG/DL
				Creatinine	13.2	H	.	+	0.8 - 1.5	MG/DL
				Uric Acid	8.8	H	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	285	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	72	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-12	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	-5	Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	322	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 3/ACUTE PHASE-WEEK 1	3	Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	335	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00183 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 3/ACUTE PHASE-WEEK 1	3	Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
18	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	09AUG96	1	13AUG96	5	5
00263	Oral	2	0 MG	14AUG96	6	20AUG96	12	7
00263	Oral	3	0 MG	21AUG96	13	27AUG96	19	7
00263	Oral	4	0 MG	28AUG96	20	03SEP96	26	7
00263	Oral	5	0 MG	04SEP96	27	10SEP96	33	7
00263	Oral	6	0 MG	11SEP96	34	17SEP96	40	7
00263	Oral	6	0 MG	18SEP96	41	24SEP96	47	7
00263	Oral	6	0 MG	25SEP96	48	03OCT96	56	9
	Oral	5	0 MG	04OCT96	57	19OCT96	72	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	18	Yes	No	72	0		PT. DOES NOT FEEL HE CAN BE COMPLIANT FOR NEXT SIX MONTHS. ALSO DOES NOT WANT TO TAKE THAT MANY PILLS ANYMORE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MONONUCLEOSIS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	6, .	14AUG96	14AUG96	375 MG	HEADACHE
			9, .	17AUG96	17AUG96	500 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	33, .	10SEP96	10SEP96	400 MG	ACHE IN SIDE
RESPIRATORY	Guaifenesin	Entex	45, .	22SEP96	23SEP96	250 MG	CONGESTION
	Phenylephrine Hydrochloride	Entex	45, .	22SEP96	23SEP96	250 MG	CONGESTION
	Phenylpropanolamine Hydrochloride	Entex	45, .	22SEP96	23SEP96	250 MG	CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE HEADACHE {SIMULTANEOUS} [STOMACH ACHE]	31, .	10 Mins	0	1	MIL	NO	PSR	No	No
	Back Pain	BACK ACHE	30, .	06:00 Hrs	0	1	MIL	NO	UNR	No	No
	Headache	HEADACHE	6, .	03:00 Hrs	0	1	MIL	NO	PBU	Yes	No
			9, .	02:00 Hrs	0	1	MIL	NO	PBU	Yes	No
			27, .	15 Mins	0	1	MIL	NO	PBU	No	No
		STOMACH ACHE HEADACHE {SIMULTANEOUS} [HEADACHE]	31, .	10 Mins	0	1	MIL	NO	PSR	No	No
	Pain	SIDE ACHE LEFT SIDE	33, .	01:30 Hrs	0	1	MIL	NO	UNR	Yes	No
Digestive System	Ulcerative Stomatitis	MOUTH SORES	59, .	8 Days	0	CON	MIL	NO	UNR	No	No
Musculoskeletal System	Arthralgia	SHOULDER PAIN RIGHT SHOULDER	34, .	12:00 Hrs	0	1	MIL	NO	UNR	No	No
Respiratory System	Respiratory Disorder	COLD AND CONGESTION	45, .	8 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24JUL96	-16, .	0	125	85	80	125	85	96	224.00	72.0
BL	09AUG96	1, .	0	130	82	68	125	78	74	230.00	
1	14AUG96	6, .	0	130	76	70	125	80	76	235.00	
2	21AUG96	13, .	0	126	80	80	118	74	88	232.20	
3	28AUG96	20, .	0	124	76	84	118	70	90	230.50	
4	04SEP96	27, .	0	126	84	78	116	76	90	233.20	
5	11SEP96	34, .	0	122	78	78	116	74	92	235.00	
6	18SEP96	41, .	0	130	86	92	118	78	96	236.50	
7	25SEP96	48, .	0	118	80	88	112	74	92	233.50	
8	09OCT96	62, .	0	118	76	100	108	70	108	237.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-16	Hemoglobin	16	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.1	.	.	.	41 - 50	%
				Red Blood Cell Count	5.6	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	56.6	.	.	.	40 - 75	%
				Lymphocytes	35.4	.	.	.	16 - 46	%
				Monocytes	5.9	.	.	.	0 - 12	%
				Eosinophils	1.3	.	.	.	0 - 7	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	322000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	7.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 1/SCREENING (WEEK -1)	-16	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.4 - 5.8	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	3.8 - 10.8	THOU/MCL
				Segmented Neutrophils	58	.	.	.	40 - 75	%
				Lymphocytes	34.9	.	.	.	16 - 46	%
				Monocytes	5.4	.	.	.	0 - 12	%
				Eosinophils	1.7	.	.	.	0 - 7	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	283000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	27 - 33	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	76	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00263 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
18	M	VISIT 10/ACUTE PHASE-WEEK 8	62	Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Black

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	01MAR96	1	07MAR96	7	7
00277	Oral	2	0 MG	08MAR96	8	14MAR96	14	7
00277	Oral	3	0 MG	15MAR96	15	21MAR96	21	7
00277	Oral	4	0 MG	22MAR96	22	28MAR96	28	7
00277	Oral	5	0 MG	29MAR96	29	04APR96	35	7
00277	Oral	5	0 MG	05APR96	36	14APR96	45	10
00277	Oral	6	0 MG	15APR96	46	18APR96	49	4
00277	Oral	6	0 MG	19APR96	50	25APR96	56	7
00156	Oral	6	0 MG	26APR96	57	24MAY96	85	29
00156	Oral	6	0 MG	25MAY96	86	21JUN96	113	28

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	113	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES{FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
PROTEINURIA	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	., .		.	PRN	HEADACHE
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	159, 103	06AUG96	06AUG96	220 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	159, 103	02:00 Hrs	0	1	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23FEB96	-7, -63	0	130	90	88	115	70	92	203.00	64.0
BL	01MAR96	1, -56	0	130	80	96	110	70	108	205.80	
1	08MAR96	8, -49	0	130	90	96	125	75	110	206.50	
3	22MAR96	22, -35	0	115	60	72	110	68	80	204.50	
4	29MAR96	29, -28	0	122	88	80	112	80	82	201.50	
6	15APR96	46, -11	0	105	90	87	134	78	87		
7	19APR96	50, -7	0	130	70	80	130	85	90	198.00	
8	26APR96	57, 1	0	129	78	77	136	78	92	198.00	
12	24MAY96	85, 29	0	130	90	72	118	80	90	204.00	
16	21JUN96	113, 57	0	132	90	90	135	96	95	208.50	
24	07AUG96	160, 104#	0	125	75	84	118	70	96	219.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.4	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	332000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1.3	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	1	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 4/ACUTE PHASE-WEEK 2	18	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 4/ACUTE PHASE-WEEK 2	18	Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	45.7	.	.	.	30 - 70	%
				Lymphocytes	40.8	.	.	.	21 - 51	%
				Monocytes	11.1	H	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	312000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	72	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.8	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57		Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick	2	.	.	.		
					Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16	165	(52)	Hemoglobin	11.7	L	.	.	12 - 15.6	G/DL
					Hematocrit	33.9	L	.	.	35 - 46	%
					Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54	.	.	.	30 - 70	%
					Lymphocytes	31.4	.	.	.	21 - 51	%
					Monocytes	11	H	.	.	0 - 10	%
					Eosinophils	2.9	.	.	.	0 - 5	%
					Basophils	0.6	.	.	.	0 - 2	%
					Platelets	317000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.8	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	70	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
					Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
					Albumin	3.7	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	82	.	.	.	70 - 115	MG/DL
					Globulin	3	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00277 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 16	165 (52)	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	6	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	09FEB96	1	15FEB96	7	7
00278	Oral	2	20 MG	16FEB96	8	22FEB96	14	7
00278	Oral	3	20 MG	23FEB96	15	29FEB96	21	7
00278	Oral	4	20 MG	01MAR96	22	07MAR96	28	7
00278	Oral	4	20 MG	08MAR96	29	14MAR96	35	7
00278	Oral	5	30 MG	15MAR96	36	21MAR96	42	7
00278	Oral	6	40 MG	22MAR96	43	28MAR96	49	7
00278	Oral	6	40 MG	29MAR96	50	04APR96	56	7
00132	Oral	6	40 MG	05APR96	57	02MAY96	84	28
00132	Oral	6	40 MG	03MAY96	85	30MAY96	112	28
00132	Oral	6	40 MG	31MAY96	113	26JUN96	139	27
00132	Oral	6	40 MG	27JUN96	140	24JUL96	167	28
00132	Oral	6	40 MG	25JUL96	168	21AUG96	195	28
00132	Oral	6	40 MG	22AUG96	196	19SEP96	224	29
00278	Oral	5	30 MG	20SEP96	225	21SEP96	226	2
00278	Oral	4	20 MG	22SEP96	227	23SEP96	228	2
00278	Oral	3	20 MG	24SEP96	229	25SEP96	230	2
00278	Oral	2	20 MG	26SEP96	231	28SEP96	233	3
00278	Oral	1	20 MG	29SEP96	234	05OCT96	240	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	Yes	240	20		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ABDOMINAL PAIN	PAIN, ABDOMINO-PELVIC	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
POLYCYSTIC OVARY	OVARIAN DYSFUNC	ENDOCR/METAB/IMMUNITY DISORD	CUR	1995
ACUTE PANCREATITIS	PANCREATITIS	DIGESTIVE SYST	PRV	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Cefalexin Monohydrate	Keflex	221, 165	16SEP96	19SEP96	4000 MG	MONONUCLEOSIS
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	-39, -95	01JAN96	.	325	ABDOMINAL PAIN
	Oxycodone Hydrochloride	Percocet	37, -20	16MAR96	17MAR96	PRN	ABDOMINAL PAIN
	Oxycodone Terephthalate	Percocet	37, -20	16MAR96	17MAR96	PRN	ABDOMINAL PAIN
	Paracetamol	Percocet	37, -20	16MAR96	17MAR96	PRN	ABDOMINAL PAIN
	Tramadol Hydrochloride	Ultram	38, -19	17MAR96	19MAR96	PRN	ABDOMINAL PAIN
RESPIRATORY	Prednisone	Prednisone	221, 165	16SEP96	17SEP96	80 MG	MONONUCLEOSIS
			223, 167	18SEP96	19SEP96	60 MG	MONONUCLEOSIS
			225, 169	20SEP96	21SEP96	40 MG	MONONUCLEOSIS
			227, 171	22SEP96	23SEP96	20 MG	MONONUCLEOSIS
			229, 173	24SEP96	25SEP96	10 MG	MONONUCLEOSIS
SYSTEMIC HORMONAL	Prednisone	Prednisone	221, 165	16SEP96	17SEP96	80 MG	MONONUCLEOSIS
			223, 167	18SEP96	19SEP96	60 MG	MONONUCLEOSIS
			225, 169	20SEP96	21SEP96	40 MG	MONONUCLEOSIS
			227, 171	22SEP96	23SEP96	20 MG	MONONUCLEOSIS
			229, 173	24SEP96	25SEP96	10 MG	MONONUCLEOSIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	ABDOMINAL PAIN(PRESENT PREVIOUSLY)	43, -14	5 Days	40	CON	SEV	NO	PBU	Yes	No
	Infection	MONONUCLEOSIS	206, 150	Not Stated	40	CON	SEV	NO	PBU	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	50, -7	6 Days	40	CON	MIL	NO	REL	No	No
Nervous System	Nervousness	RESTLESSNESS	24, -33	5 Days	20	CON	MIL	NO	PSR	No	No
Respiratory System	Larynx Disorder	LARYNGITIS	22, -35	4 Days	20	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	02FEB96	-7, -63	0	122	82	64	118	88	88	182.00	65.0
BL	09FEB96	1, -56	0	127	78	.	118	70	118	184.50	
1	16FEB96	8, -49	20	120	80	68	118	85	88	180.75	
2	23FEB96	15, -42	20	124	78	60	118	70	88	181.00	
3	01MAR96	22, -35	20	135	88	60	115	80	92	179.80	
4	08MAR96	29, -28	20	118	83	68	120	88	96	179.50	
5	15MAR96	36, -21	30	120	78	68	118	82	92	177.00	
6	22MAR96	43, -14	40	110	78	62	104	72	72	179.50	
7	29MAR96	50, -7	40	118	70	80	114	80	104	178.70	
8	05APR96	57, 1	40	112	78	60	108	72	96	178.00	
12	03MAY96	85, 29	40	123	58	72	115	72	85	182.00	
16	31MAY96	113, 57	40	110	70	60	100	80	96	176.00	
20	27JUN96	140, 84	40	110	70	72	105	80	92	179.50	
24	25JUL96	168, 112	40	105	80	72	100	75	88	178.00	
28	22AUG96	196, 140	40	124	80	68	122	85	92	179.00	
32	19SEP96	224, 168	40	100	65	76	100	70	96	181.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.2	.	.	.	30 - 70	%
				Lymphocytes	33.4	.	.	.	21 - 51	%
				Monocytes	9.7	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	1.4	.	.	.	0 - 2	%
				Platelets	257000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	69	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	31	L	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-7	Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	58	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3	.	.	.	30 - 70	%
				Lymphocytes	22.3	.	.	.	21 - 51	%
				Monocytes	7.4	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Eosinophils	1.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	306000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.2	.	.	.	30 - 70	%
				Lymphocytes	24.6	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	303000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 13/CONTINUATION-WEEK 20	140	Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	74	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	224	Hemoglobin	12.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	35	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48.6	.	.	.	30 - 70	%
				Lymphocytes	38.1	.	.	.	21 - 51	%
				Monocytes	11.5	H	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00278 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 16/CONTINUATION-WEEK 32	224	Basophils	0.9	.	.	.	0 - 2	%
				Platelets	252000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	82	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	82	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	48	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	4.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22MAR96	1	28MAR96	7	7
00279	Oral	2	100 MG	29MAR96	8	04APR96	14	7
00279	Oral	3	150 MG	05APR96	15	11APR96	21	7
00279	Oral	4	200 MG	12APR96	22	18APR96	28	7
00279	Oral	5	250 MG	19APR96	29	24APR96	34	6
00279	Oral	6	300 MG	25APR96	35	02MAY96	42	8
00279	Oral	6	300 MG	03MAY96	43	09MAY96	49	7
00279	Oral	6	300 MG	10MAY96	50	16MAY96	56	7
00147	Oral	6	300 MG	17MAY96	57	13JUN96	84	28
00147	Oral	6	300 MG	14JUN96	85	10JUL96	111	27
00147	Oral	6	300 MG	11JUL96	112	07AUG96	139	28
00147	Oral	6	300 MG	08AUG96	140	04SEP96	167	28
00147	Oral	6	300 MG	05SEP96	168	01OCT96	194	27
00147	Oral	6	300 MG	02OCT96	195	04OCT96	197	3
00147	Oral	5	250 MG	05OCT96	198	06NOV96	230	33
00279	Oral	5	250 MG	07NOV96	231	08NOV96	232	2
00279	Oral	4	200 MG	09NOV96	233	10NOV96	234	2
00279	Oral	3	150 MG	11NOV96	235	12NOV96	236	2
00279	Oral	2	100 MG	13NOV96	237	15NOV96	239	3
00279	Oral	1	50 MG	16NOV96	240	22NOV96	246	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	Yes	246	50		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
THYROID-STIMULATING HORMONE DECREASE	THYROID FUNCTION, ABN	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
WBC DECREASE	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Calcium Carbonate	Tums	193, 137	30SEP96	30SEP96	2 TABS	STOMACH PAIN
			193, 137	30SEP96	30SEP96	2 TABS	STOMACH PAIN
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erycette 2% Cream	91, 35	20JUN96	.		ACNE
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	11, -46	01APR96	01APR96	325 MG	HEADACHE
			139, 83	07AUG96	07AUG96	325 MG	MOLAR ERUPTING
DERMATOLOGICALS	Benzoyl Peroxide	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Camphor	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Chlorophyllin Sodium	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Diphenhydramine Hydrochloride	Benadryl	162, 106	30AUG96	05SEP96	50 MG	POISON IVY
		Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Edetic Acid	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Erythromycin	Erycette 2% Cream	91, 35	20JUN96	.		ACNE
	Ethanol	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Glycerol	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
	Hydrocortisone Acetate	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Isopropanol	Ivy Dry	161, 105	29AUG96	04SEP96		POISON IVY
	Parabens	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
		Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
DERMATOLOGICALS	Paraffin, Liquid	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Propylene Glycol	Vanoxide-Hc Lotion	91, 35	20JUN96	.		ACNE
	Tannic Acid	Ivy Dry	161, 105	29AUG96	04SEP96		POISON IVY
	Zinc Oxide	Caladryl Clear	110, 54	09JUL96	12JUL96		POISON IVY
			157, 101	25AUG96	29AUG96		POISON IVY
			168, 112	05SEP96	05OCT96		POISON IVY
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	162, 106	30AUG96	05SEP96	50 MG	POISON IVY
SENSORY ORGANS	Erythromycin	Erycette 2% Cream	91, 35	20JUN96	.		ACNE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH PAIN	195, 139	6 Days	300	5	MOD	DCR	PBU	No	No
		STOMACH PAINS	193, 137	02:00 Hrs	300	CON	MIL	NO	PSR	Yes	No
	Headache	HEADACHE	11, -46	03:00 Hrs	100	1	MOD	NO	PBU	Yes	No
	Infection	FLU	41, -16	3 Days	300	CON	MIL	NO	PBU	No	No
Digestive System	Nausea	NAUSEA	194, 138	03:00 Hrs	300	CON	MIL	NO	PSR	No	No
			195, 139	6 Days	300	5	MOD	DCR	PBU	No	No
	Tooth Disorder	MOLAR ERUPTING	139, 83	02:00 Hrs	300	CON	MOD	NO	UNR	Yes	No
	Ulcerative Stomatitis	MOUTH SORES	196, 140	Not Stated	300	CON	MOD	NO	PBU	No	No
Nervous System	Thinking Abnormal	"STRANGE THOUGHTS"	33, -24	2 Days	250	1	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	COLD - RUNNY NOSE, CONGESTION	48, -9	4 Days	300	CON	MIL	NO	PBU	No	No
Skin and Appendages	Acne	ACNE	86, 30	Not Stated	300	CON	MOD	NO	PBU	Yes	No
	Contact Dermatitis	POISON IVY	110, 54	11 Days	300	CON	MIL	NO	UNR	Yes	No
			155, 99	51 Days	300	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08MAR96	-14, -70	0	115	82	88	110	75	96	127.80	66.0
BL	22MAR96	1, -56	0	170	70	75	106	85	92	129.00	
1	29MAR96	8, -49	100	98	60	80	100	70	110	128.00	
2	05APR96	15, -42	150	110	70	92	108	78	108	128.00	
3	12APR96	22, -35	200	128	78	92	118	88	108	129.25	
4	19APR96	29, -28	250	110	60	70	110	70	72	129.00	
5	25APR96	35, -22	300	118	77	78	117	61	87		
6	03MAY96	43, -14	300	118	70	65	115	80	74	129.20	
7	10MAY96	50, -7	300	112	88	85	110	80	96	129.00	
8	17MAY96	57, 1	300	120	80	85	114	85	90	128.50	
12	14JUN96	85, 29	300	120	80	85	108	70	95	127.00	
16	11JUL96	112, 56	300	115	70	84	110	70	88	125.50	
20	08AUG96	140, 84	300	115	65	84	110	70	92	129.50	
24	05SEP96	168, 112	300	115	70	72	118	75	88	128.00	
28	02OCT96	195, 139	300	116	68	78	120	78	92	129.50	
32	06NOV96	230, 174	250	114	68	82	110	68	96	129.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.6	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	34.8	.	.	.	21 - 51	%
				Monocytes	13.5	H	.	.	0 - 10	%
				Eosinophils	2.5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	168000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	164	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	78	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	68	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEC		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	140	Hemoglobin	13.5	.	.	.	12 - 15.6	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	140	Hematocrit	38.4	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.2	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	4.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	163000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	132	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	67	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00279 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 13/CONTINUATION-WEEK 20	140	Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 16/CONTINUATION-WEEK 32	230	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	55.5	.	.	.	30 - 70	%
				Lymphocytes	32	.	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	3.4	.	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	178000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	1.8	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	76	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	17MAY96	1	23MAY96	7	7
00280	Oral	2	20 MG	24MAY96	8	30MAY96	14	7
00280	Oral	3	20 MG	31MAY96	15	06JUN96	21	7
00280	Oral	4	20 MG	07JUN96	22	13JUN96	28	7
00280	Oral	4	20 MG	14JUN96	29	20JUN96	35	7
00280	Oral	5	30 MG	21JUN96	36	26JUN96	41	6
00280	Oral	6	40 MG	27JUN96	42	02JUL96	47	6
00280	Oral	6	40 MG	03JUL96	48	10JUL96	55	8
	Oral	6	40 MG	11JUL96	56	29JUL96	74	19

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	Yes	No	74	40	Protocol violation, including non-compliance	PT. HAS SOME SYMPTOMS OF CONDUCT DISORDER AND OPPOSITIONAL DEFIANT DISORDER AND REFUSED TO PARTICIPATE FURTHER. PT.'S DEPRESSION DID RESPOND DURING TREATMENT, BUT HER OTHER PROBLEMS SEEMED TO WORSEN.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
ASTHMA ATTACK	ASTHMA	RESPIRATORY SYST DIS	PRV	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Acetaminophen	-10, -65	07MAY96	07MAY96#	650 MG	HEADACHE
		Tylenol	40, -16	25JUN96	25JUN96	1,000 MG	HEADACHE
			42, -14	27JUN96	27JUN96	1,000 MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	34, -22	19JUN96	21JUN96	25 MG	ALLERGIES
			39, -17	24JUN96	26JUN96	25 MG + QHS	ALLERGIES
RESPIRATORY	Clemastine Fumarate	Tavist-D	-2, -57	15MAY96	15MAY96#	1X PILL DAY	CONGESTION
	Diphenhydramine Hydrochloride	Benadryl	34, -22	19JUN96	21JUN96	25 MG	ALLERGIES
			39, -17	24JUN96	26JUN96	25 MG + QHS	ALLERGIES
	Phenylpropanolamine Hydrochloride	Tavist-D	-2, -57	15MAY96	15MAY96#	1X PILL DAY	CONGESTION

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	40, -16	60 Mins	30	1	MIL	NO	PSR	Yes	No
			42, -14	60 Mins	40	1	MIL	NO	PSR	Yes	No
Nervous System	Dizziness	LIGHT-HEADED (X2 MINUTES)	55, -1	2 Mins	40	1	MIL	NO	PSR	No	No
Respiratory System	Rhinitis	CONGESTION (NASAL)	-2, -57	2 Days	0	1	MIL	NO	UNR	Yes	No
Skin and Appendages	Acne	ACNE	31, -25	Not Stated	20	CON	MIL	NO	PSR	No	No
Urogenital System	Urine Abnormality	ABNORMAL URINALYSIS	97, 42	Not Stated	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	10MAY96	-7, -62	0	117	60	90	110	70	104	192.00	64.0
BL	17MAY96	1, -55	0	117	60	90	110	70	104	192.00	
1	24MAY96	8, -48	20	110	68	72	112	80	85	185.00	
2	31MAY96	15, -41	20	112	80	76	108	60	98	182.00	
3	07JUN96	22, -34	20	112	78	92	100	72	96	185.50	
4	14JUN96	29, -27	20	100	70	80	110	78	98	186.00	
5	21JUN96	36, -20	30	108	60	80	108	78	110	183.00	
6	27JUN96	42, -14	40	100	70	80	100	80	84	185.00	
7	03JUL96	48, -8	40	112	80	72	105	80	104	182.00	
8	11JUL96	56, 1	40	105	70	80	120	80	88	183.00	
12	21AUG96	97, 42#	0	.	76	78	110	80	92	193.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	35	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	314000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 9/ACUTE PHASE-WEEK 7	48	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEC	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Lymphocytes	40	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	6	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	102	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	80	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/UNSCHEDULED LAB 1	61	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	4	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		3100.ZZ2	71	Urine Glucose - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	3100.ZZ2	71		Urine Blood - Dipstick	6	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	3	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	97	(23)	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
					Hematocrit	37.9	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	10.4	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	73	H	.	.	30 - 70	%
					Lymphocytes	20	L	.	.	21 - 51	%
					Monocytes	3.8	.	.	.	0 - 10	%
					Eosinophils	3	.	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	298000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
					Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	109	.	.	.	44 - 280	U/L
					Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.1	.	.	.	3.1 - 5.3	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00280 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 11/CONTINUATION-WEEK 12	97	(23)	Glucose - Random	76	.	.	.	70 - 115	MG/DL
					Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	2	.	.	.		
					Urine Red Blood Cells/HPF	5	.	.	.		
					Urine White Blood Cells/HPF	5	.	.	+		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	26JUL96	1	01AUG96	7	7
00281	Oral	2	100 MG	02AUG96	8	08AUG96	14	7
00281	Oral	3	150 MG	09AUG96	15	18AUG96	24	10
00281	Oral	4	200 MG	19AUG96	25	25AUG96	31	7
00281	Oral	5	250 MG	26AUG96	32	03SEP96	40	9
00281	Oral	6	300 MG	04SEP96	41	08SEP96	45	5
00281	Oral	6	300 MG	09SEP96	46	17SEP96	54	9
00281	Oral	6	300 MG	18SEP96	55	24SEP96	61	7
00158	Oral	6	300 MG	25SEP96	62	24OCT96	91	30
00158	Oral	6	300 MG	25OCT96	92	19NOV96	117	26
00158	Oral	6	300 MG	20NOV96	118	19DEC96	147	30
00158	Oral	6	300 MG	20DEC96	148	03JAN97	162	15
00281	Oral	5	250 MG	04JAN97	163	05JAN97	164	2
00281	Oral	4	200 MG	06JAN97	165	07JAN97	166	2
00281	Oral	3	150 MG	08JAN97	167	09JAN97	168	2
00281	Oral	2	100 MG	10JAN97	169	12JAN97	171	3
00281	Oral	1	50 MG	13JAN97	172	19JAN97	178	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	178	50	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BILATERAL TUBE PLACEMENT IN EARS	OPERATION, EAR	OPERATIONS	PRV	1984
CHICKEN POX	VIRAL DIS/EXANTHEM	INFECTIOUS/PARASITIC DIS	PRV	1987
JAUNDICE DUE TO ABO INCOMPATIBILTY {NOS}	COMPLIC OF MED CARE	INJURY/POISONING	PRV	1983
REMOVAL OF BAKER'S CYST FROM RIGHT LEG	OPERATION, SOFT TISSUE	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	40, -22	03SEP96	03SEP96	1000 MG	HEADACHE
			146, 85	18DEC96	19DEC96	1500 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	146, 85	2 Days	300	CON	MIL	NO	PBU	No	No
	Asthenia	FATIGUE	133, 72	20 Days	300	CON	MOD	NO	PSR	No	No
			152, 91	30 Days	300	CON	SEV	STP	PSR	No	No
	Headache	HEADACHE	40, -22	16:00 Hrs	250	1	MOD	NO	PSR	Yes	No
			146, 85	2 Days	300	CON	MIL	NO	PBU	Yes	No
Carciovascular System	Bundle Branch Block	PROLONGED QRS DURATION	55, -7	15 Days	300	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19JUL96	-7, -68	0	118	78	68	115	78	70	138.20	67.0
BL	26JUL96	1, -61	0	110	80	62	108	76	80	138.20	
1	02AUG96	8, -54	100	118	70	80	115	68	92	138.50	
2	09AUG96	15, -47	150	122	74	68	120	72	74	138.50	
3	19AUG96	25, -37	200	122	68	76	118	65	88	135.00	
4	26AUG96	32, -30	250	118	80	64	118	78	72	133.00	
6	04SEP96	41, -21	300	120	76	86	114	70	92	138.00	
6	09SEP96	46, -16	300	120	78	80	118	74	88	136.00	
8	18SEP96	55, -7	300	116	78	92	112	72	98	138.50	
8	25SEP96	62, 1	300	118	80	80	110	76	88	138.00	
12	25OCT96	92, 31	300	122	72	84	118	66	92	141.00	
16	20NOV96	118, 57	300	118	76	88	114	80	96	140.20	
20	20DEC96	148, 87	300	116	72	88	112	76	96	137.50	
24	03JAN97	162, 101	300	128	80	88	120	70	96	139.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.8	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	9.8	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	256000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	252	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1 F2 F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	3	. . .		
				Urine Amphetamines	NEG	. . .		
				Urine Barbiturates	NEG	. . .		
				Urine Benzodiazepines	NEG	. . .		
				Urine Cannabinoids	NEG	. . .		
				Urine Cocaine	NEG	. . .		
				Urine Methadone	NEG	. . .		
				Urine Methaqualone	NEG	. . .		
				Urine Opiates	NEG	. . .		
				Urine Phencyclidine	NEG	. . .		
				Urine Propoxyphene	NEG	. . .		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.8	. . .	13.8 - 17.2	G/DL
				Hematocrit	40	L . .	41 - 50	%
				Red Blood Cell Count	4.7	. . .	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	. . .	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	. . .	30 - 70	%
				Lymphocytes	34.1	. . .	21 - 51	%
				Monocytes	9.7	. . .	0 - 10	%
				Eosinophils	0.9	. . .	0 - 5	%
				Basophils	0.6	. . .	0 - 2	%
				Platelets	250000	. . .	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	. . .	25 - 35	PG
				Mean Corpuscle Volume	84	. . .	80 - 100	FL
				Blood Urea Nitrogen	12	. . .	7 - 25	MG/DL
				Creatinine	1	. . .	0.8 - 1.5	MG/DL
				Uric Acid	4.3	. . .	4 - 8	MG/DL
				Alkaline Phosphatase	235	. . .	44 - 400	U/L
				Aspartate Aminotransferase	19	. . .	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	62	Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.4	H	.	.	30 - 70	%
				Lymphocytes	18.2	L	.	.	21 - 51	%
				Monocytes	7.8	.	.	.	0 - 10	%
				Eosinophils	0.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	238000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 13/CONTINUATION-WEEK 20	148	Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	215	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	NEC		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 14/CONTINUATION-WEEK 24	162	Hemoglobin	13.3	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	46.1	.	.	.	30 - 70	%
				Lymphocytes	42.5	.	.	.	21 - 51	%
				Monocytes	10.6	H	.	.	0 - 10	%
				Eosinophils	0.2	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	275000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	211	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	20	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	89	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00281 TREATMENT GROUP: IMIPRAMINE

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	26JUL96	1	01AUG96	7	7
00282	Oral	2	0 MG	02AUG96	8	08AUG96	14	7
00282	Oral	3	0 MG	09AUG96	15	15AUG96	21	7
00282	Oral	4	0 MG	16AUG96	22	25AUG96	31	10
00282	Oral	5	0 MG	26AUG96	32	02SEP96	39	8
00282	Oral	6	0 MG	03SEP96	40	12SEP96	49	10
00282	Oral	6	0 MG	13SEP96	50	18SEP96	55	6
00282	Oral	6	0 MG	19SEP96	56	26SEP96	63	8
	Oral	5	0 MG	27SEP96	64	12OCT96	79	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	79	0		CONTINUATION PHASE MEDICATION IS NOT AVAILABLE.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
BRONCHITIS	BRONCHITIS, OTHER	RESPIRATORY SYST DIS	CUR	1996
MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1980
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin	Amoxicillin	-17, .	09JUL96	14JUL96#	750 MG	BRONCHITIS
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	21, .	15AUG96	15AUG96	1000 MG	BACKACHE
			39, .	02SEP96	02SEP96	1000 MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Motrin	56, .	19SEP96	19SEP96	800 MG	MENSTRUAL CRAMPS

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	21, .	12 Days	0	CON	MIL	NO	UNR	Yes	No
	Headache	HEADACHE	39, .	30 Mins	0	1	MOD	NO	PBU	Yes	No
Digestive System	Diarrhea	DIARRHEA	56, .	6 Days	0	20	MOD	NO	PSR	No	No
Urogenital System	Dysmenorrhea	CRAMPS (MENSTRUAL)	56, .	12:00 Hrs	0	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19JUL96	-7, .	0	115	68	70	110	65	74	158.00	66.0
BL	26JUL96	1, .	0	118	78	78	100	72	92	157.80	
1	02AUG96	8, .	0	118	70	62	110	68	74	159.00	
2	09AUG96	15, .	0	118	74	64	110	70	78	161.00	
3	16AUG96	22, .	0	122	74	64	114	68	76	162.00	
4	26AUG96	32, .	0	116	74	70	112	70	86	160.20	
6	03SEP96	40, .	0	118	74	68	112	68	76	161.00	
7	13SEP96	50, .	0	114	78	68	110	70	76	161.00	
8	19SEP96	56, .	0	116	76	64	120	80	64	160.50	
8	27SEP96	64, .	0	118	72	72	110	68	78	161.00	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.4	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52.1	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	339000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	4	L	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.1	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	81	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54	.	.	.	30 - 70	%
				Lymphocytes	36.7	.	.	.	21 - 51	%
				Monocytes	6.6	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	326000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	73	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.010.00282 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	68	L	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	25NOV95	1	01DEC95	7	7
00163	Oral	2	100 MG	02DEC95	8	11DEC95	17	10
00163	Oral	3	150 MG	12DEC95	18	18DEC95	24	7
00163	Oral	4	200 MG	19DEC95	25	22DEC95	28	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	28	200	Adverse event, including intercurrent illness	WHEN PT.GOT SICK,THEY STOPPED GIVING MED.WITHOUT CONTACTING ANYONE.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MIGRAINE HEADACHES	MIGRAINE	NERVOUS SYST/SENSE ORGAN DIS	CUR	1989
STRESS INDUCED ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1994
TEMPOROMANDIBULAR JOINT SYNDROME	DENTOFACIAL ANOM	DIGESTIVE SYST	CUR	1994
CORRECTIVE SURGERY(BOTH EYES)FOR STRABISMUS	OPERATION, EYE	OPERATIONS	PRV	1985

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *		Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-2519,	.	01JAN89	.	500MG	MIGRAINES
			-693,	.	01JAN94	.	500MG	TEMPOROMANDIBULAR JOINT SYNDROME
			-2,	.	23NOV95	.	500MG	HEADACHE
			4,	.	28NOV95	.	500MG	HEADACHE
DERMATOLOGICALS	Diphenhydramine Hydrochloride	Benadryl	-4,	.	21NOV95	21NOV95#	25MG	DERMATITIS
			-4,	.	21NOV95	21NOV95#	OINTMENT	DERMATITIS
RESPIRATORY	Diphenhydramine Hydrochloride	Benadryl	-4,	.	21NOV95	21NOV95#	25MG	DERMATITIS
			-4,	.	21NOV95	21NOV95#	OINTMENT	DERMATITIS
	Guaifenesin	Robitussin	6,	.	30NOV95	01DEC95	1 1/2TSP	SORE THROAT
	Salbutamol	Ventolin	-603,	.	01APR94	.	2PUFFS	ASTHMA
			-603,	.	01APR94	.	2PUFFS	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *		Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	4,	.	18:00 Hrs	50	1	MOD	NO	PBU	Yes	No
			-2,	.	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
Digestive System	Nausea	NAUSEA	4,	.	18:00 Hrs	50	1	MIL	NO	PBU	No	No
			23,	.	5 Days	150	CON	MIL	NO	PBU	No	No
			28,	.	Not Stated	200	CON	MOD	STP	PSR	No	No
			29,	.	Not Stated	200	CON	MOD	STP	PSR	No	No
	Vomiting	VOMITING	28,	.	4 Days	200	4	MOD	STP	PSR	No	No
Nervous System	Dizziness	DIZZINESS	4,	.	18:00 Hrs	50	1	MIL	NO	PBU	No	No
Respiratory System	Pharyngitis	SORE THROAT	6,	.	20:00 Hrs	50	CON	MIL	NO	UNR	Yes	No
Skin and Appendages	Rash	RASH	-4,	.	Not Stated	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18NOV95	-7, .	0	108	60	90	104	60	90	136.00	58.0
BL	24NOV95	-1, .	0	110	60	76	110	68	80	134.00	
1	01DEC95	7, .	50	90	50	90	90	52	92	134.20	
2	11DEC95	17, .	100	90	50	90	92	50	90	134.70	
3	18DEC95	24, .	150	110	76	94	110	76	96	130.00	
5	27DEC95	33, .	200	110	70	80	110	70	80	130.70	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Segmented Neutrophils	SMEARS RECEI	U	.	U	30 - 70	%
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.3	H	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	4.3	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00163 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 3/ACUTE PHASE-WEEK 1	7	Hemoglobin	14.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	73.2	H	.	.	30 - 70	%
				Lymphocytes	19.7	L	.	.	21 - 51	%
				Monocytes	1.9	.	.	.	0 - 10	%
				Eosinophils	4.6	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	251000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	22DEC95	1	28DEC95	7	7
00164	Oral	2	0 MG	29DEC95	8	04JAN96	14	7
00164	Oral	3	0 MG	05JAN96	15	11JAN96	21	7
00164	Oral	4	0 MG	12JAN96	22	18JAN96	28	7
00164	Oral	5	0 MG	19JAN96	29	25JAN96	35	7
00164	Oral	6	0 MG	26JAN96	36	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	36	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
LYME DISEASE	ARTHROPOD-BORNE DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993
MENINGITIS	MENINGITIS	NERVOUS SYST/SENSE ORGAN DIS	PRV	1993

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
MUSCULO-SKELETAL	Ibuprofen	Advil	19, .	09JAN96	.	400MG	HEADACHE BACKACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	BACKACHE	21, .	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	Headache	HEADACHE	21, .	01:00 Hrs	0	1	MIL	NO	PBU	Yes	No
Nervous System	Dizziness	DIZZINESS	34, .	06:00 Hrs	0	7	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15DEC95	-7, .	0	130	90	60	130	80	68	136.50	71.0
1	28DEC95	7, .	0	120	80	60	118	80	68	134.20	
2	04JAN96	14, .	0	120	80	60	118	78	68	136.70	
3	11JAN96	21, .	0	118	70	64	118	70	64	137.20	
4	18JAN96	28, .	0	118	70	64	118	70	68	138.00	
5	25JAN96	35, .	0	120	80	58	118	78	64	140.50	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	16.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.6	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	61.7	.	.	.	30 - 70	%
				Lymphocytes	29.4	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	193000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	1028	H	.	+	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	59	L	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00164 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	06SEP96	1	11SEP96	6	6
00208	Oral	2	100 MG	12SEP96	7	17SEP96	12	6
00208	Oral	3	150 MG	18SEP96	13	26SEP96	21	9
00208	Oral	4	200 MG	27SEP96	22	03OCT96	28	7
00208	Oral	5	250 MG	04OCT96	29	10OCT96	35	7
00208	Oral	6	300 MG	11OCT96	36	17OCT96	42	7
00208	Oral	6	300 MG	18OCT96	43	24OCT96	49	7
00208	Oral	6	300 MG	25OCT96	50	03NOV96	59	10
00171	Oral	6	300 MG	04NOV96	60	07NOV96	63	4
00208	Oral	5	250 MG	08NOV96	64	09NOV96	65	2
00208	Oral	4	200 MG	10NOV96	66	11NOV96	67	2
00208	Oral	3	150 MG	12NOV96	68	13NOV96	69	2
00208	Oral	2	100 MG	14NOV96	70	16NOV96	72	3
00208	Oral	1	50 MG	17NOV96	73	23NOV96	79	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	13	Yes	No	79	50	Adverse event, including intercurrent illness	TOXIC IMIPRAMINE LEVEL (592)

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
ADENOIDECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989
TONSILLECTOMY	OPERATION, NOSE/MOUTH	OPERATIONS	PRV	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-1344,-1403	01JAN93	.	1000MG	HEADACHE
MUSCULO-SKELETAL	Naproxen Sodium	Aleve	-249, -308	01JAN96	.	1 TAB DAILY	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	STOMACH ACHE	11, -49	03:00 Hrs	100	1	MIL	NO	UNR	No	No
			15, -45	3 Days	150	6	MIL	NO	PBU	No	No
	Abnormal Laboratory Value	TOXIC IMIPRAMINE LEVEL	63, 4	Not Stated	300		MIL	STP	REL	No	No
Digestive System	Constipation	CONSTIPATION	37, -23	13 Days	300	CON	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	22AUG96	-15, -74	0	110	60	84	110	60	88	84.50	57.5
BL	05SEP96	-1, -60	0	110	60	80	110	62	84	84.50	
1	11SEP96	6, -54	50	108	62	80	110	60	84	82.00	
2	17SEP96	12, -48	100	118	70	84	116	74	88	83.20	
3	26SEP96	21, -39	150	110	80	90	110	84	86	83.20	
4	03OCT96	28, -32	200	110	70	90	110	76	90	82.70	
5	10OCT96	35, -25	250	108	70	80	110	70	84	83.00	
6	17OCT96	42, -18	300	102	60	80	100	60	86	85.50	
7	24OCT96	49, -11	300	110	70	96	110	76	100	84.70	
8	03NOV96	59, -1	300	110	72	88	112	72	90	86.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.4	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	38.6	L	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.5	.	.	.	30 - 70	%
				Lymphocytes	37.1	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	182000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.2	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	208	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.5	.	.	.	30 - 70	%
				Lymphocytes	36.9	.	.	.	21 - 51	%
				Monocytes	7.6	.	.	.	0 - 10	%
				Eosinophils	3.3	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	171000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.3	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	174	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00208 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	M	VISIT 10/ACUTE PHASE-WEEK 8	59	Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
12	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	11SEP96	1	19SEP96	9	9
00209	Oral	2	100 MG	20SEP96	10	26SEP96	16	7
00209	Oral	3	150 MG	27SEP96	17	03OCT96	23	7
00209	Oral	4	200 MG	04OCT96	24	11OCT96	31	8
00209	Oral	4	200 MG	12OCT96	32	17OCT96	37	6
00209	Oral	4	200 MG	18OCT96	38	24OCT96	44	7
00209	Oral	4	200 MG	25OCT96	45	01NOV96	52	8
00209	Oral	5	250 MG	02NOV96	53	11NOV96	62	10
00173	Oral	5	250 MG	12NOV96	63	18DEC96	99	37
00209	Oral	5	250 MG	19DEC96	100	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	12	Yes	No	100	250	Other reason	PATIENT WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES {ENVIRONMENTAL}	ALLERGY, NEC	INJURY/POISONING	CUR	1996
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-254, -316	01JAN96	.	325MG	HEADACHE
RESPIRATORY	Loratadine	Claritin	-72, -134	01JUL96	.	1PILL	ALLERGIES
	Pseudoephedrine Hydrochloride	Sudafed	20, -43	30SEP96	03OCT96	30 MG	RUNNY NOSE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory System	Rhinitis	RUNNY NOSE	20, -43	4 Days	150	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23AUG96	-19, -81	0	120	90	80	120	90	80	122.00	64.0
BL	10SEP96	-1, -63	0	118	88	86	120	90	88	122.00	
1	19SEP96	9, -54	50	110	80	84	112	84	84	117.70	
2	26SEP96	16, -47	100	120	90	90	114	88	96	115.00	
3	03OCT96	23, -40	150	120	80	100	118	78	100	117.00	
4	11OCT96	31, -32	200	118	72	96	116	74	100	117.00	
5	17OCT96	37, -26	200	118	80	80	110	78	84	116.20	
6	24OCT96	44, -19	200	118	78	80	110	76	88	116.70	
7	01NOV96	52, -11	200	120	80	86	112	84	88	116.50	
8	11NOV96	62, -1	250	120	76	84	120	80	92	115.50	
12	18DEC96	99, 37	250	108	68	80	100	64	84	110.50 L	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.5	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.8	L	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	4.4	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	253000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	80	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	8 - 21	MG/DL
				Creatinine	0.9	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	293	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	60 - 110	MG/DL
				Globulin	3.4	.	.	.	2.1 - 3.8	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	41	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	311000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	81	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	6	L	.	.	8 - 21	MG/DL
				Creatinine	0.8	.	.	.	0.4 - 1.1	MG/DL
				Uric Acid	5	.	.	.	2.6 - 7	MG/DL
				Alkaline Phosphatase	230	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	25	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00209 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
12	M	VISIT 10/ACUTE PHASE-WEEK 8	62	Alanine Aminotransferase	17	.	.	.	0 - 39	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	5.7 - 8.2	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	107	.	.	.	60 - 110	MG/DL
				Globulin	3.6	.	.	.	2.1 - 3.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	28SEP96	1	03OCT96	6	6
00210	Oral	2	0 MG	04OCT96	7	09OCT96	12	6
00210	Oral	3	0 MG	10OCT96	13	17OCT96	20	8
00210	Oral	4	0 MG	18OCT96	21	24OCT96	27	7
00210	Oral	4	0 MG	25OCT96	28	03NOV96	37	10
00210	Oral	5	0 MG	04NOV96	38	12NOV96	46	9
00210	Oral	5	0 MG	13NOV96	47	22NOV96	56	10
00210	Oral	5	0 MG	23NOV96	57	02DEC96	66	10
00177	Oral	5	0 MG	03DEC96	67	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	67	0	Lost to follow-up	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	.,	.	.	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Asthenia	FATIGUE	27, -40	12 Days	0	CON	MIL	NO	PSR	No	No
	Chest Pain	CHEST PAIN	6, -61	20 Mins	0	1	MIL	NO	PBU	No	No
	Headache	HEADACHE	6, -61	20 Mins	0	1	MIL	NO	PBU	No	No
Cardiovascular System	Arrhythmia	SINUS ARRHYTHMIA	27, -40	40 Days	0	2	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	13SEP96	-15, -81	0	108	72	84	110	70	80	113.50	64.2
BL	27SEP96	-1, -67	0	110	70	80	112	70	84	113.50	
1	03OCT96	6, -61	0	110	60	70	110	60	70	114.20	
2	09OCT96	12, -55	0	110	70	80	108	70	88	115.00	
3	17OCT96	20, -47	0	100	70	72	102	70	76	112.00	
4	24OCT96	27, -40	0	100	72	76	102	70	80	114.00	
5	04NOV96	38, -29	0	100	70	80	100	74	86	113.00	
6	12NOV96	46, -21	0	110	70	84	112	74	86	112.00	
8	22NOV96	56, -11	0	102	74	80	106	76	86	113.50	
8	02DEC96	66, -1	0	104	74	80	106	74	80	111.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	194000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	137	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.1	.	.	.	30 - 70	%
				Lymphocytes	24.8	.	.	.	21 - 51	%
				Monocytes	5.9	.	.	.	0 - 10	%
				Eosinophils	2.7	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	155000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	133	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00210 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Aspartate Aminotransferase	21	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	3	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	6	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	08FEB96	1	14FEB96	7	7
00283	Oral	2	20 MG	15FEB96	8	21FEB96	14	7
00283	Oral	3	20 MG	22FEB96	15	29FEB96	22	8
00283	Oral	4	20 MG	01MAR96	23	07MAR96	29	7
00283	Oral	4	20 MG	08MAR96	30	15MAR96	37	8
00283	Oral	4	20 MG	16MAR96	38	22MAR96	44	7
00283	Oral	4	20 MG	23MAR96	45	28MAR96	50	6
00283	Oral	4	20 MG	29MAR96	51	04APR96	57	7
00130	Oral	4	20 MG	05APR96	58	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	58	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	33, -25	11MAR96	11MAR96	650MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	18, -40	01:00 Hrs	20	1	MIL	NO	PBU	No	No
			33, -25	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
Nervous System	Tremor	"SHAKINESS"	27, -31	6 Days	20	6	MIL	NO	PSR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	30JAN96	-9, -66	0	108	70	64	108	70	68	125.00	67.0
1	14FEB96	7, -51	20	120	80	80	120	76	80	127.00	
2	21FEB96	14, -44	20	110	76	60	108	76	62	124.70	
3	29FEB96	22, -36	20	110	76	76	110	76	84	128.70	
4	07MAR96	29, -29	20	108	70	76	108	70	76	128.20	
5	15MAR96	37, -21	20	110	70	60	110	70	70	128.00	
6	22MAR96	44, -14	20	110	60	76	104	60	70	127.20	
7	28MAR96	50, -8	20	120	80	60	120	80	72	129.50	
8	04APR96	57, -1	20	110	70	70	110	70	70	129.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.7	.	.	.	30 - 70	%
				Lymphocytes	24.9	.	.	.	21 - 51	%
				Monocytes	5.4	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	228000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	150	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	34	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.9	H	.	.	6.2 - 8.8	G/DL
				Albumin	5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	14.6	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	10.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	72.6	H	.	.	30 - 70	%
				Lymphocytes	17.9	L	.	.	21 - 51	%
				Monocytes	4.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	264000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	127	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00283 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	57	Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	19	L	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	22MAR96	1	28MAR96	7	7
00284	Oral	2	100 MG	29MAR96	8	05APR96	15	8
00284	Oral	3	150 MG	06APR96	16	11APR96	21	6
00284	Oral	4	200 MG	12APR96	22	19APR96	29	8
00284	Oral	4	200 MG	20APR96	30	25APR96	35	6
00284	Oral	5	250 MG	26APR96	36	02MAY96	42	7
00284	Oral	5	250 MG	03MAY96	43	09MAY96	49	7
00284	Oral	5	250 MG	10MAY96	50	16MAY96	56	7
00134	Oral	5	250 MG	17MAY96	57	10JUN96	81	25
00134	Oral	5	250 MG	11JUN96	82	08JUL96	109	28
00134	Oral	5	250 MG	09JUL96	110	05AUG96	137	28
00134	Oral	5	250 MG	06AUG96	138	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	138	250	Protocol violation, including non-compliance	STOPPED TAKING MEDS. WITHOUT NOTIFICATION OR DOWN TITRATION

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
LOW NEUTROPHILS	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
LOW WHITE BLOOD CELLS	LEUKOPENIA	BLOOD/BLOOD FORMING ORGAN DIS	CUR	1996
CROUP	LARYNGITIS/TRACH, ACUTE	RESPIRATORY SYST DIS	PRV	1979
PECTUS EXCAVATUM	CONG ANOM, MUSCULOSKEL	ANOMALIES	PRV	1978
PSEUDOMONAS INFECTION	BACT DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1988

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Hepatitis B Vaccine	Hepatitis B Vaccine	29, -28	19APR96	19APR96		VACCINATION
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-21, -77	01MAR96	.	650MG	HEADACHE
			31, -26	21APR96	21APR96	650MG	HEADACHE
RESPIRATORY	Dextromethorphan Hydrobromide	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT
	Guaifenesin	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT
	Paracetamol	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT
	Pseudoephedrine Hydrochloride	Dayquil	9, -48	30MAR96	30MAR96	3TSP	SORE THROAT

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	31, -26	01:00 Hrs	200	1	MOD	NO	PBU	Yes	No
			78, 22	01:00 Hrs	250	CON	MIL	NO	PBU	Yes	No
Digestive System	Constipation	CONSTIPATION	32, -25	11 Days	200	CON	MIL	NO	PSR	No	No
	Diarrhea	DIARRHEA	79, 23	03:00 Hrs	250	3	MIL	NO	PBU	No	No
	Nausea	NAUSEA	-1, -57	13 Days	0	4	MIL	NO	PSR	No	No
Hemic and Lymphatic System	Leukopenia	LOW NEUTROPHILS	56, -1	Not Stated	250	CON	MOD	NO	PBU	No	No
		LOW WHITE CELL COUNT	56, -1	Not Stated	250	CON	MOD	NO	PBU	No	No
Respiratory System	Pharyngitis	SORE THROAT	9, -48	4 Days	100	CON	MIL	NO	UNR	Yes	No
Urogenital System	Dysuria	DYSURIA	80, 24	2 Days	250	3	MOD	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	13MAR96	-9, -65	0	122	78	80	122	70	80	154.70	72.0
BL	21MAR96	-1, -57	0	122	78	80	122	70	80	154.70	
1	28MAR96	7, -50	50	120	78	76	120	80	80	151.70	
2	05APR96	15, -42	100	108	70	80	110	70	88	151.70	
3	11APR96	21, -36	150	110	80	90	110	86	96	152.00	
4	19APR96	29, -28	200	110	80	80	118	80	90	152.20	
5	25APR96	35, -22	200	110	70	80	110	76	80	153.00	
6	02MAY96	42, -15	250	120	80	80	120	80	80	152.00	
7	09MAY96	49, -8	250	120	78	80	120	84	86	152.00	
8	16MAY96	56, -1	250	120	80	80	120	80	80	150.00	
12	10JUN96	81, 25	250	110	72	80	116	70	88	147.00	
16	08JUL96	109, 53	250	126	78	80	120	70	96	147.00	
20	05AUG96	137, 81	250	122	88	76	120	84	80	147.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.5	.	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	41	.	.	.	30 - 70	%
				Lymphocytes	49	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	3	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	180000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	33	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	69	L	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	-1	Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.3	.	.	.	41 - 50	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.1	L	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	2	L	.	.	4 - 12	%
				Segmented Neutrophils	43	.	.	.	30 - 70	%
				Lymphocytes	47	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	216000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	96	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	92	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	23	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	32	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	4.5	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	137	Hemoglobin	13.6	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.5	L	.	.	41 - 50	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	2.8	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	21	L	.	.	30 - 70	%
				Lymphocytes	72	H	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	0	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	165000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	97	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00284 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 13/CONTINUATION-WEEK 20	137	Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	85	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	9.2	H	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	4.7	H	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	18MAY96	1	27MAY96	10	10
00285	Oral	2	0 MG	28MAY96	11	03JUN96	17	7
00285	Oral	3	0 MG	04JUN96	18	10JUN96	24	7
00285	Oral	4	0 MG	11JUN96	25	20JUN96	34	10
00285	Oral	5	0 MG	21JUN96	35	28JUN96	42	8
00285	Oral	6	0 MG	29JUN96	43	08JUL96	52	10
00285	Oral	6	0 MG	09JUL96	53	18JUL96	62	10
00285	Oral	6	0 MG	19JUL96	63	24JUL96	68	6
	Oral	5	0 MG	25JUL96	69	31JUL96	75	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	No	75	0	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
KNEE PROBLEMS{RIGHT}	JOINT DISORD, OTHER	MUSCULOSKEL/CONNECT TISSUE DIS	CUR	1995
EPSTEIN BARR VIRUS	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1993

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-503, .	01JAN95	.	500MG	HEADACHE
MUSCULO-SKELETAL	Ibuprofen	Motrin	18, .	04JUN96	.	400 MG	TOOTHACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Tooth Disorder	TOOTHACHE	18, .	Not Stated	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	08MAY96	-10, .	0	110	70	70	100	70	80	184.70	69.5
BL	17MAY96	-1, .	0	110	70	70	106	70	80	184.70	
1	27MAY96	10, .	0	110	60	80	110	60	80	185.20	
2	03JUN96	17, .	0	108	70	80	108	70	84	185.20	
3	10JUN96	24, .	0	108	68	80	110	70	80	185.00	
5	21JUN96	35, .	0	104	72	84	110	76	88	184.50	
6	28JUN96	42, .	0	110	60	80	110	60	84	182.70	
7	08JUL96	52, .	0	120	60	80	120	60	84	185.50	
8	18JUL96	62, .	0	118	60	80	114	64	84	184.50	
8	24JUL96	68, .	0	120	70	88	120	74	88	186.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.3	L	.	.	41 - 50	%
				Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.4	.	.	.	30 - 70	%
				Lymphocytes	36.9	.	.	.	21 - 51	%
				Monocytes	8.6	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	68	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	33.9	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	0.7	.	.	.	0 - 2	%
				Platelets	281000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00285 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	68	Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	84	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	06JUN96	1	14JUN96	9	9
00286	Oral	2	100 MG	15JUN96	10	21JUN96	16	7
00286	Oral	3	150 MG	22JUN96	17	28JUN96	23	7
00286	Oral	4	200 MG	29JUN96	24	08JUL96	33	10
00286	Oral	5	250 MG	09JUL96	34	17JUL96	42	9
00286	Oral	5	250 MG	18JUL96	43	24JUL96	49	7
00286	Oral	6	300 MG	25JUL96	50	02AUG96	58	9
00286	Oral	6	300 MG	03AUG96	59	12AUG96	68	10
00154	Oral	6	300 MG	13AUG96	69	17SEP96	104	36
00154	Oral	6	300 MG	18SEP96	105	24OCT96	141	37
00154	Oral	6	300 MG	25OCT96	142	24NOV96	172	31
00154	Oral	6	300 MG	25NOV96	173	30DEC96	208	36
00154	Oral	6	300 MG	31DEC96	209	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	209	300	Lost to follow-up	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1990
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	
SINUSITIS	SINUSITIS,NOS	RESPIRATORY SYST DIS	CUR	

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-2348,-2416	01JAN90	.	1000MG	HEADACHE
RESPIRATORY	Pseudoephedrine Hydrochloride	Sudafed	-2348,-2416	01JAN90	.	2PILLS	SINUSITIS
	Salbutamol	Proventil	-2348,-2416	01JAN90	.	2PUFFS	ASTHMA
			-2348,-2416	01JAN90	.	2PUFFS	ASTHMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	15MAY96	-22, -90	0	118	80	80	110	80	80	166.20	61.5
BL	05JUN96	-1, -69	0	112	80	72	110	70	76	166.20	
1	14JUN96	9, -60	50	110	80	65	100	70	65	164.00	
2	21JUN96	16, -53	100	100	80	96	114	82	96	165.50	
3	28JUN96	23, -46	150	106	82	92	110	80	90	164.00	
5	08JUL96	33, -36	200	120	78	90	120	80	96	167.00	
6	17JUL96	42, -27	250	118	80	88	120	80	92	164.20	
7	24JUL96	49, -20	250	120	80	86	120	76	84	163.20	
8	02AUG96	58, -11	300	116	80	84	120	80	88	160.00	
8	09AUG96	65, -4	300	110	70	80	112	74	84	160.00	
16	17SEP96	104, 36	300	110	70	88	110	72	84	160.50	
20	24OCT96	141, 73	300	104	70	84	106	72	88	156.70	
24	25NOV96	173, 105	300	110	70	86	110	74	90	153.70 L	
28	30DEC96	208, 140	300	110	80	80	110	80	84	151.20 L	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.6	.	.	.	12 - 15.6	G/DL
				Hematocrit	40	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.4	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	7.1	.	.	.	0 - 10	%
				Eosinophils	8.9	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	RESULT INVAL	U	.	U	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	69	Hemoglobin	15.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.7	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	68.3	.	.	.	30 - 70	%
				Lymphocytes	19.9	L	.	.	21 - 51	%
				Monocytes	10.9	H	.	.	0 - 10	%
				Eosinophils	0.8	.	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	69	Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	173	Hemoglobin	14.5	.	.	.	12 - 15.6	G/DL
				Hematocrit	41.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	66.2	.	.	.	30 - 70	%
				Lymphocytes	23.2	.	.	.	21 - 51	%
				Monocytes	9.1	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	226000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00286 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 13/CONTINUATION-WEEK 20	173	Uric Acid	2.7	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	49	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	03JUL96	1	09JUL96	7	7
00287	Oral	2	0 MG	10JUL96	8	17JUL96	15	8
00287	Oral	3	0 MG	18JUL96	16	23JUL96	21	6
00287	Oral	4	0 MG	24JUL96	22	30JUL96	28	7
00287	Oral	5	0 MG	31JUL96	29	06AUG96	35	7
00287	Oral	6	0 MG	07AUG96	36	13AUG96	42	7
00287	Oral	6	0 MG	14AUG96	43	20AUG96	49	7
00287	Oral	6	0 MG	21AUG96	50	27AUG96	56	7
	Oral	5	0 MG	28AUG96	57	10SEP96	70	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	70	0		DID NOT WANT TO CONTINUE

* Relative to Start of Study Medication

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	25JUN96	-8, .	0	104	70	60	104	72	64	121.70	61.0
BL	02JUL96	-1, .	0	106	70	64	106	74	66	121.70	
1	09JUL96	7, .	0	110	70	70	110	74	72	124.00	
2	17JUL96	15, .	0	110	70	76	110	70	80	120.50	
3	23JUL96	21, .	0	110	70	80	112	70	84	119.20	
4	30JUL96	28, .	0	110	70	80	112	70	84	120.00	
5	06AUG96	35, .	0	110	70	80	112	72	84	120.00	
6	13AUG96	42, .	0	110	70	80	110	70	84	121.50	
7	20AUG96	49, .	0	106	70	80	110	78	84	119.00	
8	27AUG96	56, .	0	110	70	80	108	72	84	120.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.2	.	.	.	30 - 70	%
				Lymphocytes	26.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	225000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	16	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	131	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	81	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 2/ELIGIBILITY	-1	Urine Squamous Epithelial Cells	4	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	56	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	65.5	.	.	.	30 - 70	%
				Lymphocytes	26.5	.	.	.	21 - 51	%
				Monocytes	4.1	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	1.3	.	.	.	0 - 2	%
				Platelets	218000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	116	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	10	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00287 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	56	Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	25JUL96	1	31JUL96	7	7
00288	Oral	2	20 MG	01AUG96	8	08AUG96	15	8
00288	Oral	3	20 MG	09AUG96	16	18AUG96	25	10
00288	Oral	4	20 MG	19AUG96	26	29AUG96	36	11
00288	Oral	4	20 MG	30AUG96	37	05SEP96	43	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	43	20	Lack of Efficacy	PATIENT NO LONGER WANTS TO PARTICIPATE IN STUDY.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1987
PROTEINURIA	PROTEINURIA	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Carbinoxamine Maleate	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH
	Dextromethorphan Hydrobromide	Robitussin-Dm	8, .	01AUG96	.		COUGH
	Ethanol	Robitussin-Dm	8, .	01AUG96	.		COUGH
	Guaifenesin	Robitussin-Dm	8, .	01AUG96	.		COUGH
	Phenylephrine Hydrochloride	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH
	Phenylpropanolamine Hydrochloride	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH
	Phenyltoloxamine Citrate	Naldecon	2, .	26JUL96	01AUG96	2 TSP	COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Respiratory System	Cough Increased	COUGH	2, .	Not Stated	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	01JUL96	-24, .	0	110	70	84	106	70	88	105.50	65.2
BL	18JUL96	-7, .	0	110	68	88	110	70	96	105.50	
1	01AUG96	8, .	20	110	56	70	106	60	76	103.20	
2	09AUG96	16, .	20	110	60	80	100	60	80	103.00	
4	19AUG96	26, .	20	104	70	80	100	70	90	104.20	
5	29AUG96	36, .	20	100	70	80	104	70	80	103.20	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-7	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.7	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.1	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	0.6	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	240000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	230	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	11	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	67	L	.	.	70 - 115	MG/DL
				Globulin	3.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.011.00288 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 2/ELIGIBILITY	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	24OCT95	1	30OCT95	7	7
00025	Oral	2	20 MG	31OCT95	8	06NOV95	14	7
00025	Oral	3	20 MG	07NOV95	15	13NOV95	21	7
00025	Oral	4	20 MG	14NOV95	22	20NOV95	28	7
00025	Oral	4	20 MG	21NOV95	29	27NOV95	35	7
00025	Oral	5	30 MG	28NOV95	36	04DEC95	42	7
00025	Oral	6	40 MG	05DEC95	43	11DEC95	49	7
00025	Oral	6	40 MG	12DEC95	50	19DEC95	57	8
	Oral	5	30 MG	20DEC95	58	04JAN96	73	16

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	73	30	Lack of Efficacy	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES(SKIN)	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1995

CUR = Current, PRV = Past

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
RESPIRATORY	Cetirizine Hydrochloride	Reactine	-115, .	01JUL95	.	10MG	SKIN ALLERGIES

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Abdominal Pain	DISCOMFORT ACROSS ALL OF ABDOMEN	14, .	02:00 Hrs	20	1	MOD	NO	PBU	No	No
	Asthenia	FATIGUE	24, .	Not Stated	20	CON	MOD	NO	REL	No	No
Digestive System	Nausea	NAUSEA	14, .	02:00 Hrs	20	1	MOD	NO	PBU	No	No
Nervous System	Insomnia	INITIAL AND MIDDLE INSOMNIA	1, .	Not Stated	20	CON	MOD	NO	PSR	No	No
	Somnolence	DROWSINESS	24, .	20 Days	20	CON	MOD	NO	REL	No	No
	Tremor	SHAKINESS OF WHOLE BODY	1, .	02:00 Hrs	20	CON	MIL	NO	PSR	No	No
Urogenital System	Urinary Tract Infection	[URINARY INFECTION QUESTIONABLE]	57, .	9 Days	40	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	17OCT95	-7, .	0	114	80	82	118	80	92	114.66	65.0
BL	24OCT95	1, .	0	110	74	72	114	80	76	114.66	
1	31OCT95	8, .	20	110	70	94	110	74	100	114.88	
2	07NOV95	15, .	20	108	90	72	110	92	80	115.10	
3	14NOV95	22, .	20	100	70	76	90	68	76	114.66	
4	21NOV95	29, .	20	100	76	70	96	64	74	114.88	
5	28NOV95	36, .	30	90	60	96	100	70	96	113.56	
6	05DEC95	43, .	40	98	78	92	102	80	100	113.56	
7	12DEC95	50, .	40	113	69	74	113	60	85	114.44	
8	19DEC95	57, .	40	100	62	80	110	70	100	113.34	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.9	.	.	.	30 - 70	%
				Lymphocytes	34.7	.	.	.	21 - 51	%
				Monocytes	9.4	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	287000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	97	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	57	Hemoglobin	12.7	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	43.3	.	.	.	30 - 70	%
				Lymphocytes	40.3	.	.	.	21 - 51	%
				Monocytes	12	H	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	279000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.9	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	106	.	.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00025 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	57	Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.4	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 10/UNSCHEDULED LAB 1	65	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00026 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28NOV95	1	04DEC95	7	7
00026	Oral	2	100 MG	05DEC95	8	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	No	No	8	100	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00026 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	09NOV95	-19, .	0	110	70	68	100	72	80	159.20	63.8
BL	28NOV95	1, .	0	110	78	56	90	62	80	161.63	
1	05DEC95	8, .	100	100	66	80	104	80	84	163.17	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00026 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-19	Hemoglobin	13.7	L	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	47.3	.	.	.	30 - 70	%
				Lymphocytes	39.1	.	.	.	21 - 51	%
				Monocytes	8.5	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	203000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	28.1	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	83	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.4	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	256	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	104	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00026 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-19	Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	06DEC95	1	11DEC95	6	6
00027	Oral	2	0 MG	12DEC95	7	18DEC95	13	7
00027	Oral	3	0 MG	19DEC95	14	26DEC95	21	8
00027	Oral	4	0 MG	27DEC95	22	02JAN96	28	7
	Oral	3	0 MG	03JAN96	29	11JAN96	37	9

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	37	0	Other reason	EARLY WITHDRAWAL-WK 4VISIT PATIENT CHOSE TO WITHDRAW FROM STUDY BECAUSE HE WANTS TO BE TREATED BY PRIMARY THERAPIST AND WANTS TO BE ABLE TO TAKE OTHER MEDICATIONS LIKE LORAZEPAM.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	CUR	1985
OTITIS MEDIA	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	CUR	1995
TENSION HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	-8, .	28NOV95	08DEC95	1000MG	OTITIS MEDIA
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Entrophen	19, .	24DEC95	.	2TABS BID	"NECK SPASM"
	Lorazepam	Lorazepam	16, .	21DEC95	26DEC95	0.5MGX1DAY	ANXIETY
	Paracetamol	Tylenol	-1069, .	01JAN93	.	975MG PRN	HEADACHE
			-15, .	21NOV95	07DEC95	975MG PRN	OTITIS MEDIA
DERMATOLOGICALS	Erythromycin	Erythromycin	-8, .	28NOV95	08DEC95	1000MG	OTITIS MEDIA
MUSCULO-SKELETAL	Naproxen Sodium	Anaprox	-25, .	11NOV95	17NOV95#	550MG PRN	HEADACHES
RESPIRATORY	Beclometasone Dipropionate	Becloforte	-127, .	01AUG95	20NOV95#	4MCG/PRN	ASTHMA
			-127, .	01AUG95	20NOV95#	4MCG/PRN	ASTHMA
	Cromoglicate Sodium	Intal	-96, .	01SEP95	.	40MG	ASTHMA
			-96, .	01SEP95	.	40MG	ASTHMA
	Paracetamol	Neo-Citran	10, .	15DEC95	17DEC95	1TAB	COLD
	Pheniramine Maleate	Neo-Citran	10, .	15DEC95	17DEC95	1TAB	COLD
	Phenylephrine Hydrochloride	Neo-Citran	10, .	15DEC95	17DEC95	1TAB	COLD
	Pseudoephedrine Hydrochloride	Sudafed	10, .	15DEC95	17DEC95	1TAB	COLD
	Salbutamol	Ventolin	-461, .	01SEP94	17NOV95#	200MCG/PRN	ASTHMA
			-461, .	01SEP94	17NOV95#	200MCG/PRN	ASTHMA
			10, .	15DEC95	.	200MCG/PRN	ASTHMA
			10, .	15DEC95	.	200MCG/PRN	ASTHMA
SENSORY ORGANS	Betamethasone Sodium Phosphate	Garasone	-9, .	27NOV95	08DEC95	4GTTS 4XDAY	OTITIS MEDIA
	Cromoglicate Sodium	Intal	-96, .	01SEP95	.	40MG	ASTHMA
	Erythromycin	Erythromycin	-8, .	28NOV95	08DEC95	1000MG	OTITIS MEDIA
	Gentamicin Sulfate	Garasone	-9, .	27NOV95	08DEC95	4GTTS 4XDAY	OTITIS MEDIA

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Back Pain	NECK SPASM	16, .	Not Stated	0	CON	MOD	NO	PBU	Yes	No
Nervous System	Anxiety	ANXIETY	16, .	Not Stated	0	CON	MOD	NO	PBU	Yes	No
Respiratory System	Respiratory Disorder	COMMON COLD	10, .	13 Days	0	CON	SEV	NO	UNR	Yes	No
Special Senses	Otitis Media	OTITIS MEDIA(EAR INFECTION)	-10, .	12 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

Week	Visit Date	Relative Days *	Dose (mg)	Sitting Systolic (mmHg)	Sitting Diastolic (mmHg)	Sitting Pulse (bpm)	Standing Systolic (mmHg)	Standing Diastolic (mmHg)	Standing Pulse (bpm)	Weight (lbs)	Height (in)
SC	23NOV95	-13, .	0	110	64	68	104	72	80	154.13	71.7
BL	06DEC95	1, .	0	110	76	88	120	78	92	158.76	
1	12DEC95	7, .	0	126	72	96	120	86	70	158.32	
2	19DEC95	14, .	0	110	70	60	110	80	62	156.33	
3	27DEC95	22, .	0	100	62	72	110	70	100	159.64	
4	02JAN96	28, .	0	122	66	60	110	52	64	159.64	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	14	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	40.2	L	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	35	.	.	.	30 - 70	%
				Lymphocytes	48.3	.	.	.	21 - 51	%
				Monocytes	10.1	H	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	259000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	15	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	103	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	94	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	41.1	.	.	.	30 - 70	%
				Lymphocytes	42.2	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	9.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	314000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	20	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	111	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 2/ELIGIBILITY	1	Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	92	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	28	Hemoglobin	13.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	39.7	L	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	14	L	.	-	30 - 70	%
				Lymphocytes	67	H	.	.	21 - 51	%
				Monocytes	14	H	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	86	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	17	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.8	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	116	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	11	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00027 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 6/ACUTE PHASE-WEEK 4	28	Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	95	.	.	.	70 - 115	MG/DL
				Globulin	2.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	21MAY96	1	30MAY96	10	10
00217	Oral	2	0 MG	31MAY96	11	06JUN96	17	7
00217	Oral	3	0 MG	07JUN96	18	13JUN96	24	7
00217	Oral	4	0 MG	14JUN96	25	14JUN96	25	1

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	No	No	25	0	Adverse event, including intercurrent illness	ABIVALENCE ABOUT MEDICATION,VIRAL ILLNESS,MEDICATION ON IP'S ADVICE,HOSPITALIZATION TO PSYCHIATRY,AND WANTING TO KNOW WHICH MED SHE WAS ON.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHE	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1995
INJURY TO LEFT KNEE{PARAGLIDING}	TRAUMA/INJURIES, UNSPEC	INJURY/POISONING	PRV	1993
LIGAMENT TEARS{LEFT FOOT,ANKLE}	SPRAINS/STRAINS	INJURY/POISONING	PRV	1995
MONONUCLEOSIS{(2 EPISODES IN ONE YEAR)}	VIRUS/CHLAMYD DIS, OTHER	INFECTIOUS/PARASITIC DIS	PRV	1995

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Bismuth Subsalicylate	Pepto Bismol	29, .	18JUN96	19JUN96	PRN	FLU
CENTRAL NERVOUS SYSTEM	Paracetamol	Sinutab	16, .	05JUN96	05JUN96	1DOSE	COLD
		Tylenol	-81, .	01MAR96	.	PRN 500MG	HEADACHE
	Phenacetin	Sinutab	16, .	05JUN96	05JUN96	1DOSE	COLD
	Phenylpropanolamine Hydrochloride	Sinutab	16, .	05JUN96	05JUN96	1DOSE	COLD
	Phenyltoloxamine Citrate	Sinutab	16, .	05JUN96	05JUN96	1DOSE	COLD
	Sertraline Hydrochloride	Zoloft	30, .	19JUN96	.	100 MG	DEPRESSION
DERMATOLOGICALS	Budesonide	Pulmicort	29, .	18JUN96	19JUN96	400 MG	ASTHMA
RESPIRATORY	Budesonide	Pulmicort	29, .	18JUN96	19JUN96	400 MG	ASTHMA
			29, .	18JUN96	19JUN96	400 MG	ASTHMA
	Guaifenesin	Robitussin	21, .	10JUN96	12JUN96	2TBSP/DAY	COLD

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	FLU	24, .	7 Days	0	CON	MOD	STP	UNR	Yes	No
Nervous System	Depression	DEPRESSION (WORSENING)	30, .	8 Days	0	CON	SEV	NO	UNR	Yes	Yes
Respiratory System	Asthma	RECURRENT ASTHMA	26, .	5 Days	0	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	COMMON COLD	14, .	10 Days	0	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	14MAY96	-7, .	0	92	70	76	100	70	80	110.03	61.4
BL	21MAY96	1, .	0	100	66	60	96	64	84	108.93	
1	31MAY96	11, .	0	110	70	80	108	74	70	110.69	
2	07JUN96	18, .	0	110	70	74	100	76	80	111.35	
3	14JUN96	25, .	0	120	80	70	110	80	76	110.03	
4	19JUN96	30, .	0	100	60	64	100	70	72	108.49	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.4	.	.	.	30 - 70	%
				Lymphocytes	22.7	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	6.3	H	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	262000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	1	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	30 (5)	Hemoglobin	13.1		.	.	12 - 15.6	G/DL
				Hematocrit	38.5		.	.	35 - 46	%
				Red Blood Cell Count	4.2		.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.4	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	58.6		.	.	30 - 70	%
				Lymphocytes	26.2		.	.	21 - 51	%
				Monocytes	12.1	H	.	.	0 - 10	%
				Eosinophils	2.8		.	.	0 - 5	%
				Basophils	0.4		.	.	0 - 2	%
				Platelets	233000		.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31		.	.	25 - 35	PG
				Mean Corpuscle Volume	91		.	.	80 - 100	FL
				Blood Urea Nitrogen	12		.	.	7 - 25	MG/DL
				Creatinine	0.9		.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6		.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65		.	.	44 - 280	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00217 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 6/ACUTE PHASE-WEEK 4	30 (5)	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16JUN96	1	20JUN96	5	5
00218	Oral	2	0 MG	21JUN96	6	27JUN96	12	7
00218	Oral	3	0 MG	28JUN96	13	04JUL96	19	7
00218	Oral	4	0 MG	05JUL96	20	11JUL96	26	7
00218	Oral	4	0 MG	12JUL96	27	18JUL96	33	7
00218	Oral	4	0 MG	19JUL96	34	28JUL96	43	10
00218	Oral	4	0 MG	29JUL96	44	05AUG96	51	8
00218	Oral	4	0 MG	06AUG96	52	12AUG96	58	7
00117	Oral	4	0 MG	13AUG96	59	17SEP96	94	36
00218	Oral	4	0 MG	18SEP96	95	19SEP96	96	2
00218	Oral	3	0 MG	20SEP96	97	21SEP96	98	2
00218	Oral	2	0 MG	22SEP96	99	24SEP96	101	3
00218	Oral	1	0 MG	25SEP96	102	01OCT96	108	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	17	Yes	No	108	0	Other reason	WISHED TO DISCONTINUE STUDY MEDICATION, FEELS SHE CAN DO WELL WITHOUT "PILLS".

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ANXIETY	ANXIETY	MENTAL DISORD	CUR	1996
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1986

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Clonazepam	Clonazepam	-34, -92	13MAY96	16MAY96#	1MG	ANXIETY
	Paracetamol	Tylenol	-8, -66	08JUN96	08JUN96#	500 MG	HEADACHE
			26, -33	11JUL96	11JUL96	500 MG	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE (MODERATE)	-8, -66	02:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			26, -33	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04JUN96	-12, -70	0	100	68	64	104	70	88	118.63	65.7
BL	14JUN96	-2, -60	0	110	80	80	100	60	100	118.41	
1	21JUN96	6, -53	0	120	80	80	100	70	88	119.95	
2	28JUN96	13, -46	0	118	70	80	112	76	92	122.38	
3	05JUL96	20, -39	0	110	70	76	118	74	80	121.05	
4	12JUL96	27, -32	0	100	70	72	100	72	80	119.29	
5	19JUL96	34, -25	0	110	70	72	120	80	72	119.73	
6	29JUL96	44, -15	0	122	80	76	116	72	82	119.95	
7	06AUG96	52, -7	0	112	70	80	110	70	76	121.05	
8	13AUG96	59, 1	0	110	80	72	110	70	76	121.72	
12	18SEP96	95, 37	0	110	70	72	110	80	80	124.36	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-12	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	40.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64	.	.	.	30 - 70	%
				Lymphocytes	23	.	.	.	21 - 51	%
				Monocytes	6	.	.	.	0 - 10	%
				Eosinophils	7	H	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	377000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	99	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	79	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	73	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 1/SCREENING (WEEK -1)	-12	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	-2	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	59	Hemoglobin	13.3	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.8	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.5	.	.	.	30 - 70	%
				Lymphocytes	28.8	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	12.6	H	.	+	0 - 5	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 10/ACUTE PHASE-WEEK 8	59	Basophils	0.9	.	.	.	0 - 2	%
				Platelets	345000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	82	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	86	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 11/CONTINUATION-WEEK 12	95	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00218 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	F	VISIT 11/CONTINUATION-WEEK 12	95	Segmented Neutrophils	40	.	.	.	30 - 70	%
				Lymphocytes	43	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	11	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	366000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	94	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	85	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	91	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	31MAY96	1	06JUN96	7	7
00219	Oral	2	100 MG	07JUN96	8	13JUN96	14	7
00219	Oral	3	150 MG	14JUN96	15	23JUN96	24	10
00219	Oral	4	200 MG	24JUN96	25	01JUL96	32	8
00219	Oral	4	200 MG	02JUL96	33	08JUL96	39	7
00219	Oral	4	200 MG	09JUL96	40	15JUL96	46	7
00219	Oral	4	200 MG	16JUL96	47	22JUL96	53	7
00219	Oral	4	200 MG	23JUL96	54	29JUL96	60	7
00106	Oral	4	200 MG	30JUL96	61	29AUG96	91	31
00106	Oral	4	200 MG	30AUG96	92	25SEP96	118	27
00106	Oral	4	200 MG	26SEP96	119	24OCT96	147	29
00106	Oral	4	200 MG	25OCT96	148	21NOV96	175	28
00106	Oral	4	200 MG	22NOV96	176	19DEC96	203	28
00106	Oral	4	200 MG	20DEC96	204	18JAN97	233	30

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	Yes	233	200		

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1996
EAR INFECTIONS	OTITIS MEDIA	NERVOUS SYST/SENSE ORGAN DIS	PRV	1985

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	24MAY96	-7, -67	0	100	70	64	110	70	72	167.36	78.7
BL	31MAY96	1, -60	0	110	80	72	120	90	64	166.92	
1	07JUN96	8, -53	100	110	70	80	100	80	100	165.38	
2	14JUN96	15, -46	150	120	80	68	110	80	60	163.39	
3	24JUN96	25, -36	200	110	70	74	112	76	80	165.38	
5	02JUL96	33, -28	200	104	70	60	102	80	68	167.36	
6	09JUL96	40, -21	200	112	70	60	120	78	68	168.46	
7	16JUL96	47, -14	200	120	80	84	110	80	74	169.12	
8	23JUL96	54, -7	200	110	80	110	100	86	90	168.24	
8	30JUL96	61, 1	200	112	76	74	120	70	84	168.02	
12	30AUG96	92, 32	200	130	78	80	132	80	82	165.82	
16	26SEP96	119, 59	200	118	76	100	120	80	90	170.23	
20	25OCT96	148, 88	200	118	80	86	110	86	80	169.34	
24	22NOV96	176, 116	200	122	80	80	120	70	74	168.24	
28	20DEC96	204, 144	200	110	72	82	112	80	76	168.24	
32	24JAN97	239, 179	200	126	82	64	120	80	72	170.89	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	7.9	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	173000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6.2	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	176	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	22	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	1.8	H	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	105	.	.	.	70 - 115	MG/DL
				Globulin	2.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 2/ELIGIBILITY	1	Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.3	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	181	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.9	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.1	.	.	.	30 - 70	%
				Lymphocytes	37.7	.	.	.	21 - 51	%
				Monocytes	8.3	.	.	.	0 - 10	%
				Eosinophils	3.5	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Platelets	161000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	166	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	19	.	.	.	0 - 48	U/L
				Total Bilirubin	1.3	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	85	.	.	.	70 - 115	MG/DL
				Globulin	2.4	.	.	.	2.3 - 4.1	G/DL
		VISIT 11/CONTINUATION-WEEK 12	92	Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	148	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	3.4	L	.	.	4.5 - 13	THOU/MCL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	148	Segmented Neutrophils	49.2	.	.	.	30 - 70	%
				Lymphocytes	41.1	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	172000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	95	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	187	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	97	.	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
		VISIT 14/CONTINUATION-WEEK 24	176	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	2	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	239	(6)	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
					Hematocrit	44.6	.	.	.	41 - 50	%
					Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	51	.	.	.	30 - 70	%
					Lymphocytes	34.9	.	.	.	21 - 51	%
					Monocytes	11	H	.	.	0 - 10	%
					Eosinophils	2.7	.	.	.	0 - 5	%
					Basophils	0.3	.	.	.	0 - 2	%
					Platelets	163000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	31.7	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	5.6	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	172	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	28	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	22	.	.	.	0 - 48	U/L
					Total Bilirubin	1.5	H	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	91	.	.	.	70 - 115	MG/DL
					Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick	NEG		.	.		
					Urine Blood - Dipstick	NEG		.	.		
					Urine Red Blood Cells/HPF	NEG		.	.		
					Urine White Blood Cells/HPF	NEG		.	.		
					Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00219 TREATMENT GROUP: IMIPRAMINE

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	17JUN96	1	21JUN96	5	5
00220	Oral	2	20 MG	22JUN96	6	27JUN96	11	6
00220	Oral	3	20 MG	28JUN96	12	04JUL96	18	7
00220	Oral	4	20 MG	05JUL96	19	11JUL96	25	7
00220	Oral	5	30 MG	12JUL96	26	18JUL96	32	7
00220	Oral	5	30 MG	19JUL96	33	28JUL96	42	10
00220	Oral	5	30 MG	29JUL96	43	05AUG96	50	8
00220	Oral	5	30 MG	06AUG96	51	15AUG96	60	10
00110	Oral	5	30 MG	16AUG96	61	12SEP96	88	28
00110	Oral	5	30 MG	13SEP96	89	10OCT96	116	28
00110	Oral	5	30 MG	11OCT96	117	07NOV96	144	28
00110	Oral	5	30 MG	08NOV96	145	21NOV96	158	14
00220	Oral	5	30 MG	22NOV96	159	.	.	.

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	159	30	Other reason	WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIC TO SUDAFED	ADVERSE EFF ON AUTONOMIC NS	EXT CAUSES OF INJURY/POISONING	CUR	1984
ATTENTION DEFICIT HYPERACTIVE DISORDER	CONDUCT DISORD	MENTAL DISORD	CUR	1987
BED-WETTING	INCONTINENCE, URINARY	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1986
BLADDER INFECTIONS	CYSTITIS	GENITOURINARY SYST DIS	PRV	1986
OBSESSIVE COMPULSIVE SYMPTOMS	NEUROSES	MENTAL DISORD	PRV	1994
TOURETTES (TIC DISORDER).	TICS	MENTAL DISORD	PRV	1987

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
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PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS
CENTRAL NERVOUS SYSTEM	Methylphenidate Hydrochloride	Ritalin Sr	-148, -208	21JAN96	15MAY96#	20 MG	ADHD
DERMATOLOGICALS	Erythromycin	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS
SENSORY ORGANS	Erythromycin	Erythromycin	113, 53	07OCT96	14OCT96	1000 MG	BRONCHITIS

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Nausea	NAUSEA	89, 29	04:00 Hrs	30	1	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	9, -52	3 Days	20	CON	MOD	NO	REL	No	No
Respiratory System	Bronchitis	BRONCHITIS	102, 42	37 Days	30	CON	MOD	NO	PBU	Yes	No
Special Senses	Abnormal Vision	BLURRED VISION	9, -52	2 Days	20	CON	MIL	NO	REL	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04JUN96	-13, -73	0	122	82	76	128	90	80	179.93	66.9
BL	14JUN96	-3, -63	0	110	80	60	110	70	68	179.49	
1	22JUN96	6, -55	20	112	76	60	110	80	68	182.13	
2	28JUN96	12, -49	20	120	80	68	124	84	64	183.24	
3	05JUL96	19, -42	20	114	80	60	116	78	68	184.34	
4	12JUL96	26, -35	30	110	74	68	120	70	84	186.32	
5	19JUL96	33, -28	30	112	70	70	118	72	72	186.54	
6	29JUL96	43, -18	30	118	78	82	114	74	80	186.54	
7	06AUG96	51, -10	30	126	90	64	128	88	80	186.32	
8	16AUG96	61, 1	30	120	80	80	130	90	86	185.22	
12	13SEP96	89, 29	30	120	70	68	120	80	80	182.79	
16	11OCT96	117, 57	30	120	82	84	122	84	100	180.37	
20	08NOV96	145, 85	30	120	80	68	120	72	70	183.02	
24	06DEC96	173, 113	0	120	80	76	120	70	82	184.12	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.8	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	5.3	H	.	.	0 - 5	%
				Basophils	0.1	.	.	.	0 - 2	%
				Platelets	194000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	168	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	26	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	30	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	112	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-13	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	61	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.7	.	.	.	30 - 70	%
				Lymphocytes	36.3	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	4	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	236000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.7	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	159	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	21	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	6.8	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	61	Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	134	H	.	.	70 - 115	MG/DL
				Globulin	2.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 11/CONTINUATION-WEEK 12	89	Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	151	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	27	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
		VISIT 13/CONTINUATION-WEEK 20	145	Hemoglobin	16.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	47.4	.	.	.	41 - 50	%
				Red Blood Cell Count	5.4	H	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	39.4	.	.	.	30 - 70	%
				Lymphocytes	44.4	.	.	.	21 - 51	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 13/CONTINUATION-WEEK 20	145		Monocytes	9.5	.	.	.	0 - 10	%
					Eosinophils	5.8	H	.	.	0 - 5	%
					Basophils	0.9	.	.	.	0 - 2	%
					Platelets	216000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.4	.	.	.	4 - 8	MG/DL
					Alkaline Phosphatase	135	.	.	.	44 - 400	U/L
					Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	17	.	.	.	0 - 48	U/L
					Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL
					Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	110	.	.	.	70 - 115	MG/DL
					Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
					Urine Glucose - Dipstick NEG		.	.	.		
					Urine Blood - Dipstick NEG		.	.	.		
					Urine Red Blood Cells/HPF NEG		.	.	.		
					Urine White Blood Cells/HPF	3	.	.	.		
					Urine Bacteria	4	.	.	.		
					Urine Protein - Dipstick NEG		.	.	.		
					Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 14/CONTINUATION-WEEK 24	173	(15)	Hemoglobin	15.1	.	.	.	13.8 - 17.2	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 14/CONTINUATION-WEEK 24	173 (15)	Hematocrit	44.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	40.1	.	.	.	30 - 70	%
				Lymphocytes	42.4	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	9.1	H	.	.	0 - 5	%
				Basophils	1.8	.	.	.	0 - 2	%
				Platelets	202000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	123	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	19	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	23	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00220 TREATMENT GROUP: PAROXETINE

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
17	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	25JUN96	1	01JUL96	7	7
00221	Oral	2	100 MG	02JUL96	8	08JUL96	14	7
00221	Oral	3	150 MG	09JUL96	15	15JUL96	21	7
00221	Oral	4	200 MG	16JUL96	22	22JUL96	28	7
00221	Oral	5	250 MG	23JUL96	29	31JUL96	37	9
00221	Oral	4	200 MG	01AUG96	38	08AUG96	45	8
00221	Oral	4	200 MG	09AUG96	46	18AUG96	55	10
00221	Oral	4	200 MG	19AUG96	56	26AUG96	63	8
00112	Oral	4	200 MG	27AUG96	64	22SEP96	90	27
00112	Oral	4	200 MG	23SEP96	91	20OCT96	118	28
00112	Oral	4	200 MG	21OCT96	119	03NOV96	132	14

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	17	Yes	No	132	200	Adverse event, including intercurrent illness	MINOR OVERDOSE OF LORAZEPAM AND WITHDREW CONSENT TO STUDY. REFUSED DOWN-TITRATION

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HEADACHES {MODERATE}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1989

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Laxatives, Nos	Laxative (Unknown Name)	112, 49	14OCT96	01NOV96	1-2 TBSP EVERY 2ND DAY	CONSTIPATION
CENTRAL NERVOUS SYSTEM	Acetylsalicylic Acid	Aspirin	78, 15	10SEP96	10SEP96	1950 MG	HEADACHES
	Chloral Hydrate	Chloral Hydrate	56, -8	19AUG96	22SEP96	500 MG PRN	INSOMNIA
	Lorazepam	Lorazepam	132, 69	03NOV96	03NOV96	8 MG	OVERDOSE
	Paracetamol	Tylenol	-906, -969	01JAN94	.	500 MG PRN	HEADACHE

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHES (SEVERE)	78, 15	06:00 Hrs	200	1	SEV	NO	PBU	Yes	No
Digestive System	Constipation	CONSTIPATION	112, 49	19 Days	200	CON	MOD	NO	UNR	Yes	No
	Dry Mouth	DRY MOUTH	67, 4	52 Days	200	CON	MOD	NO	PSR	No	No
Nervous System	Dizziness	DIZZINESS	39, -25	8 Days	200	5	MOD	NO	PBU	No	No
	Emotional Lability	OVERDOSE {INTENTIONAL}	132, 69	19:30 Hrs	200	CON	SEV	STP	UNR	No	Yes
	Euphoria	MILD ELATION AND DISINHIBITION	30, -34	13 Days	250	CON	MIL	DCR	PSR	No	No
	Insomnia	INSOMNIA	52, -12	39 Days	200		MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JUN96	-7, -70	0	110	70	80	120	80	80	148.18	69.3
BL	25JUN96	1, -63	0	114	80	64	110	80	80	147.96	
1	02JUL96	8, -56	100	110	70	84	110	80	100	147.29	
2	09JUL96	15, -49	150	110	78	72	118	76	80	144.87	
3	16JUL96	22, -42	200	110	80	104	120	80	100	148.62	
4	23JUL96	29, -35	250	124	80	88	118	90	92	148.18	
5	30JUL96	36, -28	250	110	72	90	120	80	96	148.40	
6	09AUG96	46, -18	200	110	80	96	100	70	100	150.16	
8	19AUG96	56, -8	200	124	78	92	118	78	90	147.74	
8	27AUG96	64, 1	200	120	74	84	118	74	90	147.96	
12	23SEP96	91, 28	200	120	86	88	110	80	80	151.26	
16	21OCT96	119, 56	200	110	80	88	100	80	100	154.35	
20	04NOV96	133, 70	200	120	70	90	124	68	90	157.66	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	16.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	48.5	.	.	.	41 - 50	%
				Red Blood Cell Count	5.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.9	.	.	.	30 - 70	%
				Lymphocytes	26.6	.	.	.	21 - 51	%
				Monocytes	5.5	.	.	.	0 - 10	%
				Eosinophils	2.6	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	235000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.6	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	81	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	12	.	.	.	0 - 48	U/L
				Total Bilirubin	1.2	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	114	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 2/ELIGIBILITY	1	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Hemoglobin	15.7	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	46.2	.	.	.	41 - 50	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	56.7	.	.	.	30 - 70	%
				Lymphocytes	27.9	.	.	.	21 - 51	%
				Monocytes	6.1	.	.	.	0 - 10	%
				Eosinophils	8.3	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	270000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	84	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	9	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00221 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
17	M	VISIT 10/ACUTE PHASE-WEEK 8	64	Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	109	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	28JUN96	1	04JUL96	7	7
00222	Oral	2	20 MG	05JUL96	8	11JUL96	14	7
00222	Oral	3	20 MG	12JUL96	15	18JUL96	21	7
00222	Oral	4	20 MG	19JUL96	22	28JUL96	31	10
00222	Oral	4	20 MG	29JUL96	32	05AUG96	39	8
00222	Oral	5	30 MG	06AUG96	40	12AUG96	46	7
00222	Oral	5	30 MG	13AUG96	47	19AUG96	53	7
00222	Oral	5	30 MG	20AUG96	54	29AUG96	63	10
00113	Oral	5	30 MG	30AUG96	64	21SEP96	86	23

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	Yes	No	86	30	Other reason	NON-COMPLIANCE WITHDREW CONSENT

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
HAYFEVER-LATE SPRING,SUMMER MONTHS ONLY	RHINITIS, ALLERGIC	RESPIRATORY SYST DIS	CUR	1994

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	21, -43	18JUL96	22JUL96	1500 MG	BLADDER INFECTION
ANTINEOPLASTIC & IMMUNOSUP	Diethylstilbestrol Dipropionate	Cyclen	-119, -182	01MAR96	.	1TAB	CONTRACEPTION
DERMATOLOGICALS	Budesonide	Rhinocort	-36, -99	23MAY96	.	PRN 2SPRAYS OD	HAY FEVER
GU SYSTEM/SEX HORMONES	Diethylstilbestrol Dipropionate	Cyclen	-119, -182	01MAR96	.	1TAB	CONTRACEPTION
RESPIRATORY	Budesonide	Rhinocort	-36, -99	23MAY96	.	PRN 2SPRAYS OD	HAY FEVER
			-36, -99	23MAY96	.	PRN 2SPRAYS OD	HAY FEVER

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Urogenital System	Cystitis	BLADDER INFECTION	21, -43	4 Days	20	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	18JUN96	-10, -73	0	100	66	60	100	70	80	119.51	66.1
BL	28JUN96	1, -63	0	110	70	80	112	76	72	121.05	
1	05JUL96	8, -56	20	100	68	62	112	70	70	119.95	
2	12JUL96	15, -49	20	110	70	72	110	62	68	119.07	
3	19JUL96	22, -42	20	110	62	68	110	70	72	119.29	
4	29JUL96	32, -32	20	114	70	64	110	68	62	119.51	
6	06AUG96	40, -24	30	110	70	68	110	74	60	118.63	
7	13AUG96	47, -17	30	108	76	82	100	80	80	119.51	
8	20AUG96	54, -10	30	100	70	70	110	70	76	119.95	
8	30AUG96	64, 1	30	130	78	68	122	74	70	119.51	
12	27SEP96	92, 29	30	110	80	80	116	76	70	121.50	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	39.6	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	27.1	.	.	.	21 - 51	%
				Monocytes	6.5	.	.	.	0 - 10	%
				Eosinophils	6.2	H	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	296000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	1.5	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.8	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	63	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-10	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	64	Segmented Neutrophils	72	H	.	.	30 - 70	%
				Lymphocytes	21	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Blood Urea Nitrogen	9	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/ACUTE PHASE-WEEK 8	64	Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	54	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.8	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	70	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	2	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test NEGATIVE		.	.	.		
		VISIT 10/UNSCHEDULED LAB 1	76	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.9	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	48	.	.	.	30 - 70	%
				Lymphocytes	37	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	9	H	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 10/UNSCHEDULED LAB 1	76		Platelets	274000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
					Urine Amphetamines	NEG		.	.	.	
					Urine Barbiturates	NEG		.	.	.	
					Urine Benzodiazepines	NEG		.	.	.	
					Urine Cannabinoids	NEG		.	.	.	
					Urine Cocaine	NEG		.	.	.	
					Urine Methadone	NEG		.	.	.	
					Urine Methaqualone	NEG		.	.	.	
					Urine Opiates	NEG		.	.	.	
					Urine Phencyclidine	NEG		.	.	.	
					Urine Propoxyphene	NEG		.	.	.	
		VISIT 11/CONTINUATION-WEEK 12	92	(6)	Hemoglobin	13.1	.	.	.	12 - 15.6	G/DL
					Hematocrit	38.2	.	.	.	35 - 46	%
					Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	54.6	.	.	.	30 - 70	%
					Lymphocytes	34.6	.	.	.	21 - 51	%
					Monocytes	5.2	.	.	.	0 - 10	%
					Eosinophils	4.4	.	.	.	0 - 5	%
					Basophils	1.1	.	.	.	0 - 2	%
					Platelets	365000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	30.5	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	6	L	.	.	7 - 25	MG/DL
					Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.3	.	.	.	2.3 - 7	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00222 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 11/CONTINUATION-WEEK 12	92 (6)	Alkaline Phosphatase	64	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	83	.	.	.	70 - 115	MG/DL
				Globulin	3.7	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
13	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	30AUG96	1	05SEP96	7	7
00223	Oral	2	100 MG	06SEP96	8	15SEP96	17	10
00223	Oral	3	150 MG	16SEP96	18	22SEP96	24	7
00223	Oral	4	200 MG	23SEP96	25	30SEP96	32	8
	Oral	3	150 MG	01OCT96	33	12OCT96	44	12

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	13	No	No	44	150	Lack of Efficacy	PT WISHED TO WITHDRAW FROM THE STUDY TO BE TREATED OPENLY.

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ALLERGIES	ALLERGY, NEC	INJURY/POISONING	CUR	1996
BENIGN LUMP LEFT FOOT	SWELLING, MASS, LOCALIZED	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1995
BRONCHOSPASM	RESP DIS, OTHER	RESPIRATORY SYST DIS	CUR	1996
HEADACHES {FREQUENT}	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1994
FATTY INFILTRATION OF THE LIVER {CLINICALLY NORMAL}	LIVER DISORD	DIGESTIVE SYST	PRV	1996
HISTORY OF HIGH AVERAGE/BORDERLINE HIGH BLOOD PRESSURE	BLOOD PRESSURE, ELEVATED	SIGNS,SYMPTOMS,ILL-DEFINED CON	PRV	1995
PYELONEPHRITIS	KIDNEY INFECT	GENITOURINARY SYST DIS	PRV	1995
RADIAL FRACTURE	FRACTURE, UPPER LIMB	INJURY/POISONING	PRV	1994
URINARY TRACT INFECTION'S {FREQUENT}	URINARY TRACT INFECTION	GENITOURINARY SYST DIS	PRV	1984

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	-972, .	01JAN94	.	500 MG PRN	HEADACHE
DERMATOLOGICALS	Fluticasone Propionate	Flonase	-107, .	15MAY96	.	1 PUFF PRN	BRONCHOSPASM
RESPIRATORY	Cromoglicate Sodium	Sodium (Cromoglycate)	-107, .	15MAY96	.	2 DROPS PRN	ALLERGIC REACTION
			-107, .	15MAY96	.	2 DROPS PRN	ALLERGIC REACTION
	Fluticasone Propionate	Flonase	-107, .	15MAY96	.	1 PUFF PRN	BRONCHOSPASM
SENSORY ORGANS	Cromoglicate Sodium	Sodium (Cromoglycate)	-107, .	15MAY96	.	2 DROPS PRN	ALLERGIC REACTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Hypertension	HYPERTENSION	32, .	Not Stated	200	CON	MOD	NO	UNR	No	Yes
Nervous System	Depression	MAJOR DEPRESSION	31, .	Not Stated	200	CON	MOD	NO	UNR	No	Yes
	Emotional Lability	SELF MUTILATION	31, .	Not Stated	200	CON	MOD	NO	UNR	No	Yes
		SUICIDAL IDEATION	26, .	10 Days	200	1	MOD	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	23AUG96	-7, .	0	104	70	72	110	70	80	194.04	61.8
BL	30AUG96	1, .	0	132	86	88	136	88	90	196.25	
1	06SEP96	8, .	100	136	100	100	130	90	92	196.47	
2	16SEP96	18, .	150	130	90	108	128	90	100	195.36	
3	23SEP96	25, .	200	132	84	96	138	86	92	195.14	
5	01OCT96	33, .	150	140	98	90	140	104	100	195.14	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	14.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	43.1	.	.	.	35 - 46	%
				Red Blood Cell Count	5.1	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.8	.	.	.	21 - 51	%
				Monocytes	6.3	.	.	.	0 - 10	%
				Eosinophils	1.7	.	.	.	0 - 5	%
				Basophils	0.6	.	.	.	0 - 2	%
				Platelets	359000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	27.5	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	84	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	154	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	44	H	.	.	0 - 41	U/L
				Alanine Aminotransferase	67	H	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00223 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
13	F	VISIT 1/SCREENING (WEEK -1)	-7	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	16SEP96	1	23SEP96	8	8
00224	Oral	2	0 MG	24SEP96	9	02OCT96	17	9
00224	Oral	3	0 MG	03OCT96	18	09OCT96	24	7
00224	Oral	4	0 MG	10OCT96	25	16OCT96	31	7
00224	Oral	4	0 MG	17OCT96	32	24OCT96	39	8
00224	Oral	4	0 MG	25OCT96	40	03NOV96	49	10
00224	Oral	4	0 MG	04NOV96	50	11NOV96	57	8
00224	Oral	4	0 MG	12NOV96	58	20NOV96	66	9
00126	Oral	4	0 MG	21NOV96	67	18DEC96	94	28
00126	Oral	4	0 MG	19DEC96	95	19JAN97	126	32
00126	Oral	4	0 MG	20JAN97	127	17FEB97	155	29
00224	Oral	3	0 MG	18FEB97	156	19FEB97	157	2
00224	Oral	2	0 MG	20FEB97	158	22FEB97	160	3
00224	Oral	1	0 MG	23FEB97	161	01MAR97	167	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	14	Yes	No	167	0	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	87, 21	11DEC96	18DEC96	750 MG	STREP THROAT
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	16, -51	01OCT96	01OCT96	325 MG PRN	TOOTHACHE (ORTHODONTIST APPT)
			25, -42	10OCT96	.	650 MG PRN	MENSTRUAL CRAMPS
RESPIRATORY	Dimenhydrinate	Gravol	108, 42	01JAN97	01JAN97	1 1/2 TAB	DIFFICULTY FALLING ASLEEP

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Infection	STREP THROAT	84, 18	11 Days	0	CON	MIL	NO	UNR	Yes	No
Digestive System	Tooth Disorder	TOOTHACHE	16, -51	1 Days	0	CON	MIL	NO	UNR	Yes	No
Musculoskeletal System	Arthralgia	LEFT KNEE PAIN	18, -49	18:00 Hrs	0	CON	MIL	NO	UNR	No	No
Nervous System	Insomnia	DIFFICULTY FALLING TO SLEEP	108, 42	1 Days	0	1	MIL	NO	PBU	Yes	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS	7, -60	11 Days	0	CON	MIL	NO	UNR	No	No
Urogenital System	Dysmenorrhea	MENSTRUAL CRAMPS	24, -43	Not Stated	0		MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	30AUG96	-17, -83	0	110	80	70	118	76	74	114.66	63.8
BL	16SEP96	1, -66	0	130	84	86	126	80	82	113.78	
1	24SEP96	9, -58	0	100	70	72	100	70	100	113.56	
2	03OCT96	18, -49	0	120	72	80	108	60	90	114.88	
3	10OCT96	25, -42	0	108	64	68	100	60	84	115.32	
4	17OCT96	32, -35	0	112	68	74	110	70	86	116.42	
6	25OCT96	40, -27	0	100	80	80	100	70	82	117.31	
7	04NOV96	50, -17	0	110	60	72	112	80	72	115.98	
8	12NOV96	58, -9	0	100	70	68	100	70	88	116.42	
8	20NOV96	66, -1	0	117	78	80	120	76	100	116.42	
12	19DEC96	95, 29	0	120	80	80	116	78	84	115.10	
16	20JAN97	127, 61	0	110	70	88	120	70	92	119.07	
24	18FEB97	156, 90	0	108	70	78	100	70	86	119.95	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	1000.PRE	-19	Hemoglobin	13.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.7	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.6	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	51	.	.	.	30 - 70	%
				Lymphocytes	29	.	.	.	21 - 51	%
				Monocytes	5	.	.	.	0 - 10	%
				Eosinophils	14	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	370000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	7	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	248	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 1/SCREENING (WEEK -1)	-17	Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 1/SCREENING (WEEK -1)	-17	Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		
		VISIT 1/UNSCHEDULED LAB 1	-10	Hemoglobin	12.1	.	.	.	12 - 15.6	G/DL
				Hematocrit	35.5	.	.	.	35 - 46	%
				Red Blood Cell Count	3.9	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	7.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.9	.	.	.	30 - 70	%
				Lymphocytes	22	.	.	.	21 - 51	%
				Monocytes	5.1	.	.	.	0 - 10	%
				Eosinophils	9.2	H	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEC		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 6/ACUTE PHASE-WEEK 4	32	Serum BHCG pregnancy test	NEGATIVE		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Hemoglobin	12.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	38.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	53.1	.	.	.	30 - 70	%
				Lymphocytes	27.2	.	.	.	21 - 51	%
				Monocytes	5.8	.	.	.	0 - 10	%
				Eosinophils	12.9	H	.	+	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	367000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	205	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	113	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 10/ACUTE PHASE-WEEK 8	66	Urine Squamous Epithelial Cells	4	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 13/CONTINUATION-WEEK 20	156	Hemoglobin	12.2	.	.	.	12 - 15.6	G/DL
				Hematocrit	36.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4	L	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.4	.	.	.	4.5 - 13	THOU/MCL
				Neutrophil Bands	0	L	.	.	4 - 12	%
				Segmented Neutrophils	63	.	.	.	30 - 70	%
				Lymphocytes	15	L	.	.	21 - 51	%
				Monocytes	10	.	.	.	0 - 10	%
				Eosinophils	12	H	.	+	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	309000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.1	L	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	167	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	8	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.2	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00224 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	F	VISIT 13/CONTINUATION-WEEK 20	156	Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
14	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	0 MG	26NOV96	1	02DEC96	7	7
00225	Oral	2	0 MG	03DEC96	8	09DEC96	14	7
00225	Oral	3	0 MG	10DEC96	15	19DEC96	24	10
00225	Oral	4	0 MG	20DEC96	25	26DEC96	31	7
00225	Oral	4	0 MG	27DEC96	32	05JAN97	41	10
00225	Oral	4	0 MG	06JAN97	42	12JAN97	48	7
00225	Oral	4	0 MG	13JAN97	49	20JAN97	56	8
00225	Oral	4	0 MG	21JAN97	57	28JAN97	64	8
00129	Oral	4	0 MG	29JAN97	65	23FEB97	90	26
00129	Oral	4	0 MG	24FEB97	91	19MAR97	114	24
00129	Oral	4	0 MG	20MAR97	115	20APR97	146	32
00129	Oral	4	0 MG	21APR97	147	25MAY97	181	35
00129	Oral	4	0 MG	26MAY97	182	29JUN97	216	35
00129	Oral	4	0 MG	30JUN97	217	29JUL97	246	30
00225	Oral	3	0 MG	30JUL97	247	31JUL97	248	2
00225	Oral	2	0 MG	01AUG97	249	03AUG97	251	3
00225	Oral	1	0 MG	04AUG97	252	10AUG97	258	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	14	Yes	Yes	258	0		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Erythromycin Ethylsuccinate	Pediazole	124, 60	29MAR97	07APR97	40 CC	EAR INFECTION
			124, 60	29MAR97	07APR97	40 CC	EAR INFECTION
	Sulfafurazole Acetyl	Pediazole	124, 60	29MAR97	07APR97	40 CC	EAR INFECTION
			124, 60	29MAR97	07APR97	40 CC	EAR INFECTION
MUSCULO-SKELETAL	Ibuprofen	Ibuprofen	237, 173	20JUL97	23JUL97	300 MG	PREVENT PAIN FROM SPRAINED WRIST
RESPIRATORY	Prednisone	Prednisone	130, 66	04APR97	09APR97	50 MG	BRONCHOSPASM
	Salbutamol	Ventolin	130, 66	04APR97	04APR97	5 MG	BRONCHOSPASM
			130, 66	04APR97	04APR97	5 MG	BRONCHOSPASM
	Terbutaline Sulfate	Bricanyl Inhaler	130, 66	04APR97	08APR97	1 MG Q4H PRN	BRONCHOSPASM
SYSTEMIC HORMONAL	Prednisone	Prednisone	130, 66	04APR97	09APR97	50 MG	BRONCHOSPASM

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Trauma	SPRAINED WRIST LEFT	232, 168	Not Stated	0	CON	MIL	NO	UNR	Yes	No
Hemic and Lymphatic System	Lymphadenopathy	SLIGHTLY ENLARGED NON-TENDER LEFT JUGULO-DIGASTRIC NODE	130, 66	59 Days	0	1	MIL	NO	UNR	No	No
Nervous System	Hypesthesia	NUMB LEFT UPPER LEG	115, 51	1 Days	0	1	MIL	NO	PBU	No	No
Respiratory System	Asthma	BRONCHOSPASM	124, 60	11 Days	0	CON	MOD	NO	UNR	Yes	No
Special Senses	Otitis Media	EAR INFECTION LEFT	124, 60	11 Days	0	CON	MOD	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	19NOV96	-7, -71	0	130	78	74	124	76	72	133.40	68.1
BL	26NOV96	1, -64	0	126	60	72	118	70	92	132.30	
1	03DEC96	8, -57	0	120	80	80	118	80	90	133.40	
2	10DEC96	15, -50	0	120	68	64	118	72	68	131.20	
3	20DEC96	25, -40	0	117	68	72	120	68	80	132.30	
4	27DEC96	32, -33	0	120	80	86	117	78	90	134.51	
6	06JAN97	42, -23	0	110	60	80	110	70	76	133.40	
7	13JAN97	49, -16	0	112	70	76	120	70	92	133.40	
8	21JAN97	57, -8	0	110	70	64	120	70	72	136.71	
8	29JAN97	65, 1	0	120	70	64	112	76	96	134.51	
12	24FEB97	91, 27	0	110	70	68	110	68	78	135.61	
16	20MAR97	115, 51	0	120	70	82	110	60	88	132.30	
20	21APR97	147, 83	0	110	64	87	105	62	120	135.61	
24	26MAY97	182, 118	0	106	64	72	114	64	98	137.37	
32	30JUN97	217, 153	0	100	70	80	94	70	100	134.51	
32	30JUL97	247, 183	0	100	62	60	110	64	76	134.95	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.7	.	.	.	30 - 70	%
				Lymphocytes	37.4	.	.	.	21 - 51	%
				Monocytes	4.7	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	1.1	.	.	.	0 - 2	%
				Platelets	191000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.7	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	157	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.1	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	71	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	65	Hemoglobin	13.9	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	52	.	.	.	30 - 70	%
				Lymphocytes	36	.	.	.	21 - 51	%
				Monocytes	7	.	.	.	0 - 10	%
				Eosinophils	5	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	194000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.4	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	85	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	11	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	138	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.2	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 10/ACUTE PHASE-WEEK 8	65	Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	74	.	.	.	70 - 115	MG/DL
				Globulin	2.6	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 13/CONTINUATION-WEEK 20	147	Hemoglobin	14.3	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	9.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	75	H	.	.	30 - 70	%
				Lymphocytes	20.8	L	.	.	21 - 51	%
				Monocytes	3.1	.	.	.	0 - 10	%
				Eosinophils	1.1	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	188000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	87	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	117	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.6	.	.	.	0.3 - 1.3	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 13/CONTINUATION-WEEK 20	147	Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	96	.	.	.	70 - 115	MG/DL
				Globulin	3.1	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		
		VISIT 16/CONTINUATION-WEEK 32	247	Hemoglobin	14.4	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.1	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.3	L	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	64.1	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	3.2	.	.	.	0 - 10	%
				Eosinophils	2	.	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	190000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.4	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	113	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	12	.	.	.	0 - 41	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00225 TREATMENT GROUP: PLACEBO

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
14	M	VISIT 16/CONTINUATION-WEEK 32	247	Alanine Aminotransferase	10	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG	.	.	.		
				Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	03DEC96	1	09DEC96	7	7
00226	Oral	2	20 MG	10DEC96	8	19DEC96	17	10
00226	Oral	3	20 MG	20DEC96	18	20DEC96	18	1

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	No	No	18	20	Adverse event, including intercurrent illness	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
MILD RECURRENT HEADACHES	HEADACHE	SIGNS,SYMPTOMS,ILL-DEFINED CON	CUR	1993
FRACTURE RIGHT LEG	FRACTURE, LOWER LIMB	INJURY/POISONING	PRV	1988
SURGERY FOR STRABISMUS	OPERATION, EYE	OPERATIONS	PRV	1983

CUR = Current, PRV = Past

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Carciovascular System	Av Block	PR PROLONGATION CARDIAC CONDUCTION DELAY	18, .	4 Days	20	CON	MOD	STP	PSR	No	No
Digestive System	Nausea	NAUSEA	10, .	12 Days	20	CON	MIL	NO	PBU	No	No
Respiratory System	Respiratory Disorder	COLD SYMPTOMS (SORE THROAT, COUGH)	-3, .	24 Days	0	CON	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26NOV96	-7, .	0	110	70	100	112	80	110	176.40	73.2
BL	03DEC96	1, .	0	120	82	76	122	80	84	174.20	
1	10DEC96	8, .	20	132	80	78	128	76	80	174.20	
2	20DEC96	18, .	20	112	70	86	118	76	100	175.30	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	44.2	.	.	.	41 - 50	%
				Red Blood Cell Count	4.9	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	4.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	51.1	.	.	.	30 - 70	%
				Lymphocytes	34.8	.	.	.	21 - 51	%
				Monocytes	8.2	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.9	.	.	.	0 - 2	%
				Platelets	203000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.8	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	90	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	136	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	15	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	9	.	.	.	0 - 48	U/L
				Total Bilirubin	0.9	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.9	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	101	.	.	.	70 - 115	MG/DL
				Globulin	3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00226 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-7	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	18DEC96	1	26DEC96	9	9
00227	Oral	2	100 MG	27DEC96	10	05JAN97	19	10
00227	Oral	3	150 MG	06JAN97	20	14JAN97	28	9
00227	Oral	4	200 MG	15JAN97	29	23JAN97	37	9
00227	Oral	4	200 MG	24JAN97	38	03FEB97	48	11
00227	Oral	4	200 MG	04FEB97	49	13FEB97	58	10
00227	Oral	5	250 MG	14FEB97	59	19FEB97	64	6
00227	Oral	5	250 MG	20FEB97	65	24FEB97	69	5
00114	Oral	6	300 MG	25FEB97	70	26MAR97	99	30
00114	Oral	6	300 MG	27MAR97	100	24APR97	128	29
00114	Oral	6	300 MG	25APR97	129	25MAY97	159	31
00114	Oral	6	300 MG	26MAY97	160	24JUN97	189	30
00114	Oral	6	300 MG	25JUN97	190	20JUL97	215	26
00114	Oral	6	300 MG	21JUL97	216	18AUG97	244	29
00227	Oral	5	250 MG	19AUG97	245	20AUG97	246	2
00227	Oral	4	200 MG	21AUG97	247	22AUG97	248	2
00227	Oral	3	150 MG	23AUG97	249	24AUG97	250	2
00227	Oral	2	100 MG	25AUG97	251	27AUG97	253	3
00227	Oral	1	50 MG	28AUG97	254	03SEP97	260	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	16	Yes	Yes	260	50		

* Relative to Start of Study Medication

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Amoxicillin Trihydrate	Amoxil	42, -28	28JAN97	10FEB97	750 MG	PHARYNGITIS
	Phenoxymethylpenicillin Potassium	Penicillin V-K	21, -49	07JAN97	15JAN97	2,400 MG	AC. PHARYNGITIS
CENTRAL NERVOUS SYSTEM	Cannabis	Marijuana	32, -38	18JAN97	18JAN97	0.75 G	PT'S DECISIONS
RESPIRATORY	Chlorphenamine Maleate	Dristan	142, 73	08MAY97	09MAY97	2 TABS.	CONGESTION
	Mepyramine Maleate	Triaminic	142, 73	08MAY97	09MAY97	3 TSP.	COUGH
	Paracetamol	Dristan	142, 73	08MAY97	09MAY97	2 TABS.	CONGESTION
	Pheniramine Maleate	Triaminic	142, 73	08MAY97	09MAY97	3 TSP.	COUGH
	Phenylephrine Hydrochloride	Dristan	142, 73	08MAY97	09MAY97	2 TABS.	CONGESTION
	Phenylpropanolamine Hydrochloride	Triaminic	142, 73	08MAY97	09MAY97	3 TSP.	COUGH

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	MODERATE HEADACHE	19, -51	52 Days	100	5	MOD	NO	PSR	No	No
		SEVERE HEADACHES	7, -63	07:00 Hrs	50	2	SEV	NO	PSR	No	No
Carciovascular System	Hypertension	HYPERTENSION	129, 60	117 Days	300		MOD	NO	PBU	No	No
	Syncope	SYNCOPE	96, 27	161 Days	300		MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	31, -39	Not Stated	200	CON	MIL	NO	PBU	No	No
		SEVERE DRY MOUTH	129, 60	128 Days	300	CON	SEV	NO	PSR	No	No
Musculoskeletal System	Myalgia	MUSCLE SPASMS IN RIBS	143, 74	11:00 Hrs	300	CON	MOD	NO	PBU	No	No
Nervous System	Drug Dependence	CANNABIS USE	32, -38	1 Days	200	1	MIL	NO	UNR	No	No
	Insomnia	TERMINAL INSOMNIA	52, -18	Not Stated	200		MIL	INC	PBU	No	No
Respiratory System	Pharyngitis	PHARYNGITIS	20, -50	36 Days	150	CON	MOD	NO	PBU	Yes	No
		SORE THROAT	55, -15	11 Days	200	CON	MIL	NO	PBU	No	No
	Respiratory Disorder	COMMON COLD	139, 70	18 Days	300	CON	MIL	NO	UNR	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	12DEC96	-6, -75	0	130	70	60	130	76	70	153.25	70.1
BL	18DEC96	1, -69	0	128	82	80	122	76	84	150.38	
1	27DEC96	10, -60	100	128	80	80	126	78	90	150.38	
3	06JAN97	20, -50	150	120	90	100	120	80	95	150.38	
4	15JAN97	29, -41	200	124	80	92	120	78	94	150.38	
5	24JAN97	38, -32	200	130	90	100	124	82	102	150.38	
7	04FEB97	49, -21	200	126	90	90	122	80	92	151.04	
8	14FEB97	59, -11	250	122	82	80	120	78	82	151.04	
8	20FEB97	65, -5	250	130	80	82	120	86	88	152.15	
8	25FEB97	70, 1	300	128	90	78	120	90	90	151.48	
16	27MAR97	100, 31	300	136	90	90	134	90	100	156.56	
20	25APR97	129, 60	300	152	80	96	152	80	105	159.42	
24	26MAY97	160, 91	300	144	90	94	134	80	120	159.86	
28	25JUN97	190, 121	300	130	90	100	120	90	110	157.44	
32	21JUL97	216, 147	300	120	80	88	136	90	100	156.56	
32	19AUG97	245, 176	250	120	70	90	128	70	96	157.66	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Hemoglobin	14.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	62.1	.	.	.	30 - 70	%
				Lymphocytes	27.8	.	.	.	21 - 51	%
				Monocytes	8.4	.	.	.	0 - 10	%
				Eosinophils	1.4	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	214000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.5	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	80	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	7	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	98	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 1/SCREENING (WEEK -1)	-6	Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70	Hemoglobin	14.8	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.2	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	70.6	H	.	.	30 - 70	%
				Lymphocytes	15.4	L	.	.	21 - 51	%
				Monocytes	9	.	.	.	0 - 10	%
				Eosinophils	3.9	.	.	.	0 - 5	%
				Basophils	1	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	29.9	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	88	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	83	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	14	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8	.	.	.	6.2 - 8.8	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 10/ACUTE PHASE-WEEK 8	70	Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	90	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Bacteria	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	
				Urine Squamous Epithelial Cells	3	.	.	.		
				Urine Amphetamines	NEG		.	.	.	
				Urine Barbiturates	NEG		.	.	.	
				Urine Benzodiazepines	NEG		.	.	.	
				Urine Cannabinoids	POS		.	.	.	
				Urine Cocaine	NEG		.	.	.	
				Urine Methadone	NEG		.	.	.	
				Urine Methaqualone	NEG		.	.	.	
				Urine Opiates	NEG		.	.	.	
				Urine Phencyclidine	NEG		.	.	.	
				Urine Propoxyphene	NEG		.	.	.	
		VISIT 13/CONTINUATION-WEEK 20	160	Hemoglobin	15.5	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	45.8	.	.	.	41 - 50	%
				Red Blood Cell Count	5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.1	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	50.9	.	.	.	30 - 70	%
				Lymphocytes	33.5	.	.	.	21 - 51	%
				Monocytes	9.5	.	.	.	0 - 10	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 13/CONTINUATION-WEEK 20	160	Eosinophils	5.8	H	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	246000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	92	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	0.9	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	100	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
				Total Bilirubin	0.5	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	8.2	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.4	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	93	.	.	.	70 - 115	MG/DL
				Globulin	3.8	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	NEG		.	.	.	
				Urine Protein - Dipstick	NEG		.	.	.	
		VISIT 16/CONTINUATION-WEEK 32	245	Hemoglobin	14.1	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	41.9	.	.	.	41 - 50	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60	.	.	.	30 - 70	%

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00227 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	M	VISIT 16/CONTINUATION-WEEK 32	245	Lymphocytes	24.3	.	.	.	21 - 51	%
				Monocytes	10.4	H	.	.	0 - 10	%
				Eosinophils	4.5	.	.	.	0 - 5	%
				Basophils	0.8	.	.	.	0 - 2	%
				Platelets	189000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	93	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	12	.	.	.	7 - 25	MG/DL
				Creatinine	1.2	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	5.1	.	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	61	.	.	.	22 - 180	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	99	.	.	.	70 - 115	MG/DL
				Globulin	3.3	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.		
				Urine Blood - Dipstick	NEG		.	.		
				Urine Red Blood Cells/HPF	NEG		.	.		
				Urine White Blood Cells/HPF	NEG		.	.		
				Urine Protein - Dipstick	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00228 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	19MAR97	1	22MAR97	4	4

* DAYS RELATIVE TO START OF STUDY MEDICATION

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	15	No	No	4	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00228 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Digestive System	Dry Mouth	DRY MOUTH	2, .	4 Days	20	CON	MIL	NO	PBU	No	No
Nervous System	Insomnia	INITIAL INSOMNIA	2, .	4 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	04MAR97	-15, .	0	90	66	68	100	70	70	108.05	63.4
BL	19MAR97	1, .	0	110	70	82	100	70	90	109.15	
1	27MAR97	9, .	20	100	70	66	100	72	70	109.15	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00228 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Hemoglobin	12.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	37.2	.	.	.	35 - 46	%
				Red Blood Cell Count	4.2	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.8	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	60.5	.	.	.	30 - 70	%
				Lymphocytes	27.3	.	.	.	21 - 51	%
				Monocytes	6.9	.	.	.	0 - 10	%
				Eosinophils	5.1	H	.	.	0 - 5	%
				Basophils	0.2	.	.	.	0 - 2	%
				Platelets	260000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	30.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	89	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	0.8	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	2.6	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	67	.	.	.	44 - 280	U/L
				Aspartate Aminotransferase	13	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	5	.	.	.	0 - 48	U/L
				Total Bilirubin	0.7	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.3	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	88	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick	NEG		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00228 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	F	VISIT 1/SCREENING (WEEK -1)	-15	Urine Squamous Epithelial Cells	3	.	.	.		
				Serum BHCG pregnancy test	NEGATIVE		.	.		
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
15	Male	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	50 MG	28FEB97	1	06MAR97	7	7
00230	Oral	2	100 MG	07MAR97	8	13MAR97	14	7
00230	Oral	3	150 MG	14MAR97	15	23MAR97	24	10
00230	Oral	4	200 MG	24MAR97	25	02APR97	34	10
00230	Oral	4	200 MG	03APR97	35	10APR97	42	8
00230	Oral	4	200 MG	11APR97	43	20APR97	52	10
00230	Oral	4	200 MG	21APR97	53	01MAY97	63	11
00230	Oral	5	250 MG	02MAY97	64	07MAY97	69	6
00116	Oral	5	250 MG	08MAY97	70	12MAY97	74	5
00230	Oral	4	200 MG	13MAY97	75	13MAY97	75	1
00230	Oral	3	150 MG	14MAY97	76	14MAY97	76	1
00230	Oral	2	100 MG	15MAY97	77	16MAY97	78	2
00230	Oral	1	50 MG	17MAY97	79	26MAY97	88	10

* DAYS RELATIVE TO START OF STUDY MEDICATION

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PAROXETINE - PROTOCOL 329

Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Male	15	Yes	No	88	50	Other reason	WITHDREW CONSENT.

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ASTHMA	ASTHMA	RESPIRATORY SYST DIS	PRV	1993

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ALIMENTARY TRACT/METAB	Calcium Carbonate	Tums	15, -55	14MAR97	.	3-4 TABS	HEARTBURN
			76, 7	14MAY97	26MAY97	3-4 TABS	HEARTBURN
			15, -55	14MAR97	.	3-4 TABS	HEARTBURN
			76, 7	14MAY97	26MAY97	3-4 TABS	HEARTBURN
ANTIINFECTIVES,SYSTEMIC	Clarithromycin	Biaxin	50, -20	18APR97	24APR97	500 MG	PHOPHYLAXIS TEETH EXTRACTION
CENTRAL NERVOUS SYSTEM	Codeine Phosphate	Tylenol With Codeine	50, -20	18APR97	20APR97	14 TSPS.	IMPACTED TEETH EXTRACTION
			53, -17	21APR97	21APR97	10 TSP.	IMPACTED TEETH EXTRACTION
	Paracetamol	Tylenol	32, -38	31MAR97	31MAR97	500 MG	HEADACHE
		Tylenol With Codeine	50, -20	18APR97	20APR97	14 TSPS.	IMPACTED TEETH EXTRACTION
			53, -17	21APR97	21APR97	10 TSP.	IMPACTED TEETH EXTRACTION
DERMATOLOGICALS	Methylprednisolone Sodium Succinate	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION
MUSCULO-SKELETAL	Ibuprofen	Advil	53, -17	21APR97	23APR97	600 MG	IMPACTED TEETH EXTRACTION
RESPIRATORY	Dimenhydrinate	Gravol	69, -1	07MAY97	07MAY97	50 MG	NAUSEA
SENSORY ORGANS	Methylprednisolone Sodium Succinate	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION
SYSTEMIC HORMONAL	Methylprednisolone Sodium Succinate	Solu-Medrol	50, -20	18APR97	18APR97	250 MG	IMPACTED TEETH EXTRACTION

* days relative to start of acute phase, days relative to start of continuation phase
\# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	32, -38	1 Days	200	CON	MIL	NO	PBU	Yes	No
Cardiovascular System	Postural Hypotension	ORTHOSTATIC HYPOTENSION	50, -20	19 Days	200		MIL	NO	PBU	No	No
Digestive System	Dry Mouth	DRY MOUTH	12, -58	77 Days	100	CON	MOD	NO	PSR	No	No
	Dyspepsia	HEARTBURN	15, -55	74 Days	150		MIL	NO	PBU	Yes	No
	Nausea	NAUSEA	50, -20	7 Days	200		MOD	NO	UNR	No	No
			69, -1	14:00 Hrs	250	CON	MIL	NO	UNR	Yes	No
	Tooth Disorder	PAIN RE: 4 IMPACTED WISDOM TEETH EXTRACTED UNDER GENERAL ANESTHETIC	50, -20	1 Days	200	CON	MOD	NO	UNR	Yes	No
Nervous System	Dizziness	DIZZINESS	13, -57	3 Days	100	2	MIL	NO	PBU	No	No
Urogenital System	Cystitis	FEELING BLADDER FULL AFTER URINATING	63, -7	28 Days	200	CON	MIL	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	20FEB97	-8, -77	0	120	80	76	120	78	72	121.50	65.4
BL	28FEB97	1, -69	0	120	76	80	120	78	82	121.28	
1	07MAR97	8, -62	100	110	80	84	120	80	96	121.50	
2	14MAR97	15, -55	150	124	70	60	110	70	100	122.38	
3	24MAR97	25, -45	200	120	80	90	114	76	80	122.60	
5	03APR97	35, -35	200	114	76	82	108	80	82	121.72	
6	11APR97	43, -27	200	118	78	90	120	80	96	122.82	
8	23APR97	55, -15	200	106	74	109	90	70	120	119.07	
8	02MAY97	64, -6	250	106	74	100	104	70	116	123.04	
8	08MAY97	70, 1	250	106	68	110	104	60	120	122.16	
12	16MAY97	78, 9	100	106	58	102	100	68	120	122.38	

* days relative to start of acute phase, days relative to start of continuation phase
\# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 1/SCREENING (WEEK -1)	-8	Segmented Neutrophils	48.9	.	.	.	30 - 70	%
				Lymphocytes	41.2	.	.	.	21 - 51	%
				Monocytes	5.3	.	.	.	0 - 10	%
				Eosinophils	4.1	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	0.7	L	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.9	L	.	.	4 - 8	MG/DL
				Alkaline Phosphatase	186	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	24	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	16	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.5	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.6	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	66	L	.	.	70 - 115	MG/DL
				Globulin	2.9	.	.	.	2.3 - 4.1	G/DL
		VISIT 2/ELIGIBILITY	1	Hemoglobin	15.2	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	42.6	.	.	.	41 - 50	%
				Red Blood Cell Count	4.7	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.3	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	54.2	.	.	.	30 - 70	%
				Lymphocytes	35.5	.	.	.	21 - 51	%
				Monocytes	6.7	.	.	.	0 - 10	%
				Eosinophils	3.1	.	.	.	0 - 5	%
				Basophils	0.4	.	.	.	0 - 2	%
				Platelets	292000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
		VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Glucose - Dipstick	NEG	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
F2 (BASELINE FLAG) :
F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 3/ACUTE PHASE-WEEK 1	8	Urine Blood - Dipstick	NEG	.	.	.		
				Urine Red Blood Cells/HPF	NEG	.	.	.		
				Urine White Blood Cells/HPF	NEG	.	.	.		
				Urine Protein - Dipstick	NEG	.	.	.		
				Urine Amphetamines	NEG	.	.	.		
				Urine Barbiturates	NEG	.	.	.		
				Urine Benzodiazepines	NEG	.	.	.		
				Urine Cannabinoids	NEG	.	.	.		
				Urine Cocaine	NEG	.	.	.		
				Urine Methadone	NEG	.	.	.		
				Urine Methaqualone	NEG	.	.	.		
				Urine Opiates	NEG	.	.	.		
				Urine Phencyclidine	NEG	.	.	.		
				Urine Propoxyphene	NEG	.	.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	70	Hemoglobin	15	.	.	.	13.8 - 17.2	G/DL
				Hematocrit	43.7	.	.	.	41 - 50	%
				Red Blood Cell Count	4.8	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	5.5	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	59.6	.	.	.	30 - 70	%
				Lymphocytes	31.5	.	.	.	21 - 51	%
				Monocytes	6.2	.	.	.	0 - 10	%
				Eosinophils	2.2	.	.	.	0 - 5	%
				Basophils	0.5	.	.	.	0 - 2	%
				Platelets	356000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31.3	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	91	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	8	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4.9	.	.	.	4 - 8	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00230 TREATMENT GROUP: IMIPRAMINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
15	M	VISIT 10/ACUTE PHASE-WEEK 8	70	Alkaline Phosphatase	158	.	.	.	44 - 400	U/L
				Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	14	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.3	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	2.8	.	.	.	2.3 - 4.1	G/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

DEMOGRAPHIC CHARACTERISTICS DATA

Age (Years)	Sex	Race
16	Female	Caucasian

STUDY MEDICATION DATA

BOTLAB	ROUTE	DOSE LEVEL	DOSE	START DATE	RELATIVE* DAYS	STOP DATE	RELATIVE* DAYS	DUR DAYS
	Oral	1	20 MG	07MAR97	1	16MAR97	10	10
00231	Oral	2	20 MG	17MAR97	11	23MAR97	17	7
00231	Oral	3	20 MG	24MAR97	18	01APR97	26	9
00231	Oral	4	20 MG	02APR97	27	08APR97	33	7
00231	Oral	4	20 MG	09APR97	34	16APR97	41	8
00231	Oral	4	20 MG	17APR97	42	24APR97	49	8
00231	Oral	5	30 MG	25APR97	50	30APR97	55	6
00231	Oral	5	30 MG	01MAY97	56	06MAY97	61	6
00118	Oral	5	30 MG	07MAY97	62	03JUN97	89	28
00118	Oral	5	30 MG	04JUN97	90	29JUN97	115	26
00118	Oral	5	30 MG	30JUN97	116	05AUG97	152	37
00231	Oral	4	20 MG	05AUG97	152	06AUG97	153	2
00231	Oral	3	20 MG	07AUG97	154	08AUG97	155	2
00231	Oral	2	20 MG	09AUG97	156	11AUG97	158	3
00231	Oral	1	20 MG	12AUG97	159	18AUG97	165	7

* DAYS RELATIVE TO START OF STUDY MEDICATION

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

PATIENT CONCLUSION DATA

Sex	Age (Years)	Completed Acute	Completed Cont.	Study Day *	Dose (mg)	Reason for Withdrawal	Comments
Female	16	Yes	No	165	20	Protocol violation, including non-compliance	

* Relative to Start of Study Medication

PRESENTING CONDITIONS DATA

VERBATIM TERM	PREFERRED TERM	DISEASE CLASSIFICATION (LEVEL 1)	STATUS	DIAGYR
ECZEMA	INFLAM SKIN/SUBCUT	SKIN/SUBCUTANEOUS TISSUE DIS	CUR	1996

CUR = Current, PRV = Past

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

CONCOMITANT MEDICATION DATA

ATC Level I	Generic Term	Drug Name	Relative Days *	Start Date	Stop Date	Total Daily Dose	Indication
ANTIINFECTIVES,SYSTEMIC	Miconazole Nitrate	Micatin	84, 23	29MAY97	.		ECZEMA
CARDIOVASCULAR	Betamethasone	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
CENTRAL NERVOUS SYSTEM	Paracetamol	Tylenol	49, -13	24APR97	.	650 MG PRN	HEADACHE
			109, 48	23JUN97	.	500 MG PRN	MOD HEADACHES
DERMATOLOGICALS	Betamethasone	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
	Miconazole Nitrate	Micatin	84, 23	29MAY97	.		ECZEMA
GU SYSTEM/SEX HORMONES	Ethinylestradiol	Ortho Tri-Cyclen	32, -30	07APR97	.	1 TAB	CONTRACEPTIVE
	Miconazole Nitrate	Micatin	84, 23	29MAY97	.		ECZEMA
	Norgestimate	Ortho Tri-Cyclen	32, -30	07APR97	.	1 TAB	CONTRACEPTIVE
SENSORY ORGANS	Betamethasone	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA
SYSTEMIC HORMONAL	Betamethasone	Betamethasone	32, -30	07APR97	.	1 APPLICATION PRN	ECZEMA

* days relative to start of acute phase, days relative to start of continuation phase
# stop date earlier than start of study medication

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

ADVERSE EXPERIENCE DATA

Body System	Preferred Term	Verbatim Term	Onset Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act-ion	Inv Rel	Corr Ther	SAE
Body as a Whole	Headache	HEADACHE	43, -19	2 Days	20	CON	MOD	NO	PBU	No	No
			49, -13	02:00 Hrs	20	CON	MOD	NO	PBU	Yes	No
			53, -9	Not Stated	30		MIL	NO	PBU	Yes	No
		MODERATE HEADACHE	53, -9	Not Stated	30		MOD	NO	PSR	Yes	No
Digestive System	Dry Mouth	DRY MOUTH	14, -48	41 Days	20	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	80, 19	10 Days	30	4	MIL	NO	PBU	No	No
Nervous System	Dizziness	DIZZINESS	80, 19	10 Days	30	4	MIL	NO	PBU	No	No
Special Senses	Conjunctivitis	ITCHY EYES	48, -14	4 Days	20	CON	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

VITAL SIGN DATA

				Sitting			Standing				
Week	Visit Date	Relative Days *	Dose (mg)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	Weight (lbs)	Height (in)
SC	26FEB97	-9, -70	0	110	70	68	112	80	72	156.56	63.4
BL	07MAR97	1, -61	0	120	70	82	128	80	90	155.45	
1	17MAR97	11, -51	20	110	80	60	120	80	72	157.88	
2	24MAR97	18, -44	20	118	84	76	108	76	88	158.10	
4	02APR97	27, -35	20	110	90	80	120	80	90	161.63	
5	09APR97	34, -28	20	116	80	76	120	82	80	159.64	
6	17APR97	42, -20	20	122	80	80	126	90	86	161.19	
7	25APR97	50, -12	30	126	70	67	122	74	68	161.41	
8	01MAY97	56, -6	30	116	76	74	114	78	78	162.95	
8	07MAY97	62, 1	30	110	70	64	106	74	62	166.26	
12	04JUN97	90, 29	30	120	80	72	120	86	72	166.92 H	
16	30JUN97	116, 55	30	110	70	80	118	84	84	173.31 H	
20	05AUG97	152, 91	20	128	80	80	120	80	80	176.18 H	

* days relative to start of acute phase, days relative to start of continuation phase
# More than 14 days after day of last dose.
Vital Sign Abnormality Criteria: Systolic: L = <90,dec>=30 H = >180,inc>=40; Diastolic: L = <50,dec>=20 H = >105,inc>=30;
Pulse: L = <50,dec>=30 H = >120,inc>=30; Weight: L = dec>=7% H = inc>=7%.

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 1/SCREENING (WEEK -1)	-9	Hemoglobin	15	.	.	.	12 - 15.6	G/DL
				Hematocrit	45.1	.	.	.	35 - 46	%
				Red Blood Cell Count	4.6	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	8.4	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	57.7	.	.	.	30 - 70	%
				Lymphocytes	35.4	.	.	.	21 - 51	%
				Monocytes	4.5	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	243000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.6	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	4	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	65	.	.	.	22 - 130	U/L
				Aspartate Aminotransferase	18	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.7	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.5	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	87	.	.	.	70 - 115	MG/DL
				Globulin	3.2	.	.	.	2.3 - 4.1	G/DL
				Serum BHCG pregnancy test	NEGATIVE		.	.	.	
		VISIT 2/ELIGIBILITY	1	Urine Glucose - Dipstick	NEG		.	.	.	
				Urine Blood - Dipstick	NEG		.	.	.	
				Urine Red Blood Cells/HPF	NEG		.	.	.	
				Urine White Blood Cells/HPF	3		.	.	.	

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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F3 (CLINICAL CONCERN FLAG) : +/- = VALUE ABOVE/BELOW LEVELS OF CLINICAL CONCERN U = Unflaggable

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 2/ELIGIBILITY	1	Urine Bacteria	4	.	.	.		
				Urine Protein - Dipstick	NEG		.	.		
				Urine Squamous	4	.	.	.		
				Epithelial Cells						
				Urine Amphetamines	NEG		.	.		
				Urine Barbiturates	NEG		.	.		
				Urine Benzodiazepines	NEG		.	.		
				Urine Cannabinoids	NEG		.	.		
				Urine Cocaine	NEG		.	.		
				Urine Methadone	NEG		.	.		
				Urine Methaqualone	NEG		.	.		
				Urine Opiates	NEG		.	.		
				Urine Phencyclidine	NEG		.	.		
				Urine Propoxyphene	NEG		.	.		
		VISIT 10/ACUTE PHASE-WEEK 8	62	Hemoglobin	13.9	.	.	.	12 - 15.6	G/DL
				Hematocrit	42.3	.	.	.	35 - 46	%
				Red Blood Cell Count	4.3	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.7	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	49	.	.	.	30 - 70	%
				Lymphocytes	41.5	.	.	.	21 - 51	%
				Monocytes	7.2	.	.	.	0 - 10	%
				Eosinophils	2.1	.	.	.	0 - 5	%
				Basophils	0.3	.	.	.	0 - 2	%
				Platelets	211000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	32.2	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	14	.	.	.	7 - 25	MG/DL
				Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
				Uric Acid	3.3	.	.	.	2.3 - 7	MG/DL
				Alkaline Phosphatase	52	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Appendix G

Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 10/ACUTE PHASE-WEEK 8	62	Aspartate Aminotransferase	20	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	13	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.6	.	.	.	6.2 - 8.8	G/DL
				Albumin	4.1	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	79	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick NEG		.	.	.		
				Urine Red Blood Cells/HPF NEG		.	.	.		
				Urine White Blood Cells/HPF NEG		.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	3	.	.	.		
		VISIT 13/CONTINUATION-WEEK 20	152	Hemoglobin	13.8	.	.	.	12 - 15.6	G/DL
				Hematocrit	44.5	.	.	.	35 - 46	%
				Red Blood Cell Count	4.5	.	.	.	4.1 - 5.3	MILL/MCL
				White Blood Cell Count	6.9	.	.	.	4.5 - 13	THOU/MCL
				Segmented Neutrophils	63.9	.	.	.	30 - 70	%
				Lymphocytes	29.9	.	.	.	21 - 51	%
				Monocytes	4.3	.	.	.	0 - 10	%
				Eosinophils	1.8	.	.	.	0 - 5	%
				Basophils	0	.	.	.	0 - 2	%
				Platelets	223000	.	.	.	130000 - 400000	PER CUMM
				Mean Corpuscle Hemoglobin	31	.	.	.	25 - 35	PG
				Mean Corpuscle Volume	100	.	.	.	80 - 100	FL
				Blood Urea Nitrogen	13	.	.	.	7 - 25	MG/DL

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS		LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 13/CONTINUATION-WEEK 20	152		Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.6	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	54	.	.	.	22 - 130	U/L
					Aspartate Aminotransferase	17	.	.	.	0 - 41	U/L
					Alanine Aminotransferase	18	.	.	.	0 - 48	U/L
					Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
					Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
					Albumin	4	.	.	.	3.1 - 5.3	G/DL
					Glucose - Random	116	H	.	.	70 - 115	MG/DL
					Globulin	3.4	.	.	.	2.3 - 4.1	G/DL
					Serum BHCG pregnancy test	NEGATIVE		.	.		
		VISIT 17/DOWN TITRATION	166	(1)	Hemoglobin	14.2	.	.	.	12 - 15.6	G/DL
					Hematocrit	43.5	.	.	.	35 - 46	%
					Red Blood Cell Count	4.4	.	.	.	4.1 - 5.3	MILL/MCL
					White Blood Cell Count	7.6	.	.	.	4.5 - 13	THOU/MCL
					Segmented Neutrophils	63	.	.	.	30 - 70	%
					Lymphocytes	29.1	.	.	.	21 - 51	%
					Monocytes	5.9	.	.	.	0 - 10	%
					Eosinophils	1.6	.	.	.	0 - 5	%
					Basophils	0.4	.	.	.	0 - 2	%
					Platelets	232000	.	.	.	130000 - 400000	PER CUMM
					Mean Corpuscle Hemoglobin	32.1	.	.	.	25 - 35	PG
					Mean Corpuscle Volume	98	.	.	.	80 - 100	FL
					Blood Urea Nitrogen	10	.	.	.	7 - 25	MG/DL
					Creatinine	1	.	.	.	0.8 - 1.5	MG/DL
					Uric Acid	4.5	.	.	.	2.3 - 7	MG/DL
					Alkaline Phosphatase	49	.	.	.	22 - 130	U/L

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

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Case Report Form Tabulations by Patient
Intent-to-Treat Population

PATIENT ID: 329.012.00231 TREATMENT GROUP: PAROXETINE

LABORATORY DATA

AGE	SEX	OBSERVATION	RELATIVE * DAYS	LAB TEST	LAB VALUE	F1	F2	F3	INVESTIGATOR REFERENCE RANGE	LAB UNITS
16	F	VISIT 17/DOWN TITRATION	166 (1)	Aspartate Aminotransferase	16	.	.	.	0 - 41	U/L
				Alanine Aminotransferase	15	.	.	.	0 - 48	U/L
				Total Bilirubin	0.8	.	.	.	0.3 - 1.3	MG/DL
				Total Protein	7.4	.	.	.	6.2 - 8.8	G/DL
				Albumin	3.9	.	.	.	3.1 - 5.3	G/DL
				Glucose - Random	82	.	.	.	70 - 115	MG/DL
				Globulin	3.5	.	.	.	2.3 - 4.1	G/DL
				Urine Glucose - Dipstick NEG		.	.	.		
				Urine Blood - Dipstick	6	.	.	.		
				Urine Red Blood Cells/HPF	5	.	.	+		
				Urine White Blood Cells/HPF	3	.	.	.		
				Urine Protein - Dipstick NEG		.	.	.		
				Urine Squamous Epithelial Cells	4	.	.	.		

* DAYS RELATIVE TO START OF STUDY MEDICATION (DAYS RELATIVE TO STOP OF STUDY MEDICATION)

F1 (REFERENCE RANGE FLAG) : H/L = VALUE ABOVE/BELOW REFERENCE RANGE U = Unflaggable
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